

**Development of a physical activity intervention for
managing fatigue in rheumatoid arthritis**

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Abstract

Rheumatoid arthritis (RA) is a chronic, inflammatory auto-immune disease. Fatigue is a major symptom of RA and has a considerable impact on patients' daily lives. RA patients report that they struggle to manage their fatigue and receive little professional support. Currently there are no physical activity (PA) interventions that have been specifically designed to manage RA fatigue. However, secondary outcomes for fatigue in PA trials in RA suggest that it may be beneficial. This is supported by evidence in other long-term conditions. A pragmatic mixed methods approach was undertaken to explore the potential use of PA to manage RA fatigue and to develop a PA intervention specifically for fatigue management.

A series of iterative studies was conducted using a range of methodologies, including systematic literature reviews, semi-structured interviews, focus groups, systematic intervention development and a proof-of-concept study. A review of existing evidence demonstrated a small beneficial short-term effect of PA for managing RA fatigue but this was based on secondary outcomes in low quality studies. A lack of evidence was also identified for theory-based interventions to promote engagement in and long-term maintenance of PA in RA.

Semi-structured interviews with healthcare professionals (HCPs) delivering existing PA interventions in other long-term conditions confirmed a lack of an explicit theoretical basis for these programmes. However, participants acknowledged the importance of addressing motivational and psychosocial issues in order to change PA behaviour in patients with fatigue. Programmes varied in terms of format and delivery, but consistent findings included graded approaches to exercise and a flexible approach to implementation and delivery. Findings were subsequently discussed in focus groups with RA patients and rheumatology HCPs. Preferences for similar interventions in RA were identified, for example, a face-to-face group programme incorporating a practical PA session to develop self-management skills and address barriers to PA. Practicalities regarding implementation were noted, including staffing and resource issues.

Existing evidence and primary data generated by the qualitative studies were used to develop a PA self-management programme using the Behaviour Change Wheel, a theoretical framework for behaviour change interventions. The novel intervention was delivered to a group of RA patients to model implementation and delivery processes and to explore acceptability. Findings suggested that the intervention was deliverable, and content and support materials were acceptable to this group of participants.

These findings have implications for clinical practice as RA patients and rheumatology HCPs acknowledged that current fatigue management could be improved. The use of PA for managing fatigue was supported by patients and professionals. This theoretically-informed intervention should now be considered for further evaluation in a feasibility and pilot study prior to full scale testing in a randomised controlled trial.

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List of abbreviations

ACR	American College of Rheumatology
AHP	Allied health professional
Apps	Mobile technology applications
BCT	Behaviour change technique
BCW	Behaviour change wheel
BRAF-NRS	Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scale
CBT	Cognitive behavioural therapy
CFS	Chronic fatigue syndrome
CI	Confidence interval
COM-B	Capability, Opportunity, Motivation – Behaviour model of behaviour change
CRF	Cancer-related fatigue
DMARD	Disease-modifying anti-rheumatic drug
DVD	Digital versatile disc
EQ-5D	EuroQol 5 dimensions health outcome measure
EULAR	European League Against Rheumatism
EXTRA	Education, self- management, and upper extremity EXercise Training in people with Rheumatoid Arthritis (clinical trial)
FINE	Fatigue Intervention by Nurses Evaluation (clinical trial)
GET	Graded exercise therapy
HBC	Health behaviour change
HCP	Healthcare professional
IPAQ	International Physical Activity Questionnaire
IPAQ-SF	IPAQ short form
MCID	Minimal clinically important difference
MDT	Multi-disciplinary team
MRC	Medical Research Council
MS	Multiple sclerosis
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRAS	National Rheumatoid Arthritis Society
OT	Occupational therapist
PA	Physical activity
PACE	Pacing, cognitive behaviour therapy, graded Activity and Cognitive behaviour therapy: a randomised Evaluation (clinical trial)
PRISMA	Preferred Items for Systematic reviews and Meta-Analyses
PRP	Patient research partner
QALY	Quality adjusted life year
RA	Rheumatoid arthritis
RAFT	Reducing Arthritis Fatigue - clinical Teams using cognitive behavioural approaches (clinical trial)
RCT	Randomised controlled trial
SCT	Social cognitive theory
SD	Standard deviation
SDT	Self-determination theory
SF-36	36 item Short Form Health Survey
SMD	Standardised mean difference
TPB	Theory of planned behaviour
UK	United Kingdom

Chapter 1: Introduction to the thesis

This thesis explores the use of physical activity (PA) for managing fatigue in rheumatoid arthritis (RA) and subsequently describes the development of a PA intervention to facilitate fatigue self-management. It explores existing evidence for the effectiveness of PA for fatigue management in other long-term conditions, identifies ideas from patients and health professionals regarding PA for managing fatigue in RA, and describes the development of a new intervention.

This chapter provides an introduction to the thesis, describing RA and its management, with particular reference to fatigue and PA. An outline of the thesis rationale, aims and structure is provided, as well as information about the researcher and involvement of patient research partners.

1.1 Rheumatoid arthritis

RA is a chronic, inflammatory autoimmune disease, predominantly affecting peripheral joints (Hill, 2006). It can result in severe disability and can have a major impact on patients' daily lives, leading to physical and psychosocial symptoms such as pain, stiffness, fatigue, sleep disturbance and anxiety (Hill, 2006).

There is no gold standard for diagnosing RA. Currently, diagnosis is made by a rheumatologist based on a set of classification criteria developed by the American College of Rheumatology (ACR) (Arnett *et al*, 1988). A patient must satisfy at least four of seven 1987 ACR criteria to be given a diagnosis of RA:

1. Morning stiffness
2. Arthritis of three or more joint areas
3. Arthritis of hand joints
4. Symmetrical arthritis
5. Rheumatoid nodules
6. Serum rheumatoid factor
7. Radiographic changes

Criteria 1 to 4 must have been present for at least six weeks (Arnett *et al*, 1988).

More recent criteria have been developed to aid early diagnosis of RA (Aletaha *et al*, 2010). These 2010 ACR/European League Against Rheumatism (EULAR) criteria do not include morning stiffness or radiographic changes. For the purpose of participant recruitment, a clinical diagnosis of RA confirmed by a rheumatologist using either set of criteria was accepted for all studies presented in this thesis.

The prevalence of RA has been reported as 0.5% to 1.1% of the population of Northern Europe and North America (Tobón, Youinou and Saraux, 2010), affecting 1.16% of women and 0.44% of men in the United Kingdom (UK) (Symmons, 2002). Risk factors for developing RA include gender, with women approximately three times more likely to be affected than men (Crowson *et al*, 2011), genetic predisposition, smoking and obesity (Symmons, 2002).

RA is a progressive, systemic disease and has been associated with considerable morbidity and increased mortality (Pincus *et al*, 1984, Conaghan, Green and Emery, 1999), although a more recent study suggested that the long-term mortality rate in a Swedish community-based RA population was not significantly higher than age- and gender-matched controls in the general population (Kapetanovic *et al*, 2011). The authors postulate that advances in the treatment and management of RA may have contributed to their findings. However, these data should be interpreted with caution given the small sample size (n=183). Indeed, a recent examination of mortality rates in a large cohort of UK patients (n=2,517) with early RA between 1990 and 2011 concluded that all-cause mortality in the first seven years of RA remains higher than the general population (Humphreys *et al*, 2014). Meta-analyses of observational (Avina-Zubieta *et al*, 2008) and cohort studies (Meune *et al*, 2009) have suggested that RA is associated with 50-60% increased risk of cardiovascular mortality compared with the general population.

1.1.1 Patient reported problems in rheumatoid arthritis

A qualitative exploration of outcomes that are important to RA patients highlighted, amongst other themes, two key symptoms: pain and fatigue (Carr *et al*, 2003).

1.1.1.1 Pain

RA patients have reported pain as the most important issue in early disease (Carr *et al*, 2003). This is likely caused by inflammation, although the pain experience is complex involving multiple mechanisms, including sensory and emotional components. Pain experiences may vary over the course of the disease, during times of variable disease activity, or flares, and between individual patients (Walsh and McWilliams, 2012).

Despite recent advances in the treatment and management of RA, pain is still a significant problem, with survey data suggesting that 75% of respondents (n=2,795) experienced moderate-to-severe pain (Taylor *et al*, 2010). Results from this survey indicated that pain levels corresponded to disease severity and were related to fatigue. A longitudinal study of 15,282 Swiss RA patients found that pain was the most important predictor of psychosocial health (Courvoisier *et al*, 2012).

1.1.1.2 Fatigue

For over a decade, fatigue has been consistently highlighted as an important issue in RA (Carr *et al*, 2003). Fatigue has been described as 'extreme and persistent tiredness, weakness or exhaustion - mental, physical or both' (p. 157, Dittner, Wessely and Brown, 2004). This subjective experience is frequently reported as a major symptom of RA causing distress and disruption to the daily lives of patients, and influencing everyday tasks, attitudes and leisure activities (Tack, 1990, Hewlett *et al*, 2005, Repping-Wuts *et al*, 2008, Nikolaus *et al*, 2010). Qualitative exploration of RA fatigue shows that it is often a frustrating and overwhelming experience that can be frequent, unpredictable and unresolving, and often as severe, or more severe, than pain (Hewlett *et al*, 2005, Repping-Wuts *et al*, 2008). This is clearly distinguished from general tiredness that patients experienced prior to the onset of RA (Hewlett, Nicklin and Treharne, 2008).

Prevalence

Reported rates of fatigue in RA vary, possibly due to differences in definition and outcome measurement. However, it is well recognised that fatigue is experienced by large numbers of RA patients. Rates of severe, clinically relevant fatigue reported in RA vary from 41% (Wolfe, Hawley and Wilson, 1996, van Hoogmoed *et al*, 2010) to over 80% (Belza *et al*, 1993, Pollard *et al*, 2006). Despite differences in the degree of fatigue, all of these results confirm that fatigue is a commonly experienced and highly significant symptom of RA.

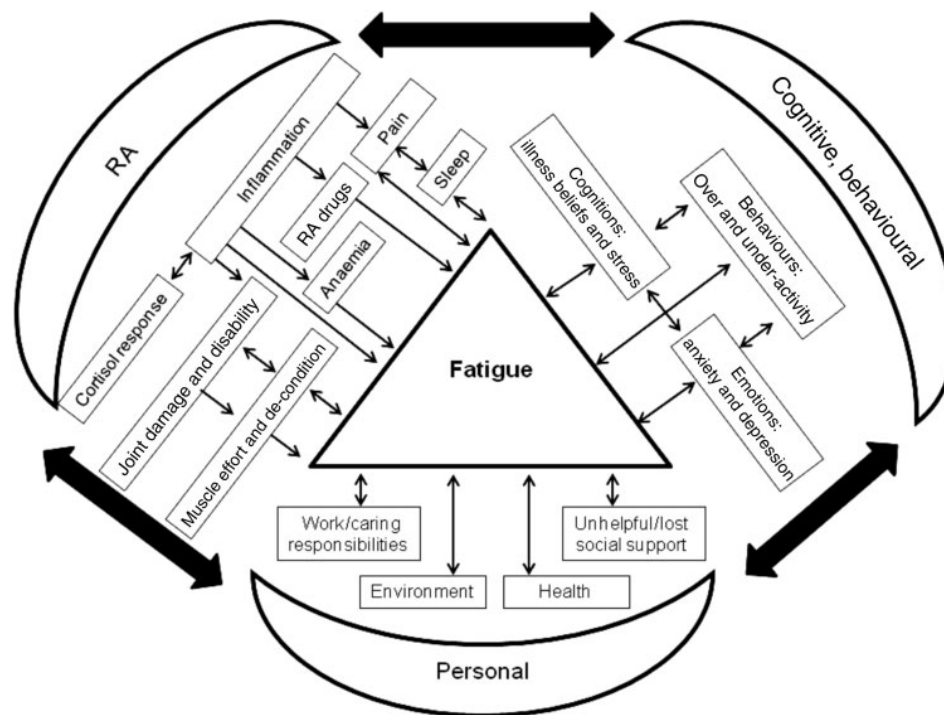
Mechanisms for fatigue in RA

The exact mechanisms and causality of fatigue in RA remain unclear. This is in part due to the complex and multi-factorial nature of fatigue, combined with a lack of standardised measurement, making comparisons between studies challenging. Predictors of fatigue are reported to include disease activity markers, such as inflammation, pain and disability, and coping, mood, and attitudes and beliefs (Hewlett, Nicklin and Treharne, 2008). Fatigue is also associated with high comorbidity burden (Gron *et al*, 2014).

A conceptual model of RA fatigue (figure 1.1) has been proposed, suggesting potential interactions between various factors that might influence a person's fatigue experience (Hewlett *et al*, 2011b). Three main contributing factors are identified: disease processes (for example, inflammation, pain, disability, joint damage, muscle effort and deconditioning, sleep disturbance); thoughts, feelings and behaviours (for example, illness beliefs and stress, anxiety and depression); and personal life issues (for example, work, health, environment, support networks). Causal factors might predispose, precipitate or perpetuate fatigue (Sharpe and Wilks, 2002) or may do all three (Hewlett *et al*, 2011b).

Figure 1.1: Conceptual model of RA fatigue

(reproduced from Hewlett, S., Chalder, T., Choy, E., Cramp, F., Davis, B., Dures, E., Nicholls, C. and Kirwan, J. Fatigue in rheumatoid arthritis: time for a conceptual model. (2011b) *Rheumatology*. 50 (6), pp.1004-1006 by permission of Oxford University Press)



A recent literature review sought to identify possible causes and consequences of RA fatigue (Nikolaus *et al*, 2013). Many of the included studies found possible causes that fitted with Hewlett and colleagues' (2011b) conceptual model. RA-related causal factors included pain, sleep disturbance and sleep quality, disability and physical functioning. However, the review authors noted less evidence in included studies to support other illness-related dimensions such as inflammation, joint damage, cortisol response, muscle effort and deconditioning, anaemia and drugs (Nikolaus *et al*, 2013). This is likely a reflection of lack of investigation of these variables rather than lack of association. Cognitive and behavioural factors such as depression, anxiety and perceptions of self-efficacy were also identified. Personal factors included interpersonal events and inadequate social support. Less evidence was available to demonstrate relationships between fatigue and the dimensions of cognitive and behavioural factors and personal factors than for pain, disability and depression. The association of all identified factors with fatigue was inconsistent across studies (Nikolaus *et al*, 2013).

Similar results were noted for possible consequences of fatigue. These included RA-related consequences, such as stiffness and physical functioning, cognitive and behavioural consequences, such as depression and psychological distress, and personal

consequences, such as work ability, positive and negative daily events and parenting (Nikolaus *et al*, 2013). Qualitative research has also suggested differences in fatigue according to gender, age and daily roles; young women with multiple daily roles being particularly affected (Nikolaus *et al*, 2010). However, findings from the systematic review noted that other studies have not found gender differences in fatigue (Nikolaus *et al*, 2013). Despite suggestions that pain may be a cause of fatigue, a longitudinal study of 198 RA patients investigating the association between pain and fatigue found a synchronous rather than temporal association (van Dartel *et al*, 2013).

These variable and inconsistent results across studies emphasise the complex, multifactorial nature of fatigue and highlight the difficulty of trying to establish directional associations, supporting multi-directional relationships indicated in figure 1.1. As a result, fatigue must be managed as a symptom in its own right, rather than attempting to identify and treat specific causal factors. The inclusion of fatigue measurement in all clinical trials was a major step forward in recognising this symptom as a significant target of disease management (Kirwan *et al*, 2007). However, the need for research to develop effective interventions that reduce the personal impact of fatigue for RA patients is increasingly evident.

1.2 Management of rheumatoid arthritis

Management of RA focuses on controlling signs and symptoms of the disease, maintaining physical function and mobility, and improving self-management and coping skills (Luqmani *et al*, 2006). Treatment must take into account the individual preferences and needs of each patient (National Institute for Health and Care Excellence (NICE), 2009). The management of RA is multi-disciplinary and includes pharmacological and non-pharmacological approaches. Patients should have ongoing access to members of the multi-disciplinary team (MDT), including specialist nurses, physiotherapists and occupational therapists (OTs) (NICE, 2009). RA patients should also have access to a podiatrist for their foot care needs, and psychological interventions to aid adjustment to living with RA (NICE, 2009).

1.2.1 Pharmacological approaches

Advances in the understanding of the pathogenesis of RA have led to a rapidly evolving range of pharmacological treatment options (Smolen *et al*, 2014). The primary aim of pharmacological therapy is to reduce disease activity. The use of conventional disease-modifying anti-rheumatic drugs (DMARDs) (for example, methotrexate) is recommended as first-line therapy in early RA (Luqmani *et al*, 2006, NICE, 2009) and may

be combined with corticosteroids. Local corticosteroid injections into specific joints may be beneficial to reduce inflammation of the synovial lining (synovitis). Biological therapies (for example, anti-tumour necrosis factor) have been recommended for use in patients who have had an inadequate response to conventional DMARD therapy (NICE, 2009).

DMARDs or biologics should be sufficient to control synovitis and consequently reduce pain and functional impairment (Luqmani *et al*, 2009). However, most RA patients require additional medication for pain relief. This may include simple analgesics such as occasional paracetamol or regular non-steroidal anti-inflammatory drugs (Luqmani *et al*, 2006).

1.2.2 Non-pharmacological approaches

Clinical guidelines for managing RA recommend non-pharmacological approaches to reduce the impact of physical and psychosocial factors associated with RA (Luqmani *et al*, 2006, Luqmani *et al*, 2009, NICE, 2009). These approaches aim to prevent joint deformity and improve symptoms, function, independence and quality of life (NICE, 2009). Many of these approaches are delivered by members of the MDT such as specialist nurses, physiotherapists and OTs. Amongst other things, this might include PA programmes and lifestyle and behaviour-change interventions to enhance self-management and coping skills.

1.2.2.1 Self-management of rheumatoid arthritis

Patients should be encouraged to improve self-management of their disease through participation in education programmes (Luqmani *et al*, 2009, NICE, 2009). Recommendations for patient education in inflammatory arthritis have recently been published based on evidence from a systematic review (Zangi *et al*, 2015). These reiterate the importance of education as a central component of condition management, citing evidence for improved knowledge, coping skills and physical and psychological health status. A key aim of education programmes should be to facilitate lifestyle adjustment and self-management through an interactive learning process, rather than simply providing information based on clinical experience (Zangi *et al*, 2015). A previous systematic review of patient education in RA noted that interventions providing information only had no significant effect on outcomes, whereas interventions incorporating behavioural strategies had a significant effect on functional disability, patient global assessment of disease and depression compared with control participants (Riemsma *et al*, 2004). However, these effects were only observed post-treatment with no significant effects reported three to fourteen months post-intervention. The authors concluded that behavioural programmes

appear to be most effective but variation in content, methods of delivery and format mean that optimal parameters remain unknown (Riemsma *et al*, 2004).

Recent reviews emphasise the need for a psycho-behavioural basis for education and self-management interventions (Iversen, Hammond and Betteridge, 2010, Zangi *et al*, 2015), suggesting that education programmes should be underpinned by a theoretical framework such as social cognitive theory (SCT) (Bandura, 1977, Bandura, 1986) or cognitive behavioural theory (Sage *et al*, 2008). Despite these recommendations, more than 50% of programmes included in the review by Zangi and colleagues (2015) were reported to employ didactic, information-giving methods and were not based on theory. However, a trend towards the inclusion of behavioural approaches was noted. As well as specifying a theoretical basis, it is recommended that self-management interventions incorporate exercise (Iversen, Hammond and Betteridge, 2010).

1.2.2.2 Physical activity in rheumatoid arthritis

PA is universally defined as “*any bodily movement produced by skeletal muscles that results in energy expenditure*” with exercise defined as “*a subset of physical activity that is planned, structured, and repetitive and has as a final or an intermediate objective the improvement or maintenance of physical fitness*” (p.126, Caspersen, Powell and Christenson, 1985). Examples provided by the Department of Health (2011) help to clarify this definition:

“Physical activity includes all forms of activity, such as everyday walking or cycling to get from A to B, active play, work-related activity, active recreation (such as working out in a gym), dancing, gardening or playing active games, as well as organised and competitive sport.” (p.9, Department of Health, 2011)

Levels of physical activity in rheumatoid arthritis

In order to achieve health-enhancing benefits of PA, UK national guidelines recommend that adults undertake daily PA, accumulating a minimum of 150 minutes of moderate-intensity PA per week. This may be broken down into bouts of at least 10 minutes. Alternatively, 75 minutes of vigorous-intensity PA may be performed per week, or a combination of moderate- and vigorous-intensity activities. Additionally, strength training should be carried out twice weekly and the amount of time spent sitting (sedentary) should be reduced (Department of Health, 2011).

Despite these guidelines, many adults are insufficiently active and the low levels of PA in the general population in the UK are a growing health concern. Public health intelligence highlights a need to increase activity levels to reduce the risk of health problems such as obesity, cardiovascular disease and diabetes (Department of Health, 2011). A recent inquiry by the UK government into the impact of PA and diet on health has

recognised the need to promote the benefits of PA as a health priority in its own right (House of Commons Health Committee, 2014).

Physical inactivity is more prevalent in RA patients compared to the general population (Eurenius *et al*, 2005, Sokka *et al*, 2008). A cross-sectional study of 5,235 RA patients in 21 countries reported that the majority of patients did not perform regular weekly exercise (Sokka *et al*, 2008). The authors noted that inactivity was greater for those patients with worse functional capacity, higher disease activity and higher pain and fatigue scores. Findings from a review of studies measuring PA levels or energy expenditure in adults with RA also suggested that PA levels were lower in RA than healthy controls (Tierney, Fraser and Kennedy, 2012). However, the authors reported that methodological issues relating to measurement of PA in the included studies limited their confidence in these results. Similarly, recent cross-sectional studies of adults with rheumatic conditions, including self-reported RA, have suggested that many patients are inactive (Manning *et al*, 2012, O'Dwyer *et al*, 2014). These findings cannot be generalised to the general RA population, as separate data for RA were not reported and both studies were conducted in single-centre inner city outpatient departments. Nonetheless, these consistent findings might be a reflection of PA in similar urban populations.

Factors associated with participation in physical activity

Many patients with arthritis, including RA, are aware of the potential benefits of PA (Wilcox *et al*, 2006, Law *et al*, 2010, Law *et al*, 2013, Wang *et al*, 2014). However, several perceived barriers prevent engagement in adequate PA. A qualitative focus group study in the United States of America explored perceived barriers, benefits and enablers to PA in arthritis (Wilcox *et al*, 2006). Participants were stratified into exercisers and non-exercisers. Barriers and benefits each fell into four themes: physical, psychological, social and environmental. Physical barriers included pain, fatigue, mobility and comorbidities. Although these barriers were reported by exercisers and non-exercisers, the former were more likely to adapt their PA to accommodate these. For example, while non-exercisers would reduce the frequency of PA if they experienced fatigue, exercisers were more likely to reduce the intensity. Psychological barriers included attitudes and beliefs, fear and perceived negative outcomes from PA. Lack of time, motivation and enjoyment were reported to affect participation. Exercisers reported difficulty with prioritising PA under these circumstances, while non-exercisers appeared to believe that they were unable or unskilled in performing PA. Social barriers related to lack of support and competing role responsibilities, while environmental barriers included a lack of available programmes for patients with arthritis, environmental conditions, such as weather, cost and transportation. Although barriers were reported by both groups, they were more prevalent for non-

exercisers (Wilcox *et al*, 2006). Similar findings have been reported in RA (Cooney *et al*, 2011), with patients reporting particular concerns regarding joint pain, fatigue, fear of causing harm and uncertainty regarding how to exercise (Law *et al*, 2010, Wang *et al*, 2014).

A cross-sectional study of 176 RA patients identified lack of motivation for PA and lack of belief related to its benefits as the two factors most strongly associated with inactivity (Lee *et al*, 2012). This supports the findings of Wilcox and colleagues (2006) that non-exercisers were less convinced that they would benefit from PA. Increased motivation has also been positively associated with PA participation in RA patients (Hurkmans *et al*, 2010). Similarly, higher self-efficacy (the belief in one's ability to perform a specific behaviour (Bandura, 1977)) for PA has been associated with achievement of PA goals (Knittle *et al*, 2011). Other patient-reported enablers for participation in PA in patients with arthritis include improvements in symptoms and functional ability, weight loss and reduced medication use for symptom control (Wilcox *et al*, 2006). Maintaining independence, increased self-confidence and a sense of achievement are also important, with enjoyment of PA and exercise being particularly motivating. Patients with arthritis who exercise have reported other behavioural enablers such as internal motivation for exercise, with an emphasis on self-regulatory skills such as prioritising and scheduling PA and setting PA goals (Wilcox *et al*, 2006).

Benefits of physical activity in RA

The safety of PA in RA is well-established (Kennedy, 2006, Baillet *et al*, 2010, Baillet *et al*, 2012), and aerobic exercise combined with strength training is recommended as routine practice (Hurkmans *et al*, 2009). To date, much PA research in RA has focused on investigating the safety and effectiveness of specific exercise programmes, for example high-intensity resistance training and cardiorespiratory aerobic exercise for improving RA-related outcomes (Hurkmans *et al*, 2009, Baillet *et al*, 2010, Baillet *et al*, 2012). Benefits of resistance exercise include a positive impact on disability and functional capacity (Baillet *et al*, 2012), and cardiorespiratory aerobic exercise has been shown to improve function, quality of life and pain (Baillet *et al*, 2010). Additional benefits may include improved bone mineral density (de Jong *et al*, 2004b), although few existing investigations are sufficiently long to detect changes in bone health (Kennedy, 2006, Cooney *et al*, 2011). However, exercise is only a subset of PA and few studies have investigated this broader concept (Tierney, Fraser and Kennedy, 2012), although there is a growing body of research exploring factors associated with PA participation and interventions to promote engagement.

Physical activity interventions

Participation in regular exercise is recommended to improve general fitness and function, reduce bone loss and manage cardiovascular risk factors (Luqmani *et al*, 2009, NICE, 2009). NICE (2009) recommends access to specialist physiotherapy for advice and education regarding PA and exercise. Studies investigating the effectiveness of PA interventions, for example, a one year coaching programme, have not demonstrated long-term improvements in self-reported PA (Sjöquist *et al*, 2011). The authors acknowledged that behavioural components that might support engagement in and continuation of PA were not included in the intervention, such as self-monitoring and relapse prevention strategies. A meta-analysis of PA interventions in the wider arthritis population reported that many self-management programmes that recommend exercise do not measure PA outcomes (Conn *et al*, 2008) thus offering another explanation for the lack of available evidence for PA interventions.

Despite knowledge of the benefits of PA and exercise, patients with arthritis express a lack of confidence with performing PA and report a desire for reassurance from healthcare professionals (HCPs) to encourage participation (Wilcox *et al*, 2006). Lack of support from HCPs has been noted as a barrier to PA and RA patients report a perceived lack of PA knowledge amongst HCPs (Law *et al*, 2010, Law *et al*, 2013) as well as receiving conflicting advice (Wang *et al*, 2014). Perceptions and behaviours of rheumatology HCPs are therefore important factors affecting PA participation (Cooney *et al*, 2011). A survey of 126 Dutch rheumatologists, 132 rheumatology clinical nurse specialists and 112 expert physical therapists found that participants believed PA guidelines were important and achievable for RA patients with stable disease (Hurkmans *et al*, 2011). While they reported giving advice on PA, many HCPs, including 72% of expert physical therapists, did not feel competent and expressed a desire for further training. Other research investigating educational needs of rheumatology nurses and allied health professionals (AHPs) also noted a need to develop knowledge and skills for the provision of appropriate PA advice (Lillie, Ryan and Adams, 2013). Further research into PA training needs for HCPs is warranted.

It has been suggested that there is a particular need to develop interventions to increase motivation for PA and enhance beliefs regarding benefits in order to enhance PA participation in RA (Lee *et al*, 2012). The effectiveness of an SCT-based 12-week education, self-management and upper extremity exercise training programme for people with RA (EXTRA) has recently been reported (Manning *et al*, 2014). At 12 weeks, significant between-group differences favouring the intervention were found for upper limb disability, function, handgrip strength, self-efficacy and disease activity. However, apart

from self-efficacy, differences were not maintained at 36 weeks. Manning and colleagues (2014) suggest that SCT may be inadequate to address motivation for ongoing exercise adherence after groups have ceased to meet. Other authors have also proposed this as an explanation for short-lived effects of interventions based on SCT (Knittle *et al*, 2013). However, the EXTRA programme only included four supervised exercise sessions in the first two weeks (Manning *et al*, 2014). Additional input might enhance adherence. Indeed, a six week, 12 session SCT-based intervention to improve self-management and exercise for adults with chronic knee pain demonstrated significant improvements in exercise health beliefs and self-efficacy that were sustained for 18 months following the intervention (Hurley *et al*, 2012). Long-term improvements in physical function were also noted. To date, similar long-term improvements in symptoms and functional outcomes have not been demonstrated in RA, although this may be a reflection of limited measurement rather than limited effectiveness (Knittle, De Gucht and Maes, 2012).

Qualitative approaches were not reported as part of the EXTRA study (Manning *et al*, 2014). Participants completed an exercise diary but this was to record participation and intensity rather than feedback on the programme. Qualitative evaluation may help to identify barriers and enablers for PA, which, if addressed, could enhance engagement in and maintenance of PA in the longer term. Use of qualitative methods to enhance quantitative findings has been recommended for exploring participants' well-being and the processes of behaviour change brought about by complex interventions to improve health (Medical Research Council (MRC), 2000) and for self-management interventions for rheumatic diseases (Iversen, Hammond and Betteridge, 2010).

1.3 Management of fatigue in rheumatoid arthritis

Many RA patients report that they struggle to manage fatigue, and receive little professional support (Hewlett *et al*, 2005). A survey of UK and Dutch nursing staff reported that RA fatigue is often poorly managed (Repping-Wuts *et al*, 2009). Furthermore, a review of the literature has identified that, historically, the multi-dimensional nature of RA fatigue and its effect on daily living has often been ignored, with little treatment targeted specifically at fatigue (Mayoux-Benhamou, 2006). In a survey investigating the impact of fatigue in RA, 51% of respondents (n=2,029) never or rarely spoke to their general practitioner about fatigue, and 47% never or rarely spoke to their rheumatology HCP. The majority of participants (79%) reported that their HCP never measured their level of fatigue (National Rheumatoid Arthritis Society (NRAS), 2014).

Very few studies have addressed the management of fatigue in RA as a primary outcome. However, pharmacological and non-pharmacological interventions that target

other factors have shown an improvement in reported fatigue (Hewlett, Nicklin and Treharne, 2008).

1.3.1 Pharmacological approaches

DMARDs and biologic therapies can reduce fatigue in RA (Pollard *et al*, 2006). These drugs may have an indirect effect on fatigue through reduction of inflammation and/or pain. Results from a long-term cohort study in the UK have suggested substantial improvements in RA fatigue after commencing anti-tumour necrosis factor therapy (Druce *et al*, 2015). However, few clinical trials have reported the effect of biologics, although this is likely due to the relatively recent inclusion of fatigue measurement in all trials (Kirwan *et al*, 2007). Indeed, in a meta-analysis of randomised controlled trials (RCTs) investigating the effects of biologics on RA fatigue, it was noted that nine of the ten included studies had been published in the three years prior to publication of the review (Chauffier *et al*, 2012). The review reported only a small positive effect. This might reflect limitations of pharmacological treatments for addressing other psychosocial factors affecting RA fatigue, suggesting that non-pharmacological approaches are also required.

1.3.2 Non-pharmacological approaches

Non-pharmacological interventions may improve self-reported fatigue through their influence on some of the potential causal pathways (Hewlett *et al*, 2011b). These may include psychosocial interventions, such as self-management programmes, cognitive-behavioural approaches and lifestyle interventions, or interventions based on PA. Psychosocial interventions have the potential to improve factors affecting fatigue identified in the conceptual model (figure 1.1) such as depression and anxiety, and illness beliefs and behaviours. Education and self-management programmes may enhance coping skills and self-efficacy for fatigue management.

A Cochrane review investigated the effectiveness of non-pharmacological interventions, including PA and psychosocial interventions, for managing RA fatigue (Cramp *et al*, 2013b). Psychosocial interventions included cognitive behavioural therapy (CBT), mindfulness, lifestyle management, energy management, self-management, group education, benefit finding and expressive writing. Meta-analysis of fatigue outcomes for 843 participants who received psychosocial interventions and 713 control participants demonstrated a small significant positive effect, although the overall methodological quality of the studies was low. Also, fatigue management was not the primary focus for the majority of studies (Cramp *et al*, 2013b). The only study to include fatigue as a primary outcome measure was an RCT of CBT (Hewlett *et al*, 2011a). A significant improvement in fatigue impact ($p=0.008$) in the CBT arm compared with controls was found at 18 weeks

after baseline assessment. Significant improvements in fatigue severity, coping, disability, depression, helplessness, self-efficacy and sleep quality were also noted (Hewlett *et al*, 2011a). These encouraging findings support the use of CBT for fatigue management in RA. However, further research is needed to confirm this effectiveness, to investigate application of CBT in clinical practice and to establish the effectiveness of other psychosocial interventions for managing RA fatigue. Some of this work is ongoing in the “Reducing Arthritis Fatigue - clinical Teams using cognitive behavioural approaches” (RAFT) multicentre trial (www.isrctn.com/ISRCTN52709998).

1.3.1.1 Physical activity to reduce the impact of RA fatigue

Fatigue is frequently cited as a barrier to PA, with higher levels of fatigue associated with reduced participation in PA (Neuberger *et al*, 2007, Henchoz *et al*, 2012, Larkin and Kennedy, 2014). Low levels of PA may contribute to a vicious cycle of fatigue and inactivity, highlighting a need to improve activity levels in RA patients who experience fatigue. Indeed, higher levels of daily PA have been associated with lower levels of fatigue (Rongen-van Dartel *et al*, 2014). When asked about fatigue management in an NRAS survey (NRAS, 2014), 72% of respondents reported reducing activity levels in response to fatigue, suggesting that PA may be counter-intuitive for fatigued patients.

Although the aetiology of RA fatigue is unclear the conceptual model shown in figure 1.1 (Hewlett *et al*, 2011b) provides a basis for identification of potential modes of action through which PA might modify this symptom. For example, the model suggests that RA inflammation results in pain, which in turn might cause fatigue. There is evidence that PA can reduce pain in RA (Hurkmans *et al*, 2009, Baillet *et al*, 2010, Cooney *et al*, 2011). Therefore, if pain is a potential causal factor for fatigue then reduction of pain through PA might subsequently reduce fatigue. A second example of how PA might reduce fatigue caused by RA-related symptoms might be via its influence on disability or physical function (figure 1.1). A meta-analysis evaluating the efficacy of cardio-respiratory aerobic exercise in RA demonstrated improvements in pain, quality of life and physical function (Baillet *et al*, 2010), all of which are associated with fatigue severity (van Hoogmoed *et al*, 2010). If participation in PA can improve these symptoms then it might consequently reduce their causal influence on fatigue. Further evidence demonstrates that PA can benefit physical de-conditioning and cachexia, and improve muscle strength in RA patients, resulting in a positive effect on aerobic capacity (Hurkmans *et al*, 2009, Lemmey *et al*, 2009, Baillet *et al* 2012). If these factors are also potential causes of fatigue, then improvements in cardiorespiratory fitness and muscle strength as a result of PA might contribute to a decrease in RA fatigue, with less physical effort required to achieve the same level of function.

It has been suggested that psychosocial factors, indicated by cognitive, behavioural and personal factors in the conceptual model (figure 1.1, Hewlett *et al*, 2011b) are important determinants of fatigue severity in RA (van Hoogmoed *et al*, 2010). PA may influence some of these causal factors thus suggesting another potential mechanism for PA to reduce RA fatigue. For example, regular participation in moderate to high-intensity exercise might improve self-efficacy, well-being and a sense of self-control for this patient population (Lorig and Holman, 2003, Reinseth *et al*, 2011). The positive influence of PA on these PA-related cognitions might subsequently affect cognitions related to illness beliefs and stress that potentially drive RA fatigue, as suggested by the conceptual model (figure 1.1). The beneficial effect on PA-related cognitions might also indirectly affect RA fatigue through modification of behaviours such as over- and under-activity that could accentuate fatigue symptoms. PA might also influence fatigue via its effect on emotional status, as there is evidence that PA can improve anxiety and depression in RA patients (de Jong *et al*, 2003). According to the conceptual model (figure 1.1) such an improvement in emotional status might in turn reduce its causal effect on fatigue. Additionally, being physically active despite experiencing high fatigue levels appears to buffer the negative effect of fatigue on positive mood (Hegarty *et al*, 2015).

PA might reduce fatigue through its effect on personal factors that potentially influence this symptom (figure 1.1). For example, evidence that PA can help in the management of health issues that are not unique to RA, such as cardiac disease (Heran *et al*, 2011) and diabetes (Thomas, Elliott and Naughton, 2006), is well reported. If PA can improve a person's general health status then this might reduce the influence of poor health and comorbidities as causal factors for RA fatigue, as suggested in the conceptual model (figure 1.1).

The Cochrane review of non-pharmacological interventions for fatigue management suggested a small significant positive effect of PA on RA fatigue (Cramp *et al*, 2013b). However, the methodological quality of included studies was variable, none investigated fatigue as a primary outcome and none of the interventions were designed specifically to reduce fatigue (Cramp *et al*, 2013b). There is also evidence for the effectiveness of PA for managing fatigue in other long-term conditions in which it is a major symptom (Edmonds, McGuire and Price, 2004, Cramp and Byron-Daniel, 2012). Therefore the effectiveness of existing PA and exercise interventions for reducing RA fatigue warrants further exploration. This will be discussed in more detail in chapter 2.

1.4 Purpose of the thesis

1.4.1 Rationale

There is a lack of evidence-based interventions for managing RA fatigue. Promising results have been seen in a recent meta-analysis for the use of PA to manage fatigue in RA (Cramp *et al*, 2013b), suggesting that a specific PA intervention could be beneficial.

1.4.2 Aim

The overall aim of this research was to develop a PA intervention to support people with RA to manage symptoms of fatigue.

1.4.3 Objectives

The intervention development process presented in this thesis was based on MRC guidance for developing complex interventions to improve health (MRC, 2000, Craig *et al*, 2008, MRC, 2008). Designing successful complex interventions involves careful, diligent work to ensure that they are likely to be worth implementing in clinical practice (MRC, 2008). This process requires due consideration of the preferences of the target population and those involved in delivery, and practical issues relating to implementation. Complex interventions often have several dimensions, including the number of and interactions between intervention elements, the number and difficulty of behaviours required by recipients and those delivering the intervention, the number and range of potential outcomes and the permissible degree of flexibility or tailoring of the intervention (MRC, 2008).

MRC guidance recommends three phases during early development of complex interventions: 1. identifying an existing evidence base; 2. identifying appropriate theory; and 3. modelling process and outcomes (MRC, 2008).

The thesis objectives set out to demonstrate each stage of intervention development. These objectives were:

1. To identify the evidence for the use of PA for fatigue management in RA and other long-term conditions
2. To understand the experiences of HCPs using PA for fatigue management in clinical practice
3. To explore RA patients' preferences and opinions relating to PA intervention format, content and delivery
4. To identify the thoughts of rheumatology AHPs regarding practicalities of implementing and delivering a PA intervention in clinical practice
5. To develop an outline PA self-management intervention to manage RA fatigue informed by a theoretical framework of behaviour change

6. To model intervention processes in order to determine acceptability to RA patients and to inform further development.

1.4.4 Researcher perspective

1.4.4.1 Prior knowledge

The PhD candidate (referred to as the candidate throughout this thesis) began this research with a clinical background as a musculoskeletal physiotherapist, with only a basic knowledge of RA. Knowledge and skills in this area were developed through familiarisation with the RA literature and observing rheumatologist, specialist nursing and physiotherapy clinics. Patient research partners provided an account of their personal experiences of living with RA to aid the candidate with developing a better understanding of this condition.

1.4.4.2 Epistemological position

In a framework for assessing the rigour and quality of qualitative research, Meyrick (2006) recommends that researchers clearly state their epistemological and theoretical stance. Epistemology is considered by some as foundational to the research design process, as this will influence methods and methodology (Carter and Little, 2007).

A pragmatic approach was taken for this study. Pragmatism is frequently associated with mixed methods research and allows for a flexible, practical approach to data collection (Cresswell and Clark, 2011). This research philosophy places the primary focus on the research question rather than methods. Pragmatist ontology views reality as both singular and multiple, believing that there may be a theory to explain the phenomenon being studied, but individual input into the nature of the phenomenon should also be assessed (Cresswell and Clark, 2011).

1.4.5 Patient research partner involvement

The research presented in this thesis was developed and carried out with input from two people who have RA. These individuals were considered partners in the research process and are referred to as “patient research partners” (PRPs) throughout this thesis (Hewlett *et al*, 2006, de Wit *et al*, 2011).

Although the impact of patient involvement in research has yet to be established, there is some evidence that it improves the quality of research (INVOLVE, 2013). Benefits experienced in rheumatology include a fresh perspective, changes to study designs and novel outcomes (Hewlett *et al*, 2006). Public involvement in research is often a requirement of funding bodies such as the National Institute of Health Research (www.nihr.ac.uk). Although involving patients in research may present some challenges,

guidelines are available offering solutions and recommendations for effective collaboration (Hewlett *et al*, 2006, de Witt *et al*, 2011). These include having a minimum of two PRPs per project, selected for their relevant experience, taking into account their communication skills, motivation and willingness to participate constructively in team meetings (de Witt *et al*, 2011). The lead researcher should ensure that PRPs receive adequate support and training to enable them to fulfil their role. PRPs should be respected and valued as equal members of the research team. Due consideration must be given to specific needs regarding access to meeting venues and reimbursement of travel costs (Hewlett *et al*, 2006, de Witt *et al*, 2011).

PRPs involved in this research provided insight into their experiences of RA and brought different research experiences. Marie Urban is an experienced PRP who has been involved in research looking at measuring fatigue in RA (Nicklin *et al*, 2010a, Nicklin *et al*, 2010b). Maria Morris has experience of taking part in a research project relating to fatigue management in RA (Hewlett *et al*, 2011a). Both Marie and Maria attended all research supervision team meetings as respected colleagues with valuable experiences of living with RA. They were involved in all aspects of the research process, giving feedback on study design, facilitating data collection and contributing to data analysis. Research supervisors and the candidate provided relevant training to allow PRPs to carry out their roles and all travel expenses were paid. Further details of PRP involvement in individual studies are discussed in the relevant chapters.

1.4.6 Thesis structure

The following three chapters present a summary of existing evidence that supports the development of a PA self-management intervention. This is further built upon by primary qualitative research presented in chapters 5 and 6. The development of the current intervention, including underpinning theory, is described in chapter 7. Chapter 8 presents a proof-of-concept study to model intervention processes and explore acceptability. The overall conclusions are presented in chapter 9, including implications for clinical practice and future research.

Chapter 2: Physical activity for managing fatigue in rheumatoid arthritis

Chapter 1 provided an introduction to RA, PA and fatigue and the management of RA. This chapter presents a review of existing evidence for the effectiveness of PA and exercise therapy for managing fatigue in RA. A recent Cochrane review of non-pharmacological interventions for RA fatigue reported that PA was statistically more effective than control interventions (standardised mean difference (SMD) -0.36, 95% confidence interval (CI) -0.62 to -0.10, $p=0.0066$) (Cramp et al, 2013b). This chapter provides a discussion of the Cochrane review and identifies new evidence. It is written according to Cochrane guidelines to aid comparison (Higgins and Green, 2011).

2.1 Background

2.1.1 Description of the condition

A description of RA and RA fatigue has been presented in chapter 1.

2.1.2 Description of the intervention

As reported in chapter 1, non-pharmacological approaches, including PA and self-management interventions, may be used to manage RA fatigue. PA interventions may aim to improve general PA or may include prescribed exercise programmes. Interventions might specify the mode of PA, for example, aerobic exercises, such as walking or cycling, or other forms of exercise, such as resistance training or yoga. Prescribed PA or exercise programmes might specify a target duration, intensity and/or frequency. In addition the intervention might take place in a wide range of settings and may be land- or pool-based, such as hydrotherapy. Interventions may or may not be supervised by an HCP or exercise professional, and delivery may be one-to-one or class based.

2.1.3 How the intervention might work

Evidence suggests that the level of fatigue and perceived benefits and barriers to PA affects the amount of activity carried out by RA patients, with those experiencing higher levels of fatigue completing fewer minutes of PA (Neuberger et al, 2007). This may create a vicious cycle of fatigue and inactivity.

There are currently few published trials primarily investigating interventions for RA fatigue. Nevertheless, PA interventions may indirectly affect fatigue even if this was not

the primary intention. For example, a Cochrane review of evidence for dynamic exercise programmes in RA noted a positive effect on aerobic capacity (Hurkmans *et al*, 2009). This type of PA might contribute to an improvement in RA fatigue if cardio-respiratory fitness and muscle strength increased. A potential improvement in physiological function could result in less effort required for specific tasks, thus reducing subsequent experiences of fatigue. However, given the multi-factorial nature of fatigue, improvements in physiological function alone are unlikely to have a large impact. Increased levels of PA might also improve psychosocial aspects of fatigue, for example, regular participation in PA might increase self-efficacy and a sense of self-control for RA patients (Lorig and Holman, 2003, Reinseth *et al*, 2011). This could positively impact on cognitive and behavioural issues that might contribute to RA fatigue (Hewlett *et al*, 2011b), helping to break a fatigue-inactivity cycle. Additionally, there is evidence that PA can address other causal factors for fatigue that are not unique to RA, such as depression and anxiety (Cooney *et al*, 2013). Regular participation in PA might reduce the impact of RA fatigue by addressing these associated risk factors.

2.1.4 Why is it important to do this review

Preliminary results from the Cochrane review by Cramp and colleagues (2013b) suggest that PA interventions have the potential to reduce fatigue in RA. The search conducted in the review identified research reports up to October 2012. Therefore, it was important to identify recent evidence that has been published since this date.

2.2 Objectives

To identify existing evidence and investigate the effectiveness of PA interventions for reducing fatigue in adults with RA

2.3 Methods

Methods were based on the Cochrane review for non-pharmacological interventions for fatigue in RA (Cramp *et al*, 2013b).

2.3.1 Criteria for considering studies for this review

Inclusion criteria from the original Cochrane review were utilised (Cramp *et al*, 2013b). These included RCTs of adults with confirmed RA (Arnett *et al*, 1988), with fatigue reported as a primary or secondary outcome measure and data reported separately for RA. Where studies reported outcomes for rheumatic conditions or diseases as one population these data were excluded. An additional criterion for the current review

specified that the study must investigate a PA intervention. Studies investigating pharmacological interventions only were excluded.

2.3.2 Search methods for identification of studies

The search strategy for the Cochrane review was repeated (see appendix A for example), with the addition of search terms to identify PA interventions (see box 2.1), using the same electronic databases (Cramp *et al*, 2013b) (box 2.2). These were searched between October 2012 and March 2015.

Box 2.1: Search terms to identify PA interventions

exercise\$
resistance adj (train\$ OR prog\$)
strength adj (train\$ OR prog\$)
flexibility adj (train\$ OR prog\$)
endurance adj (train\$ OR prog\$)
aerobic\$
physical\$ activ\$
physical\$ therap\$
physical\$ exercise\$
interval training
sport\$
movement therap\$
stretching
dance therap\$
Tai Ji or Tai Chi or Tai-Ji or Tai-Chi
Walking
Yoga
Hydrotherap\$

\$=stem word used to identify any words beginning with the stem

Box 2.2: Electronic databases used in the Cochrane review (Cramp *et al*, 2013b)

Cochrane Central Register of Controlled Trials (CENTRAL)
MEDLINE
EMBASE
Allied and Complementary Medicine (AMED)
Cumulative Index to Nursing and Allied Health Literature (CINAHL)
PsycINFO
Social Science Citation Index
Web of Science
Dissertation Abstracts International
Current Controlled Trials Register (United States of America)
The National Research Register (NRR)
The UKCRN Portfolio Database (UK)

2.3.3 Data collection and analysis

2.3.3.1 Selection of studies

Titles and abstracts were screened for inclusion criteria. Full text reports were retrieved where studies appeared to meet these criteria, or where it was unclear whether a study should be excluded from the abstract or title alone. Potentially relevant reports were discussed with the candidate's director of studies, Fiona Cramp, who was also first author on the Cochrane review (Cramp *et al*, 2013b) to ensure consistency. Data from conference abstracts were not included in the current review unless corresponding full text articles were available. Abstract authors were not contacted.

2.3.3.2 Data extraction and management

Data extraction from newly identified studies was performed by the candidate using a data extraction form (appendix B) modified from the original Cochrane review, and included: intervention details; participants' health status; assignment to study arm; outcome measures; timing of measurements; adherence to intervention and control; sample size; statistical analysis methods; results for fatigue outcomes; and long-term follow-up data (Cramp *et al*, 2013b).

2.3.3.3 Risk of bias

Risk of bias was assessed using the Cochrane risk of bias tool (Higgins and Green, 2011, Higgins *et al*, 2011) used in the original Cochrane review (Cramp *et al*, 2013b). Six domains were assessed:

1. Sequence generation (selection bias)

The method used to generate the allocation sequence was assessed to determine whether it would produce comparable groups. The risk of bias was judged as low (a random process was described), high (non-random process) or unclear (insufficient information was available to make a judgement).

2. Allocation concealment (selection bias)

The method used to conceal allocation to interventions was assessed to determine whether allocations could have been foreseen prior to or during recruitment. Risk of bias was judged as low (for example, central allocation, sequentially numbered sealed opaque envelopes), high (any unconcealed procedure including open random allocation, unsealed or non-opaque envelopes, date of birth) or unclear (insufficient information or poor reporting of concealment process).

3. Blinding of participants, personnel and outcome assessors (performance and detection bias)

Methods to blind study participants, personnel and outcome assessors and the effectiveness of these techniques were assessed. Risk of bias was judged as low (successful blinding, or incomplete blinding unlikely to affect the outcome or outcome measurement), high (unsuccessful blinding that is likely to affect the outcome or outcome measurement) or unclear (insufficient information or outcome not addressed in the study).

4. Incomplete outcome data (attrition bias)

The completeness of fatigue outcome data was assessed, including attrition and exclusions from the analysis. Risk of bias was judged as low (for example, no missing data, missing data imputed using appropriate methods, missing data balanced across groups), high (numbers or reasons for missing data imbalanced across groups, inappropriate imputation of missing values) or unclear (insufficient reporting or outcome not addressed)

5. Selective outcome reporting (reporting bias)

Possible selective reporting of outcomes was assessed. Risk of bias was judged as low (all pre-specified fatigue outcomes were reported), high (not all pre-specified outcomes were reported) or unclear (insufficient information).

6. Other sources of bias

Other important concerns regarding bias were considered including group contamination evidenced by control arm performing PA, differences in monitoring of attendance and/or PA or exercise participation in both groups, significant imbalance in fatigue between groups at baseline, financial incentives for participation and stopping the trial early. Risk of bias was judged as low (study appears free from other sources of bias), high (at least one important risk of bias identified), or unclear (there is a potential risk of bias but there is insufficient information to make a clear judgement).

Evidence from the research report providing justification for the decision was recorded.

2.3.3.4 Measures of treatment effect

The Cochrane review used a meta-analysis to combine mean change scores from pre- to post-test for five of the included PA studies (Cramp *et al*, 2013b). The Cochrane handbook advises that a new meta-analysis incorporating data from newly identified and included studies should only be performed if deemed appropriate by review authors (Higgins and Green, 2011). It was decided that data from additional studies would be incorporated into the meta-analysis if the size of the treatment effect, indicated by SMD, differed sufficiently that it would strengthen or alter the existing conclusions. If effect sizes were not available these would be calculated from the published data using methods described in the Cochrane handbook, section 7.7.3.3 (Higgins and Green, 2011). Methodological quality of included studies would be considered when making this decision.

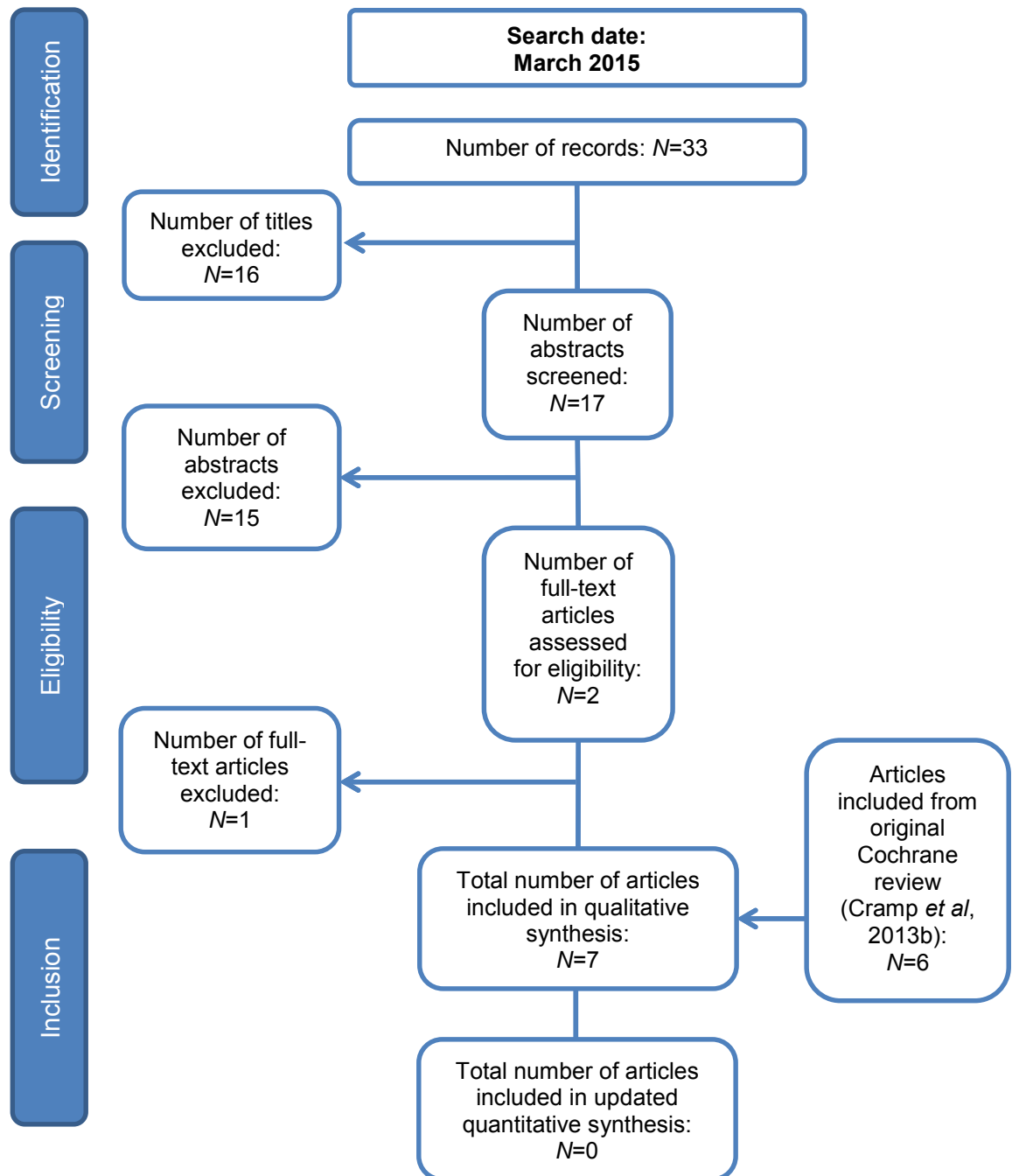
2.4 Results

2.4.1 Results of the search

Figure 2.1 illustrates the study selection process.

The six studies investigating PA in the original Cochrane review were retrieved. Following removal of duplicates an additional 33 studies were identified using the keyword search. After title screening 17 articles remained, with six remaining after screening of abstracts. Of these six, four were conference abstracts and were not included in this review (Mahidashtizad and Salajegheh, 2013, Rouse *et al*, 2013, Azeez *et al*, 2014, Durcan, Wilson and Cunnane, 2014a). Another study was not an RCT (Di Gioia *et al*, 2013). The remaining study was included (Durcan, Wilson and Cunnane, 2014b).

Figure 2.1: Flow diagram showing study selection process



2.4.2 Description of studies

The seven included studies are described in table 2.1. It should be noted that data from the study by Evans and colleagues (2013) presented in the Cochrane review was obtained from study authors prior to publication (Cramp *et al*, 2013). Data for the study presented in this update was obtained from the published article (Evans *et al*, 2013).

2.4.3 Participants

Data were available for 470 participants with RA (receiving an intervention: n=273; controls: n=197). The number of participants completing the studies ranged from 20 (Wang, 2008) to 220 (Neuberger *et al*, 2007). The mean age ranged from 28.5 (Evans *et al*, 2013) to 60 (Durcan, Wilson and Cunnane, 2014b) years old. Average age was in the second decade for one study (Evans *et al*, 2013), fourth decade for four studies (Harkcom *et al*, 1985, Hakkinen *et al*, 2003, Bilberg, Ahlmen and Mannerkorpi, 2005, Wang, 2008) and the fifth (Neuberger *et al*, 2007) and sixth (Durcan, Wilson and Cunnane, 2014b) decade for the two remaining studies. Both males and females were recruited in five studies, all with a higher percentage of females. Two studies only recruited female participants (Harkcom *et al*, 1985, Evans *et al*, 2013). All studies reported disease duration with the mean ranging from 8 months (Hakkinen *et al*, 2003) to 16 years (Durcan, Wilson and Cunnane, 2014b).

2.4.4 Interventions

Interventions are summarised in table 2.1.

2.4.4.1 Length of intervention

The majority of interventions (n=5) were 12 weeks in length. The remaining interventions were six weeks (Evans *et al*, 2013) and 24 months (Hakkinen *et al*, 2003).

Table 2.1: Description of interventions in included studies (n=7)

Lead author, (year)	Bilberg, (2005) ^a	Durcan, (2014b) ^b	Evans, (2013) ^a	Hakkinen, (2003) ^a	Harkcom, (1985) ^a	Neuberger, (2007) ^a	Wang, (2008) ^a
Primary outcome measure	Aerobic capacity, SF-36 physical	FSS, PSQI	HRQoL	Not identified	Not identified	Not identified	Attainment of ACR 20 response criteria
Fatigue scale	SF-36 vitality	FSS	SF-36 vitality, FACIT-F	VAS fatigue	Likert scale rating of fatigue	MAF	VAS fatigue, SF-36 vitality
Type of PA	Aerobic capacity, dynamic and static strengthening and endurance exercises in a temperate pool	Home exercise programme (resistance exercise, ROM, walking)	Iyengar Yoga	Dynamic strength training, using elastic bands and dumbbells, plus recreational PA, e.g. walking, cycling	Bicycle ergometer	Low-impact aerobics plus strengthening, Intervention arm I = class exercise, Intervention arm II = home exercise	Tai Chi
Duration and frequency of PA	45 min, 2 x weekly	30-60 min, Resistance training 3 x weekly, daily ROM, walking 5 x weekly	90 min, 2 x weekly	2 sets per exercise, 8-12 repetitions, 2 x weekly	15-35 min, 3 x weekly	60 min, 3 x weekly	60 min, 2 x weekly

Lead author, (year)	Bilberg, (2005) ^a	Durcan, (2014b) ^b	Evans, (2013) ^a	Hakkinen, (2003) ^a	Harkcom, (1985) ^a	Neuberger, (2007) ^a	Wang, (2008) ^a
Intensity of PA	75% HRmax	Resistance: 40-50% 1 RM; walking: light- to moderate-intensity (moderately short of breath on exertion)	N/A	50-70% RM	70% HRmax	60-80% HRmax	N/A
Length of intervention	12 weeks	12 weeks	6 weeks	24 months	12 weeks	12 weeks	12 weeks
Control intervention	Continue daily activities	Advice on benefits of exercise in RA	Usual care waitlist control	ROM and stretching exercises 2 x weekly, continue recreational activity, no strength training	Continue daily activities	Continue baseline exercise levels	Stretching training and wellness education
Adherence to intervention and control	Mean attendance at intervention sessions = 78%	Not reported	96% intervention sessions attended	Intervention group compliance: Months 0-12: Average 1.5 x weekly exercising; Months 13-24: average 1.4 x weekly	Not reported	Median of 30 of 36 sessions completed by both class and home exercise groups	Not reported

Lead author, (year)	Bilberg, (2005) ^a	Durcan, (2014b) ^b	Evans, (2013) ^a	Hakkinen, (2003) ^a	Harkcom, (1985) ^a	Neuberger, (2007) ^a	Wang, (2008) ^a
Results for fatigue outcome	Significant between group difference at 12 weeks in favour of the intervention (p<0.05) Between-group difference in change scores = 10.1 (MCID: 10.7) ^c	Significant between-group difference in change in fatigue score at 12 weeks in favour of the intervention (p=0.04) Reported between-group difference in change scores = 11.3 (18%) (MCID: 15%) ^c	SF-36 significant post-treatment group differences in favour of the intervention (p<0.01) Between-group difference in change scores = 17 (MCID: 10.7) ^c FACIT-F significant changes (p<0.05) Between-group difference in change scores = 7.9 (MCID: 3-4) ^c	No significant change	Subjective reporting of improvement in fatigue in intervention arm	Intervention arm I: Significant decrease in overall symptoms at 12 weeks in favour of the intervention (p<0.04) Between-group difference in fatigue change scores (class vs control) = 3.17 (significance not reported) (MCID: 5.0) ^c Intervention arm II: not significant	Significant between-group difference on SF-36 vitality in favour of the intervention (p=0.01) Between-group difference in change scores = 18 (MCID: 10.7) ^c

FACIT-F=Functional Assessment of Chronic Illness Therapy Fatigue Subscale; FSS=Fatigue Severity Scale; HAQ=Health Assessment Questionnaire; HRmax=maximum heart rate; HRQoL=Health Related Quality of Life; MACTAR=McMaster Toronto Arthritis Patient Preference Disability Questionnaire; MAF=Multidimensional Assessment of Fatigue questionnaire; MCID=minimal clinically important difference; N/A=not applicable; PA=physical activity; PSQI=Pittsburgh Sleep Quality Index; RA=rheumatoid arthritis; RM=repetition maximum; ROM=range of movement; SF-36=36 item Short Form Health Survey; VAS=visual analogue scale

^aArticle included in Cochrane review (Cramp et al, 2013b)

^bArticle identified in updated search

^cData from Hewlett, Dures and Almeida, (2011)

2.4.4.2 Type of physical activity

The type of PA included in the interventions varied, and included pool-based (Bilberg, Alhmen and Mannerkorpi, 2005) and land-based aerobic exercise (Harkcom *et al*, 1985, Neuberger *et al*, 2007, Durcan, Wilson and Cunnane, 2014b), resistance training (Hakkinen *et al*, 2003, Neuberger *et al*, 2007, Durcan, Wilson and Cunnane, 2014b), range of movement exercises (Durcan, Wilson and Cunnane, 2014b), yoga (Evans *et al*, 2013) and Tai Chi (Wang, 2008). Control interventions also varied and included usual care (Evans *et al*, 2013), usual PA (Harkcom *et al*, 1985, Bilberg, Alhmen and Mannerkorpi, 2005, Neuberger *et al*, 2007), and advice and education (Wang, 2008, Durcan, Wilson and Cunnane, 2014b). In one study the control arm also performed range of movement and stretching exercises alongside usual recreational PA, with the exception of strength training (Hakkinen *et al*, 2003).

2.4.4.3 Frequency and duration of physical activity

Exercises were generally performed two to three times weekly for both class- and home-based interventions. Daily range of movement exercises and walking at least five times weekly was encouraged in one study (Durcan, Wilson and Cunnane, 2014b). The duration of each exercise session varied from 15 to 90 minutes. For one study the focus of the intervention was strength training, therefore the number of sets and repetitions were targeted rather than exercise duration (Hakkinen *et al*, 2003).

2.4.4.4 Intensity of physical activity

Aerobic exercise intensity was targeted at 70-90% maximum heart rate in three studies (Harkcom *et al*, 1985, Bilberg, Alhmen and Mannerkorpi, 2005, Neuberger *et al*, 2007). A more general target of light- to moderate-intensity walking, where participants felt moderately short of breath, was reported in another study (Durcan, Wilson and Cunnane, 2014b). Interventions that included resistance training set a target intensity of either 40-50% (Durcan, Wilson and Cunnane, 2014b) or 50-70% (Hakkinen *et al*, 2003) repetition maximum. Of those studies reporting a prescribed aerobic intensity, two reported that adherence to the intensity was not known (Bilberg, Alhmen, and Mannerkorpi, 2005, Neuberger *et al*, 2007). The remaining studies did not adequately describe adherence to PA intensity therefore this is unknown.

2.4.4.5 Intervention delivery

Exercise interventions were often supervised, although two studies investigated the effects of an unsupervised home exercise programme (Neuberger *et al*, 2007 – intervention arm II, Durcan, Wilson and Cunnane, 2014b). One study reported that a

physiotherapist guided initial exercises (Hakkinen *et al*, 2003), but it was unclear whether ongoing exercise was performed with or without supervision. Not all studies described the professional background of the person delivering the intervention. Where reported, physiotherapists (Hakkinen *et al*, 2003, Bilberg, Ahlmen and Mannerkorpi, 2005), a yoga instructor (Evans *et al*, 2013) or physical education graduate students (Harkcom *et al*, 1985) provided supervision.

2.4.4.6 Intervention adherence

Intervention adherence was reported in four studies. These included a mean attendance rate at sessions of 96% (Evans *et al*, 2013) and 78% (Bilberg, Ahlmen and Mannerkorpi, 2005), median number of sessions attended as 30 out of 36 for both class and home exercise groups (Neuberger *et al*, 2007), and mean exercise frequency as 1.5 times weekly in months zero to 12, and 1.4 times weekly in months 13 to 24 (Hakkinen *et al*, 2003). Adherence data for this last study were collected via self-reported exercise diaries, therefore the authors acknowledged that they may be subject to recall bias and inaccurate reporting (Hakkinen *et al*, 2003).

2.4.5 Outcome measures

A range of self-reported fatigue outcome measures was used (see table 2.1). Two studies used two scales (Wang, 2008, Evans *et al*, 2013). Only one study reported fatigue as a primary outcome measure (Durcan, Wilson and Cunnane, 2014b), although the primary outcome was not identified in three studies (Harkcom *et al*, 1985, Hakkinen *et al*, 2003, Neuberger *et al*, 2007). None of the interventions were designed specifically to manage fatigue. Presence of fatigue was not an inclusion criteria for participants in any of the included studies.

2.4.6 Adverse events

Only one study explicitly reported that there were no adverse events associated with the intervention (Wang, 2008). None of the remaining studies reported adverse events. It is unclear whether this was due to a true absence of adverse events or poor reporting.

2.4.7 Risk of bias

Risk of bias in the included studies is presented in table 2.2. Overall, three studies met three criteria (Bilberg, Ahlmen and Mannerkorpi, 2005, Neuberger *et al*, 2007, Wang, 2008), three met two criteria (Hakkinen *et al*, 2003, Evans *et al*, 2013, Durcan, Wilson and Cunnane, 2014b), and one met one criterion (Harkcom *et al*, 1985). The percentage risk of bias for each domain across all studies is presented in figure 2.2.

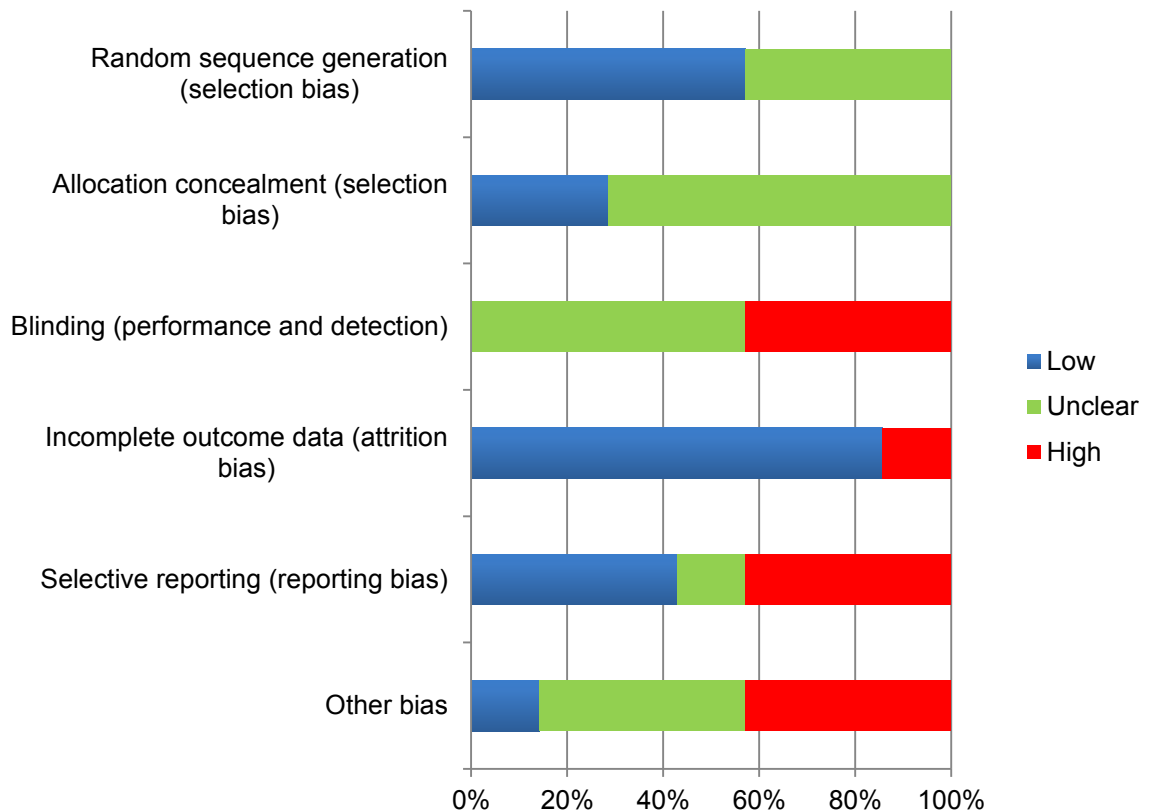
Table 2.2: Risk of bias summary for included studies (n=7)

Lead author, year	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance and detection)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bilberg, (2005)	+	?	?	+	+	?
Durcan, (2014b)	+	?	?	+	?	?
Evans, (2013)	?	?	-	+	+	-
Hakkinen, (2003)	?	?	?	+	+	-
Harkcom, (1985)	?	+	-	-	-	?
Neuberger, (2007)	+	?	-	+	-	+
Wang, (2008)	+	+	?	+	-	-

+ = low risk; ? = unclear risk; - = high risk

2.4.7.1 Random sequence generation and allocation concealment (selection bias)

Although random sequence generation was adequately described in four studies, it was not clearly reported in the remaining three (table 2.2). Randomisation was performed using computer-generated random numbers (Bilberg, Ahlmen and Mannerkorpi, 2005, Wang, 2008, Durcan, Wilson and Cunnane, 2014b) or an *a priori* list of randomly generated permutations of three numbers (Neuberger *et al*, 2007). Only two studies adequately reported allocation concealment (table 2.2). Methods included patients independently choosing a time slot prior to randomisation (Harkcom *et al*, 1985) and use of sealed opaque envelopes (Wang, 2008).

Figure 2.2: Risk of bias presented as percentages for included studies (n=7)

2.4.7.2 Blinding (performance and detection bias)

Blinding of participants, personnel and assessors was not reported in three studies (Harkcom *et al*, 1985, Hakkinen *et al*, 2003, Durcan, Wilson and Cunnane, 2014b). The remaining four studies reported blinding of outcome assessors only (Bilberg, Alhmen and Mannerkorpi, 2005, Neuberger *et al*, 2007, Wang, 2008, Evans *et al*, 2013).

2.4.7.3 Incomplete outcome data (attrition bias)

The majority of studies (n=5) were considered at low risk of attrition bias, reporting all outcome data and giving reasons for missing data. The remaining studies either did not explain missing data for three participants who withdrew and no fatigue data were presented for controls (Harkcom *et al*, 1985), or no data were provided for withdrawals between randomisation and baseline (Neuberger *et al*, 2007).

2.4.7.4 Selective outcome reporting (reporting bias)

Selective reporting was noted in three studies (Harkcom *et al*, 1985, Neuberger *et al*, 2007, Wang, 2008). Outcome data for three intervention arms were combined in one study, thus providing insufficient detail regarding the effect of each intervention (Harkcom *et al*, 1985). Another study reported collecting social support data but did not report these

in the published article (Neuberger *et al*, 2007). The third study reported recording the number of and reasons for missing both intervention and control arm sessions, but did not present these data (Wang, 2008)

2.4.7.5 Other sources of bias

Only one study was considered free from other sources of bias as specified for this review (Neuberger *et al*, 2007). Of the remaining six studies, three were considered at high risk (Hakkinen *et al*, 2003, Wang, 2008, Evans *et al*, 2013) and three had unclear risk of bias from other sources (Harkcom *et al*, 1985, Bilberg, Alhmen and Mannerkorpi, 2005, Durcan, Wilson and Cunnane, 2014b). Reasons for these judgements are presented in table 2.3.

Table 2.3: Reasons for judgement of the risk of other sources of bias

Lead author, (year)	Risk of other sources of bias	Reason for judgement of risk of bias
Bilberg, (2005)	?	No reporting of monitoring of adherence of control arm to home exercise and daily activities
Durcan, (2014b)	?	No reporting of adherence to physical activity or exercise in either group
Evans, (2013)	-	\$10 travel expenses paid for intervention participants travelling more than 25 miles
Hakkinen, (2003)	-	Control group performed exercises, n=3 started exercising in a gym, monitoring by diaries not reported for control arm
Harkcom, (1985)	?	Control data for fatigue not reported so unable to determine baseline differences. Monitoring of adherence to physical activity not reported for either group
Neuberger, (2007)	+	No evidence of other sources of bias
Wang, (2008)	-	Control group performed daily stretching exercises. Monitoring of adherence to physical activity not reported

+ = low risk; ? = unclear risk; - = high risk

2.4.8 Effect on fatigue

Table 2.1 shows fatigue outcomes for each individual study. A statistically significant post-test improvement in fatigue scores was reported in the intervention arm compared with controls in four studies ($p < 0.05$) (Bilberg, Alhmen and Mannerkorpi, 2005, Wang, 2008, Evans *et al*, 2013, Durcan, Wilson and Cunnane, 2014b). The clinical significance was not described in any study reports. However, information on the ability of each scale to detect change (Hewlett, Dures and Almeida, 2011) suggests that pre- to post-test between-group differences in change scores in three studies were clinically significant (Wang, 2008, Evans *et al*, 2013, Durcan, Wilson and Cunnane, 2014b). Changes in the 36 item Short Form Health Survey (SF-36) vitality scores in the remaining study fell short

of the minimal clinically important difference (MCID) (defined in Hewlett, Dures and Almeida, (2011)) by 0.6 points (Bilberg *et al*, 2005). Although Neuberger and colleagues (2007) reported statistically significant changes in overall symptoms, the significance of changes in fatigue were not reported. The fatigue change scores presented in the research report did not meet the criteria for MCID for the Multidimensional Assessment of Fatigue scale (defined in Hewlett, Dures and Almeida (2011)). The remaining two studies did not report statistically significant improvements. One study only recorded subjective improvements in fatigue (Harkcom *et al*, 1985).

2.4.8.1 Meta-analysis

In the original Cochrane review mean change scores from pre- to post-test were combined in a meta-analysis for six comparisons (Hakkinen *et al*, 2003, Bilberg, Alhmen and Mannerkorpi, 2005, Neuberger *et al*, 2007 – I and II, Wang, 2008, Evans *et al*, 2013). Change data for fatigue were not available for one comparison (Harkcom *et al*, 1985).

Results indicated that PA was statistically more effective than control immediately post-intervention (SMD -0.36, 95% CI -0.62 to -0.10, $p=0.0066$), indicating a small beneficial effect of PA on fatigue (Cramp *et al*, 2013b). A summary effect size was not presented in the newly included study (Durcan, Wilson and Cunnane, 2014b). SMD for fatigue outcome was calculated using methods presented in the Cochrane handbook, section 7.7.3.3 (Higgins and Green, 2011). SMD, unadjusted for baseline differences, was -0.47 indicating a small effect. When calculating SMD, errors in the data were noted in the presented change in means for the intervention arm (-11.2) (Durcan, Wilson and Cunnane, 2014b). This figure did not correspond with the presented mean fatigue scores at baseline (29.5) and 12 weeks (21.4), which would result in a change in means of -8.1. SMD was calculated according to the mean fatigue scores presented in the study. This study was not included in the meta-analysis due to the poor methodological quality and errors in reported figures, making it difficult to trust the accuracy of the results. Although the SMD was slightly larger than that already obtained, methodological issues mean it would not strengthen or alter the conclusions from the original review.

2.4.8.2 Long-term follow-up

In the Cochrane review, meta-analyses were only performed on post-test data as follow-up data were not available for the majority of studies (Cramp *et al*, 2013b). One study re-assessed outcomes two months after treatment (Evans *et al*, 2013). However, follow-up data were combined for both intervention and control arms, as control participants received the intervention at the end of the initial test period. As a result, no

control data were available. Whilst significant effects of the intervention on fatigue were noted post-treatment, these were not maintained at 2-month follow-up (Evans *et al*, 2013).

2.5 Discussion

This review aimed to investigate the effectiveness of PA interventions for reducing RA fatigue. Seven RCTs that investigated PA interventions and included a fatigue outcome measure were included, providing data for 470 RA patients. PA interventions were varied and included pool-based aerobic exercise, yoga, Tai Chi and land-based aerobic and resistance training. Delivery methods included supervised class programmes and unsupervised home exercise.

A meta-analysis incorporating data from five of the seven studies demonstrated a small significant effect for PA when compared with a control intervention, suggesting that PA may be useful for managing fatigue in RA in the short-term (Cramp *et al*, 2013b). Additionally, a recent RCT reported statistically significant changes in fatigue outcomes following a home exercise intervention compared with controls ($p=0.04$) (Durcan, Wilson and Cunnane, 2014b). Although initial results seem promising there are several limitations in the current evidence that are worth noting. First, it is disappointing that the quality of the recent study was not markedly greater than previous studies (Durcan, Wilson and Cunnane, 2014b). Poor methodological quality and reporting errors meant that its inclusion in the meta-analysis could have been misleading. This brings into question whether studies in the original Cochrane review should have been combined in a meta-analysis, as two of these only met two out of six criteria for risk of bias. The three other studies incorporated in the meta-analysis only met three of six criteria.

The seven studies were of moderate methodological quality, with small group sizes and lack of blinding being particularly problematic. Blinding of participants in behavioural or exercise interventions is often not possible for PA interventions (Bourke *et al*, 2013). Also, the use of self-reported questionnaires for measuring fatigue outcome negates the usefulness of blinding the outcome assessor. Therefore, risk of performance and detection bias is difficult to minimise for these interventions. Nonetheless, attempts to minimise this risk were not reported. Poor reporting in several articles did not allow adequate assessment of the risk of bias, making it difficult to determine the overall quality of the research. The majority of studies were at high risk of bias from sources such as contamination between groups, further limiting the internal validity of the research findings, for example, where control participants performed range of movement and stretching exercises alongside recreational PA (Hakkinen *et al*, 2003).

None of the interventions were specifically designed to manage fatigue, even where the aim of the study was to investigate the effect of exercise on sleep quality and fatigue (Durcan, Wilson and Cunnane, 2014b). Descriptions of intervention design and development were minimal for all studies. Although studies may have indicated aims, such as investigating the effect of exercise on quality of life (Evans *et al*, 2013), physical function (Hakkinen *et al*, 2003), general RA symptoms (Neuberger *et al*, 2007) or safety of a type of PA in RA (Wang 2008), there was no explicit evidence that interventions were specifically designed to address these aims.

Intervention length was reasonably consistent, with the majority lasting 12 weeks. However, the type, frequency, duration and intensity of PA varied. Several studies prescribed the intensity, duration and frequency of PA, but it is unclear whether these parameters were successfully adhered to throughout the intervention period. Some authors acknowledged that actual PA intensity was unknown. Similarly, there was limited information regarding overall adherence to PA interventions, making it difficult to determine reasons for participation or non-participation in these programmes. Where adherence was reported, this related to the number of sessions attended or frequency of exercise. The lack of follow-up data for any of the studies further limits our understanding of ongoing effects of PA on RA fatigue.

There is insufficient information from these interventions to judge whether specific PA parameters are more or less likely to be effective for fatigue management in RA. Indeed, there are no data available regarding dose response for exercise in general. Recently updated American College of Sports Medicine guidance for exercise prescription recommends that while moderate- to vigorous-intensity PA is appropriate for most adults, light- to moderate-intensity may be beneficial for people who are deconditioned (Garber *et al*, 2011). The guidance also suggests that less than 20 minutes of PA per day can be beneficial in sedentary persons. This suggests that encouraging patients to do any PA initially might be more appropriate than insisting on a specific intensity or duration. It may be more appropriate to focus on addressing barriers to participation, such as lack of motivation and negative beliefs regarding PA (Lee *et al*, 2012), in order to initiate PA. A prescriptive approach may not be easily applied in clinical practice if HCPs do not have sufficient time or knowledge to implement and supervise a prescribed programme (Knittle, De Gucht and Maes, 2012).

Only two studies reported a sample size calculation (Neuberger *et al*, 2007, Durcan, Wilson and Cunnane, 2014b) but neither was based upon fatigue as the primary outcome. It was unclear whether any of the studies reporting significant changes in fatigue were adequately powered to detect changes in these outcomes. Small samples and lack of

statistical power limit the ability to generalise results to the wider RA population (external validity). Also, the included studies used a variety of fatigue outcome measures, making it difficult to make direct comparisons. Consistent use of validated outcomes in future research would improve comparison.

PA research relies on voluntary participation. Consequently, recruitment is often biased towards those who are interested in or motivated to perform PA (Nordgren *et al*, 2014). Reasons for declining participation in the included studies were often not reported. Where they were, reasons included being busy, travel distance or disinterest (Evans *et al*, 2013). These reasons have been cited in other PA trials in RA (de Jong *et al*, 2004a, Nordgren *et al*, 2014). One study noted that failure to collect baseline data for 62 participants who withdrew between randomisation and baseline data collection may have meant that the sample was biased towards more motivated participants (Neuberger *et al*, 2007). Self-selection of participants in PA trials also has implications for the control arm. As a sub-group of motivated participants, they might be more likely to engage in PA even if they have been asked not to, thus increasing the potential for contamination and reducing potential effect size for the PA intervention. This further limits external validity of the findings.

An in-depth analysis of participants and non-participants in a recent PA trial in RA concluded that only 8% of the initial target population were assessed at baseline, despite 62% expressing interest prior to receiving information about location, timing and cost of the PA interventions (Nordgren *et al*, 2014). These factors are recognised barriers to participation in PA in RA (Wilcox *et al*, 2006). It is possible that PA interventions only reach a small minority of eligible participants in clinical practice as well. This suggests a need to address the priority placed on PA by RA patients, including during times of wellness, to encourage engagement in PA as a proactive strategy to prevent further disability and comorbidities.

Participants in the included studies were not selected for the presence of fatigue. Therefore this symptom may not have been a significant problem for some participants. Consequently, fatigue data from these studies are likely to underestimate the effectiveness of PA for RA fatigue management, as fatigue has been cited as a barrier to PA (Law *et al*, 2010). Participants who withdrew from a recent PA trial between agreeing to take part and baseline assessment reported more fatigue than those who were assessed ($p=0.009$), even though they did not report this as a reason for withdrawing (Nordgren *et al*, 2014). It is possible that eligible patients who experienced greater fatigue who were approached to take part in trials included in the current review declined participation. Therefore, the resulting participants might be less representative of fatigued

RA patients. As a result, the true effectiveness of PA for reducing fatigue in RA is difficult to determine.

Variations in characteristics of participants in included studies may also limit the external validity of the results. This includes imbalances in gender, with the inclusion of women only in two studies and fewer men included overall. Although RA affects more women than men (Symmons, 2002) men tend to be under-represented in PA trials in RA (Vervloesem *et al*, 2012, Nordgren *et al*, 2014). Also, men with RA may require different support strategies than women (Flurey *et al*, 2015). As a result, recruitment of predominantly women to a PA intervention may not simply be indicative of gender differences in prevalence rates of RA, but may also reflect different coping styles and management preferences. It cannot be presumed, therefore, that these PA interventions would be effective for reducing fatigue in both men and women with RA.

The range of ages included in studies was also not representative of the general RA population. Peak age of incidence in the UK has been reported as 55-64 years old in women and 65-75 years old in men (Symmons, 2002). However, only two studies reported the average age of participants as falling within the fifth and sixth decades. This may reflect other observations that participants in PA trials tend to be younger (de Jong *et al*, 2004a, Nordgren *et al*, 2014).

2.5.1 Other systematic reviews

This chapter has focused on a recent Cochrane review investigating evidence for the effect of PA interventions on RA fatigue (Cramp *et al*, 2013b). Two other reviews have attempted to investigate this topic (Balsamo *et al*, 2014, Rongen-van Dartel *et al*, 2015).

A recent systematic review and meta-analysis investigated the effectiveness of aerobic land-based exercise on fatigue in RA both post-intervention (12 weeks) and in the longer term at 24 weeks (Rongen-van Dartel *et al*, 2015). Firstly, authors identified RCTs comparing aerobic exercise in RA with 'no exercise' controls even if they did not report fatigue data. Authors were contacted to retrieve fatigue data. Of the 19 RCTs identified, it was reported that five had collected fatigue data and these were analysed in the review (Rongen-van Dartel *et al*, 2015). Details of the remaining 14 studies were not reported. The authors only included one of the studies (Neuberger *et al*, 2007) identified for inclusion in other reviews of PA and fatigue (Cramp *et al*, 2013b, Balsamo *et al*, 2014). Of the additional four studies included in their review one was a protocol with no published data available (Reid *et al*, 2011). Fatigue was not reported as an outcome in the remaining three studies articles, therefore fatigue data would only have been identified as a result of contacting study authors. These articles would not have been found in a literature search where fatigue was specified as an outcome. This may indicate selective

reporting, whereby researchers have collected fatigue data but not reported that they have done so. Authors of the review paper were also authors on the included papers that did not report fatigue, so are likely to have had insight into the availability of unpublished fatigue data.

Other studies included in the review presented in this chapter are likely to have been excluded by Rongen-van Dartel and colleagues (2015) due to their inclusion criteria:

- RA diagnosed according to ACR criteria
- Supervised land-based aerobic exercise
- Exercise intensity between 50 and 90% maximum heart rate
- Exercise duration at least 15 minutes, and a minimum of twice weekly for at least four weeks
- Randomised study
- No exercise performed by the control arm

Despite these criteria, one of the included studies did have a control arm that performed supervised exercises (van den Ende *et al*, 2000).

These strict criteria may limit the usefulness of the results for clinical practice. For example, studies that used a water-based programme, a dance-based programme where intensity was not 50-90% maximum heart rate, did not report training intensity or did not include supervised training were excluded. Failure to include these may omit important findings that could contribute to our understanding of this topic. Although stricter criteria might reduce heterogeneity from a research perspective, they may limit the clinical usefulness of the results. For example, training intensity may not be measured accurately in clinical practice and supervised exercise twice weekly for a minimum of four weeks is unlikely to be realistic. Lack of time or limited knowledge and skills may prohibit some clinicians from prescribing and supervising such rigid exercise programmes (Hurkmans *et al*, 2011). A more person-centred approach is likely to improve engagement in lifestyle and behaviour change interventions (Knittle, De Gucht and Maes, 2012). The justification for choosing supervised programmes as potentially more effective than home exercise is weak, as it was based on one paper in female Chinese RA patients (Hsieh *et al*, 2009) and another in cancer patients (Lin *et al*, 2014) and therefore cannot be generalised to the RA population. Excluding these programmes may omit data relevant to the real-world setting, underestimating the clinical effectiveness of PA for managing RA fatigue.

Nonetheless, the review does make an initial attempt to refine the meta-analysis by using more homogeneous interventions based on aerobic PA alone (Rongen-van Dartel, 2015). Whilst this was a recommendation for future research in the Cochrane review

(Cramp *et al*, 2013b), the current lack of research on PA interventions for managing RA fatigue limits the availability of appropriate data.

An additional systematic review has been published investigating exercise and fatigue in RA (Balsamo *et al*, 2014). However, the aim of the review was unclear with authors stating that they “reviewed the assessment of fatigue as an outcome measure and a predictor of exercise in rheumatoid arthritis” (p.58, Balsamo *et al*, 2014). Descriptions of the methods were vague and the inclusion criteria were poorly articulated. Only four articles were included. Of these, three were excluded from the Cochrane review (Cramp *et al*, 2013) as they either did not report data separately for RA patients (Daltroy *et al*, 1995) or were not an RCT (Noreau *et al*, 1995, Neuberger *et al*, 1997). Given RCTs were an inclusion criterion, the inclusion of these studies is unexpected. The extremely poor methodological quality of the review, including poor reporting of review aims, methods and results severely limits its utility.

2.5.2 Limitations of the review

There are several limitations to the current review. Conference abstracts were excluded, study authors were not contacted and grey literature was not searched. This may have resulted in omission of relevant data.

Only the candidate completed data extraction and critical appraisal of the new study by Durcan and colleagues (2014b). However, overall results were discussed with a member of the supervision team who had been involved with the original review (Fiona Cramp). Similarly, the Cochrane meta-analysis was not revised to include data from the additional study. However, its inclusion is unlikely to have altered the current conclusions.

Finally, the search was limited to RCTs in order to determine effectiveness of the interventions of interest. By limiting the search in this way potentially useful evidence from non-randomised and qualitative studies may have been missed.

2.6 Conclusions

Although the Cochrane review indicated that there is some evidence of the potential for PA to be effective in reducing symptoms of fatigue in RA (Cramp *et al*, 2013b), this evidence remains limited. Since publication of the review, one further RCT has been published, also suggesting a positive effect of exercise on fatigue (Durcan, Wilson and Cunnane, 2014b). However, methodological flaws and poor reporting undermine the trustworthiness of these findings. Additionally, none of the PA interventions in the included studies were specifically designed to manage RA fatigue. These findings support the need to develop a specific PA intervention to address this issue.

Due to the limited availability of evidence within an RA population, it is necessary to explore the broader literature for other long-term conditions where fatigue is a symptom. An exploration of existing evidence for the use of PA interventions for fatigue management in these conditions may provide valuable lessons for intervention development. The following chapter presents a narrative literature review of this evidence in order to inform the design of an intervention for use in RA.

Chapter 3: Physical activity for managing fatigue in long-term conditions

Chapter 2 identified limited available evidence for the potential of PA interventions to improve RA fatigue. This chapter discusses the presence of fatigue as a symptom of other long-term conditions and explores existing evidence for the effectiveness of PA and exercise therapy interventions for fatigue management in these conditions. Characteristics of interventions, such as the type of PA, duration, frequency and intensity and methods of delivery are described. Long-term follow-up and maintenance of PA and cost-effectiveness of interventions are also considered.

3.1 Fatigue in long-term conditions

Fatigue is a frequent and distressing problem in many long-term conditions, including but not limited to multiple sclerosis (MS), chronic fatigue syndrome (CFS) and cancer. Experiences of fatigue in these different conditions often have similar features to musculoskeletal and RA fatigue, including physical and cognitive elements that impact on emotional and functional aspects of daily life (Hewlett, Nicklin and Treharne, 2008). However, there are some key differences between musculoskeletal fatigue and fatigue related to other long-term conditions. These are discussed below.

3.1.1 Multiple sclerosis

Excessive fatigue is an important symptom of MS and has a significant effect on patients' quality of life (Asano and Finlayson, 2014). As in RA, MS fatigue is thought to be multifactorial with physical, psychological and psychosocial causes and consequences (Heine *et al*, 2012). It is often associated with neurological symptoms and may be related to neurodegenerative disease processes (Pilutti *et al*, 2013), suggesting key differences in its aetiology compared with RA fatigue. Nonetheless, it has been suggested that physical inactivity resulting in deconditioning may also have a role in the onset and persistence of MS fatigue (Heine *et al*, 2012, Pilutti *et al*, 2013).

3.1.2 Chronic fatigue syndrome

Fatigue is a definitive feature of CFS, also known as myalgic encephalitis. The aetiology of fatigue in CFS is uncertain. However, it is increasingly recognised that interactions between physical and psychological factors can drive and sustain fatigue, with psychosocial factors being important (Edmonds, McGuire and Price 2004). This fits with

the conceptual model of RA fatigue proposed by Hewlett and colleagues (2011b). Unlike in RA, fatigue in CFS occurs in the absence of an identifiable underlying pathology or alternative diagnosis (Prins *et al*, 2006). Despite this, CFS can result in significant distress and disability (Edmonds, McGuire and Price 2004). The impact on patients' daily lives tends to be more extreme than with RA fatigue, despite comparable fatigue severity (Repping-Wuts *et al*, 2007, van Hoogemoed *et al*, 2010). Therefore, it is useful to consider CFS treatment strategies when developing interventions for managing RA fatigue.

3.1.3 Cancer

Cancer-related fatigue (CRF), like RA fatigue, has been described as overwhelming, unexpected and unrelieved by rest, and is often overlooked or ignored by HCPs (Wu *et al*, 2007). Significant disruption to function and quality of life has been reported as a result of CRF (Bower, 2014). Although the mechanisms of CRF may be different from that of RA, and may be related to chemotherapy and radiotherapy, the physical, emotional and mental consequences, and subsequent impact on patients' lives, appear to be comparable (Ahlberg *et al*, 2003). Hence, as for CFS, evidence of effective PA and exercise interventions may offer useful lessons for fatigue management in RA.

3.2 Evidence of effectiveness of physical activity for managing fatigue

3.2.1 Search strategy

A comprehensive search was carried out using relevant electronic databases (box 3.1) to identify research published up to November 2014. Searches for keywords and subject headings were conducted to identify relevant literature (see table 3.1 for search terms, see appendix C for search strategy). Where possible recent high quality meta-analyses, such as those using Cochrane methodology, were selected along with relevant RCTs, non-RCTs and qualitative research papers.

Box 3.1: Electronic databases used in the narrative review

MEDLINE (via EBSCO)
Allied and Complementary Medicine (AMED)
Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus
Cochrane Controlled Trials Register (CENTRAL)
EMBASE
PsycINFO
SportDiscus
Science Citation Index

Table 3.1: Search terms for narrative literature review

Search term 1: Disease	Search term 2: Symptom	Search term 3: Intervention
Long term condition* OR Chronic disease* OR Chronic condition* OR chronic illness*	Fatigue OR Chronic fatigue syndrome OR Cancer related fatigue	Physical* activit* OR Exercise* OR Walk* OR Cycl* OR Swim* OR gym* OR Aerobic exercise* OR Yoga OR Tai chi OR Physical exercise* OR Sport* OR fitness OR Fitness level* OR Activity level* OR Nordic walking OR exercise therapy OR exercise intervention

**=stem word to identify any words beginning with the stem*

SMD was used as a measure of effect size where available. This summary statistic is used when the same outcome is being assessed by all studies but has been measured in different ways (Higgins and Green, 2011). Interpretation of the statistical importance of the effect size is often based on figures suggested by Cohen (1988) relating to power analysis of 0.2, 0.5 and 0.8 for small, medium and large effects respectively, with the equivalent of 0.1, 0.3 and 0.5 for r (the Pearson product-moment correlation coefficient) (Rice and Harris, 2005, Durlak, 2009). Whilst these figures are used here as a guide, they should not be used in isolation to determine the significance of an effect. The context of the specific measurement of interest, including the practical and clinical importance must also be considered (Durlak, 2009).

3.3 Overall findings

3.3.1 Effectiveness of interventions

Despite a large number of RCTs examining the effects of exercise training on fatigue in MS there were a limited number of systematic reviews reporting inconsistent results (Pilutti *et al*, 2013). However, two recent meta-analyses reported effect sizes of 0.45 (95% CI 0.22 to 0.68; $p < 0.001$) (Pilutti *et al*, 2013) and 0.57 (95% CI 0.10 to 1.04; $p = 0.02$) (Asano and Finlayson, 2014) for the effectiveness of exercise on fatigue reduction, suggesting significant small to moderate effects. Pilutti and colleagues (2013) commented that individual studies had variable effects and many did not sufficiently report details of training parameters such as exercise intensity and duration. Both review papers noted that few studies specified the presence of fatigue in their inclusion criteria, which might explain variability in results if participants did not experience significant fatigue at baseline (Pilutti *et al*, 2013, Asano and Finlayson, 2014). Given these limitations, and the absence of a Cochrane review investigating the effectiveness of PA interventions in this patient population, the evidence for exercise for MS fatigue will not be explored in further detail.

Investigations into the use of PA and exercise for managing fatigue have received more attention in CFS and cancer and therefore may provide more insight. These are discussed in further detail below.

3.3.1.1 Chronic fatigue syndrome

NICE recommend that specialist care for CFS should include graded exercise therapy (GET) (NICE, 2007b). GET is a structured exercise programme based on theories of deconditioning and exercise intolerance that assume that fatigue is driven by physiological changes resulting from activity avoidance (White *et al*, 2011). Treatment aims to assist patients to regain appropriate levels of PA, helping to reduce fatigue and disability. Initial treatment focuses on establishing an achievable baseline of PA through shared decision-making between patient and HCP, followed by a mutually agreed, gradual, incremental increase in PA duration. Intensity is steadily increased once the target duration has been reached. Increases in PA are carefully managed to avoid over-exertion and exacerbation of symptoms (White *et al*, 2011).

A Cochrane meta-analysis concluded that GET might be beneficial for some patients with CFS (Edmonds, McGuire and Price, 2004). However, only nine studies were identified. Of these, only five met the inclusion criteria. All were single-centre RCTs, three of which were conducted in the UK, with a total of 336 participants. A significant improvement in fatigue of moderate effect size was seen in the exercise therapy arm

compared to controls at three months (SMD -0.77; 95% CI -1.26 to -0.28). The exercise arm also showed significant moderate improvements in physical functioning (SMD -0.64; CI 0.96 to -0.33). Control interventions included usual care, relaxation and flexibility exercises, pharmacotherapy and patient education (Edmonds, McGuire and Price, 2004). The authors reported that the studies were of reasonable quality, but acknowledged that the small evidence base limited the precision of the results.

These findings have been replicated in a more recent meta-analysis (Castell, Kazantzis and Moss-Morris, 2011) and confirmed in a high quality multicentre RCT (White *et al*, 2011). In this study, known as the PACE trial, mean fatigue scores 16 weeks after the intervention were 3.2 (95% CI 1.7 to 4.8) points lower for the GET arm (n=159) compared with specialist medical care alone (n=157) (p=0.0003). Mean physical function scores were 9.4 (CI 4.4 to 14.4) points higher for GET (p=0.0005). GET was also found to be significantly more effective for improving fatigue (mean difference -2.5; CI -4.2 to -0.9; p=0.0059) and physical function (mean difference 12.8; CI 7.7 to 17.9; p<0.0001) compared with adaptive pacing therapy (White *et al*, 2011).

These results must be considered in the context of their clinical importance (Durlak, 2009). The PACE trial authors defined a clinically useful difference as 2 points on the Chalder fatigue scale and 8 points for SF-36 physical function (White *et al*, 2011). These figures were calculated as 0.5 of the standard deviation (SD) of baseline data for these outcome measures. According to these figures, data suggested a clinically meaningful improvement in fatigue and physical function following a GET intervention. However, it is over-simplistic to compare the mean difference and MCID alone. Instead, the proportion of patients who have met the criteria for this change should be considered. This must take into account not only group differences between those who improve, but also between those who remain unchanged or deteriorate by the same amount (Guyatt *et al*, 2002).

In the PACE trial it was reported that 94 (61%) of 154 participants in the GET arm had improvements in fatigue and physical function that met the MCID, compared with 64 (45%) of 152 for specialist medical care alone (White *et al*, 2011). Although these figures are helpful when considering the application of the intervention in clinical practice, the authors did not present the difference between study arms in the proportion of participants who remained unchanged or deteriorated by the same amount. This makes it difficult to judge if these data represent a true overall clinical benefit in this patient group.

3.3.1.2 Cancer

Access to an exercise programme is recommended for managing CRF in clinical guidelines, such as NICE guidance for advanced breast cancer (NICE, 2014a) and

American Society of Clinical Oncology guidelines for CRF following completion of primary treatment (Bower, 2014).

Exercise has been shown to be statistically more effective than control interventions (SMD -0.27; 95% CI -0.37 to -0.17) for the management of CRF (Cramp and Byron-Daniel, 2012). The authors set out to calculate the number needed to treat to benefit as an indicator of clinical significance, based on the number of participants experiencing 50% reduction in fatigue. However, they found that this could not be determined due a lack of validated cut-off scores for fatigue severity and MCIDs for fatigue measures used in the studies (Cramp and Byron-Daniel, 2012). It is possible to estimate the overall proportion benefiting and the number needed to treat from effect sizes in the absence of MCIDs (Guyatt *et al*, 2002), but these were not available for the included studies (Cramp and Byron-Daniel, 2012). As a result the clinical significance of the results remains difficult to assess.

Fatigue outcomes for participants receiving an exercise intervention (n=1,461) were compared with those receiving a comparison intervention (n=1,187), such as usual care or no intervention, waitlist control, or alternative therapy, for example, relaxation therapy or flexibility exercises (Cramp and Byron-Daniel, 2012). It is worth noting that comparing the intervention of interest with other active interventions may dilute the effect sizes. Comparisons were based on post-intervention data, as only 12 of the 56 included studies reported follow-up data. The risk that results were biased in favour of exercise was noted, as not all studies contributed to the meta-analysis. It may be that these studies did not find exercise to be effective and did not report negative findings. In addition, the diverse range of studies, many with small sample sizes, limits the accuracy of these findings (Cramp and Byron-Daniel, 2012). Nonetheless, another recent meta-analysis has demonstrated a significant small to moderate effect of exercise therapy on CRF (SMD -0.45; 95% CI -0.57 to -0.32; n=56 studies; p<0.001) (Tomlinson *et al*, 2014). Both meta-analyses concluded that aerobic exercise is beneficial for the management of CRF (Cramp and Byron-Daniel, 2012, Tomlinson *et al*, 2014).

3.3.2 Type of physical activity

3.3.2.1 Chronic fatigue syndrome

All interventions investigated in the Cochrane review reported using an aerobic GET approach. However, details of the type of PA or exercise performed were not reported (Edmonds, McGuire and Price, 2004). A recent RCT reported that walking was the exercise most often chosen by participants receiving GET (White *et al*, 2011). Other trials of GET have described an approach referred to as pragmatic rehabilitation, consisting of

GET combined with patient education (Powell, Edwards and Bentall, 1999, Powell *et al*, 2001, Wearden *et al*, 2010). This approach includes PA, such as walking, cycling on an exercise bike and a step-up programme, and educational information about physical deconditioning, sleep disruption and circadian rhythms, and the effects of anxiety on the body (Powell, Edwards and Bentall, 1999). Self-chosen PA was encouraged in a self-regulation PA intervention for unexplained chronic fatigue but the selected activities were not specified (Marques *et al*, 2015).

3.3.2.2 Cancer

RCTs included in the Cochrane review of exercise for managing CRF investigated a variety of types of PA (Cramp and Byron-Daniel, 2012). These mainly included aerobic exercise, with walking specified in 14 studies and a range or choice of exercise in 23 of the 56 included studies. This was occasionally combined with resistance or flexibility exercises, with a minority of studies (n=2) comparing aerobic exercise with resistance exercise. Tomlinson and colleagues (2014) noted similar variety in the type of PA, with the majority of studies specifying multi-modal exercise, walking or aerobic exercise.

Meta-analysis of data from five studies in the Cochrane review noted a lack of effect for resistance exercise (n=237) compared with the control arm (n=164) (SMD -0.18; CI -0.39 to 0.02). Analysis of three studies investigating low-level mind-body exercises such as yoga or Qigong did not indicate an effect on fatigue (SMD -0.10; CI -0.39 to 0.19) (Cramp and Byron-Daniel, 2012). This suggests that the type of PA included in interventions may be important for fatigue management. However, another meta-analysis did not identify any difference in benefits of exercise for CRF according to type of PA (Tomlinson *et al*, 2014). A recent RCT reported that a 12-week programme of twice-weekly progressive resistance therapy (n=77) during radiotherapy significantly improved general fatigue (effect size 0.25; p=0.044) and physical fatigue (effect size 0.33; p=0.013) in breast cancer patients compared with relaxation therapy controls (n=78) (Steindorf *et al*, 2014).

An RCT of resistance training (n=34) compared with aerobic exercise training (n=32) in prostate cancer survivors reported no significant between-group differences for fatigue post-treatment or at six month follow-up (Santa Mina *et al*, 2014). The authors noted that the aerobic training arm engaged in significantly more PA than the resistance training arm at each time point (p<0.05). It was suggested that aerobic exercise, such as walking, may be more familiar to participants, with minimal requirements for specialist instruction or equipment making it more accessible and reproducible than resistance training (Santa Mina *et al*, 2014). Given the low levels of PA reported for many patients this may be important to consider when encouraging participation.

A six-week supervised multi-modal exercise programme delivered during chemotherapy demonstrated a significant post-treatment effect on fatigue compared with wait-list controls (effect size=0.44; $p=0.002$) (Andersen *et al*, 2013). The intervention combined high- and low-intensity activities, including heavy resistance and cardiovascular training. However, it also included relaxation training, body-awareness training and massage making it difficult to attribute the findings to exercise therapy alone. Additionally, the heterogeneity of cancer diagnosis and treatment limits the usefulness of the results.

Given the above findings, it would seem pertinent to advocate aerobic exercise or aerobic plus resistance exercise for fatigue management.

3.3.3 Duration, intensity and frequency of physical activity

3.3.3.1 Chronic fatigue syndrome

All programmes included in the Cochrane review were 12 weeks in duration. However, the interventions varied in terms of target exercise intensity (40% to 70% VO_2max), and frequency of exercise (3 to 5 sessions per week) with each session lasting 30 minutes (Edmonds, McGuire and Price, 2004). It has been suggested that commencing GET at a lower intensity might be more effective in the treatment of CFS (Castell, Kazantzis and Moss-Morris, 2011). Other trials investigated longer GET programmes, such as 14 sessions over 23 weeks with a booster at 36 weeks (White *et al*, 2011) and 10 sessions over 18 weeks (Wearden *et al*, 2010). Exercise intensity was not specified in terms of VO_2max in these studies. White and colleagues (2011) reported that treatment aimed to build up to 30 minutes of light exercise five times a week before gradually increasing the intensity and aerobic nature of the exercise in accordance with participant feedback and goals.

3.3.3.2 Cancer

Considerable variation in the duration, intensity and frequency of exercise sessions and the duration of interventions for CRF has been reported (Cramp and Byron-Daniel, 2012, Tomlinson *et al*, 2014). The duration and frequency of PA in studies included in the Cochrane review ranged from twice weekly to daily with each session lasting 10 to 120 minutes (Cramp and Byron-Daniel, 2012). Some interventions increased these parameters by specific increments and others based progression on individual tolerance. Increasing PA according to individual capability mirrors GET approaches used in CFS. PA intensity was not always specified and methods for monitoring intensity varied greatly between studies. The total amount of time spent exercising was not known, as this was rarely reported (Cramp and Byron-Daniel, 2012). Recent RCTs did not report the amount of exercise undertaken (Andersen *et al*, 2013, Steindorf *et al*, 2014).

3.3.4 Intervention delivery

3.3.4.1 Chronic fatigue syndrome

The frequency of therapist contact varied between CFS interventions, and was reported as “usually once a week” in the Cochrane review (p.5, Edmonds, McGuire and Price, 2004), staggered from weekly to fortnightly (White *et al*, 2011) or monthly (Wearden *et al*, 2010). Although contact was often face-to-face, some interventions included telephone sessions (Powell *et al*, 2001, Wearden *et al*, 2010, Marques *et al*, 2015). Where the location of intervention delivery was specified, interventions mostly took place in tertiary care settings in the UK and were delivered on an individual rather than group basis (Edmonds, McGuire and Price, 2004, White *et al*, 2011). An RCT of nurse-led pragmatic rehabilitation (the Fatigue Intervention by Nurses Evaluation (FINE) trial) was delivered at home (Wearden *et al*, 2010).

Details regarding the experience and professional background of therapists delivering interventions were not always available and not reported in the Cochrane review (Edmonds, McGuire and Price, 2004). The FINE trial was delivered by nurses with no previous experience of CFS who had received training over a six month period (Wearden *et al*, 2010). The nurses delivered both treatment and control interventions. In this instance the control arm received supportive listening therapy based on non-directive counselling (Wearden *et al*, 2010). Characteristics of physiotherapists and one exercise physiologist delivering PACE trial interventions were described in an appendix to the research report (White *et al*, 2011). Therapists had substantial experience in CFS and received regular supervision.

3.3.4.2 Cancer

In the Cochrane review studies were reported to use home-based or unsupervised exercise (n=19) or supervised, institution-based programmes (n=37) (Cramp and Byron-Daniel, 2012). It is not clear whether these were delivered in groups or on an individual basis. The majority of the 72 studies included in another meta-analysis were also supervised (n=46), with the remaining interventions undertaken at home (n=26) (Tomlinson *et al*, 2014).

Frequency of therapist contact was not reported in either review of exercise interventions for CRF discussed in this chapter (Cramp and Byron-Daniel, 2012, Tomlinson *et al*, 2014). It was also unclear who supervised the intervention sessions. Recent RCTs have reported group-based exercise sessions supervised by trained and experienced physiotherapists (Steindorf *et al*, 2014), or physiotherapists and specialist nurses (Andersen *et al*, 2013). Details of their experience and training were not provided.

Another trial reported home-based treatment and control interventions based on a manual containing an individualised exercise prescription provided by a certified exercise physiologist (Santa Mina *et al*, 2014). Additional face-to-face group-based booster sessions were held fortnightly.

3.3.5 Adherence

3.3.5.1 Chronic fatigue syndrome

Adherence to therapy is useful to know when considering the validity of trial data, as high dropout rates might indicate low levels of satisfaction or high rates of adverse effects experienced by participants. White and colleagues (2011) reported small numbers of dropouts from the PACE trial with a high rate of acceptance and satisfaction: the median number of GET sessions attended was 13 (interquartile range 12-14) out of 15, with 10 (6%) dropouts from treatment and a reported satisfaction rate of 88%. Adverse events and treatment safety information were recorded. Non-serious adverse events were common (93% for GET) but were not significantly different to other arms in the trial. Examples included a cold, an eye infection or experience of new pain not previously reported as a symptom of CFS (Dougall *et al*, 2014).

Despite a larger number of more serious adverse events in the GET arm (n=13, 8%) compared with specialist medical care (n=7, 4%), these events were uncommon (White *et al*, 2011) and independent scrutinisers did not feel they were related to treatment (Dougall *et al*, 2014). Serious adverse events for all trial treatments were categorised as life threatening, hospital admission or an increase in severe and persistent significant disability/incapacity (White *et al*, 2011), although specific events were not reported separately for the GET arm. Serious adverse reactions were recorded for two participants for GET and included deterioration in mobility and self-care, and worse CFS symptoms and function (White *et al*, 2011).

In the FINE trial 12 of the 92 participants (13%) who received pragmatic rehabilitation dropped out of treatment (Wearden *et al*, 2010). Examples of reported reasons included dissatisfaction with randomisation, too busy, not benefitting or feeling worse. A mean of 9.62 (SD 0.88) out of ten pragmatic rehabilitation sessions were delivered to patients. Adherence to the trial was good, with 85% of those randomised to treatment and 86% of control participants completing final outcomes. Treatment safety was reported to be satisfactory, with a small number of serious adverse events reported as unrelated to trial treatments (Wearden *et al*, 2010). Assessors masked to treatment allocation reported high levels of treatment fidelity in the FINE and PACE trials (Wearden

et al, 2010, White *et al*, 2011). Use of treatment manuals enhanced the delivery of interventions in these studies and heightened fidelity.

It is reported that adherence was measured in four studies in the Cochrane review via exercise logs (Edmonds, McGuire and Price, 2004). However, data from these logs were not reported and the number of hours of exercise or PA was unknown. Attrition from the trials was reported to be more common in the exercise therapy arms, although this was not significant. Studies with the highest reported exercise intensity had the highest dropout and poorest outcome (Edmonds, McGuire and Price, 2004). This supports the idea that starting GET at a lower intensity is more effective (Castell, Kazantzis and Moss-Morris, 2011). It is not known whether dropouts related to adverse effects, as no data were reported for this outcome in any of the included studies (Edmonds, McGuire and Price, 2004).

3.3.5.2 Cancer

Several studies (n=16) included in the Cochrane review did not report adherence to the intervention (Cramp and Byron-Daniel, 2012). Those studies that did report it (n=40) used a variety of methods. The percentage of sessions attended ranged from 61% to 98.4%. The majority of studies (n=45) were reported to have provided sufficient information about participants who withdrew or dropped out of the study early (Cramp and Byron-Daniel, 2012). Data regarding adverse events related to treatment were not discussed in the review. Tomlinson and colleagues (2014) acknowledged that safety issues have not been fully described in the current literature.

Adherence to a progressive resistance training programme was good with a median of 19 out of 24 sessions attended for both the intervention and relaxation control arm (Steindorf *et al*, 2014). Trial completion rate was 97%. No serious adverse effects or events were reported related to the interventions, therefore they were considered to be safe (Steindorf *et al*, 2014). Adherence to a multi-modal exercise intervention was reasonable (73%) with reasons for dropout mainly related to health problems (Andersen *et al*, 2013). No safety data were reported for this trial.

Adherence to a home-based aerobic or resistance training programme investigated in a recent RCT was not known, as too few participants completed their exercise logs (Santa Mina *et al*, 2014). However, attendance at fortnightly booster sessions over a period of six months was poor, with the aerobic exercise arm attending a mean of 16.4% and the resistance arm 5.5% of sessions. Non-attendance was mainly cited as related to distance and travel time to access the classes. Attrition rates for the trial were 26% for aerobic training and 44% for resistance training. Reasons for dropouts were varied, including lack of time, too far to travel or health related issues preventing exercise

participation (Santa Mina *et al*, 2014). These high attrition rates raise concerns regarding the validity of the findings and acceptability of the intervention.

3.3.6 Follow-up

3.3.6.1 Chronic fatigue syndrome

While PA and exercise appear to be beneficial for managing fatigue in CFS, it is worth noting that meta-analyses of GET interventions have only used post-treatment data to determine the treatment effect due to a lack of available follow-up data (Edmonds, McGuire and Price, 2004, Castell, Kazantzis and Moss-Morris, 2011). Only 118 participants contributed to analysis at six months in the Cochrane review, thus limiting the power to detect an effect (Edmonds, McGuire and Price, 2004). Primary outcomes at one year for an RCT of pragmatic rehabilitation were greater for fatigue levels ($p < 0.001$) and physical functioning ($p < 0.001$) for the intervention arms compared with controls (Powell *et al*, 2001). Follow-up data at two years demonstrated that effects were maintained, although control data were not available (Powell *et al*, 2004). Small sample sizes ($n < 40$ per arm) limit the generalisability of these results.

The FINE trial found that fatigue outcomes post-treatment were significantly improved in the intervention arm ($n=85$) compared with treatment as usual ($n=92$) (effect estimate -1.18; 95% CI -2.18 to -0.18; $p=0.021$) (Wearden *et al*, 2010). Improvements were also noted for secondary outcomes for depression (-1.18, CI -2.16 to -0.20; $p=0.018$) and sleep (-1.54; CI -2.96 to -0.11; $p=0.035$). However, physical functioning was not significantly improved post-treatment. Follow-up assessment at one year after treatment revealed no statistically significant differences for either primary outcome compared with controls (Wearden *et al*, 2010). The PACE trial reported positive outcomes for fatigue and physical functioning at 16 weeks post-intervention (White *et al*, 2011), as discussed in section 3.3.1.1.

3.3.6.2 Cancer

Few studies ($n=12$ of 56) provided follow-up data for the effect of PA interventions on CRF (Cramp and Byron-Daniel, 2012). Of these 12 studies, ten did not find differences in fatigue post-treatment or at follow-up. The remaining two studies indicated that significant differences in fatigue post-treatment were maintained at three months (Cramp and Byron-Daniel, 2012). Follow-up data were not available for any of the recent RCTs conducted with CRF patients discussed in this review (Andersen *et al*, 2013, Santa Mina *et al*, 2014, Steindorf *et al*, 2014).

3.3.7 Cost-effectiveness

3.3.7.1 Chronic fatigue syndrome

In addition to clinical effectiveness it is useful to consider the cost-effectiveness of proposed interventions to inform decisions regarding implementation in clinical practice. Unfortunately there were no cost-effectiveness data available for the majority of studies discussed in this chapter. However, a cost-effectiveness analysis has been conducted for treatments in the PACE trial (McCrone *et al*, 2012). As well as investigating the effectiveness of GET, this trial also looked at CBT and adaptive pacing therapy (White *et al*, 2011). Cost-effectiveness of GET was second to CBT in the analysis of the four groups (McCrone *et al*, 2012). Quality adjusted life years (QALYs) were calculated. Results indicated that GET had a 26.8% chance of being the most cost-effective treatment option in relation to healthcare costs at a threshold of £30k per QALY. The incremental healthcare cost per QALY for GET compared with specialist medical care alone was £23,615. It was suggested that consideration of societal cost savings with reduced need for informal care may mean that relative cost-effectiveness was even greater. However, the authors urged caution when interpreting these findings, as analysis relied on self-reported service use and lost employment data. Similarly, EuroQol-5 dimensions (EQ-5D) health outcome measure was used to estimate QALYs in this study even though sensitivity to changes in CFS clinical measures are not known (McCrone *et al*, 2012).

3.3.7.2 Cancer

No cost-effectiveness data were found for PA or exercise interventions for the management of CRF.

3.3.8 Maintaining changes in physical activity

In addition to the lack of information regarding sustained effects on fatigue, there is a lack of evidence to indicate whether PA levels are changed or maintained over time. The theoretical basis of CFS studies, where described, related to causal factors of fatigue such as fear avoidance, deconditioning and exercise intolerance (Powell *et al*, 2001, White *et al*, 2011) rather than behaviour change. Although pragmatic rehabilitation is said to include elements of CBT, these are focused on addressing patients' illness beliefs specifically related to fear avoidance behaviours (Powell, Edwards and Bentall, 1999). Consequently, CBT techniques employed in this approach may not adequately tackle other issues relating to changing PA behaviour such as motivation and self-efficacy for PA.

Data regarding PA and exercise levels during treatment and long-term maintenance are rarely reported in RCTs investigating the management of CRF (Cramp and Byron-

Daniel, 2012). Therefore, it is not known whether PA is initiated by these interventions or maintained over time. Exercise programmes accompanied by a behavioural intervention might enhance support for ongoing PA (Cramp and Byron-Daniel, 2012).

It was not reported whether any of the studies in either Cochrane review for CFS or CRF were under-pinned by health behaviour change (HBC) theory (Edmonds, McGuire and Price, 2004, Cramp and Byron-Daniel, 2012). However, it is possible that some interventions implicitly included techniques that might be effective in changing behaviour and that are derived from HBC theory. Theoretically-derived behaviour change techniques (BCTs) have been explored and defined by a group of international behaviour change experts and published in a taxonomy (Michie *et al*, 2013). An example of their implicit use is where recognised BCTs such as goal setting and graded tasks are mentioned in the PACE GET trial manual (White *et al*, 2011), even though the authors may not have selected them on the basis of a specific HBC theory. Unfortunately many trials do not provide an adequate description of interventions that might allow BCTs to be identified. Although techniques may be in use, the lack of explicit HBC theory may limit their effectiveness for changing and maintaining PA behaviour in these interventions if the therapists using them are not focussed on the processes likely to achieve this outcome.

A recent RCT suggested that a self-regulation-based PA programme had significant beneficial effects for managing unexplained chronic fatigue (Marques *et al*, 2015). This 12-week multicentre RCT demonstrated significant improvements post-treatment of medium effect size for subjective experience of fatigue (4.73 points difference; effect size=0.51) in the intervention arm (n=45) compared with controls (n=46; standard medical care plus leaflet with information about benefits of PA and PA guidelines). BCTs based on self-regulation included goal setting, action planning, problem-solving and self-monitoring of behaviour. Follow-up data were not available for this study (Marques *et al*, 2015). Preliminary results must be interpreted with caution due to limitations, such as a small sample size and potential selection bias due to differing recruitment strategies. Reasons for not participating also suggest self-selection bias, as a high rate (29%) of those eligible reported that they were not interested in the study. Attrition was high in both intervention and control arms (>20%), with the majority of reasons reported as lack of time or lack of interest. The authors acknowledged these limitations (Marques *et al*, 2015). Evidence of maintenance of PA following an intervention based on HBC theory therefore remains uncertain.

3.4 Discussion

Overall, evidence suggested that PA and exercise, particularly an aerobic GET approach, are effective for managing fatigue in CFS in the short-term, with evidence of maintained effects at 16 weeks post-intervention (White *et al*, 2011). Long-term follow-up data were scarce. Evidence suggests that the specific type of aerobic PA may be less important than the intensity at which it is commenced, with incremental increases from a lower level proposed to yield better outcomes. Optimum effectiveness seemed to be achieved when GET was delivered on an individual basis by appropriately trained, experienced therapists in a tertiary care setting. However, this was probably a reflection of the limited available evidence, with most studies investigating individual therapy rather than group programmes. Some evidence existed for short-term effectiveness of pragmatic rehabilitation (GET combined with patient education) delivered in patients' homes by nurses with specialist training but without previous experience of CFS. These effects were not maintained in the long-term. Further research is required to establish how treatment benefits can be achieved and sustained in primary care settings.

There was evidence for the short-term effectiveness of aerobic exercise for managing CRF, with some evidence for combined aerobic and resistance training. However, current evidence for resistance training, flexibility training or mind-body interventions alone was weak in this patient group. Optimal intervention parameters, such as duration, frequency and intensity of exercise and delivery methods (e.g. group versus individual, supervised or unsupervised) remain unclear. The American College of Sports Medicine guidance for prescribing exercise indicates that light- to moderate-intensity PA for less than 20 minutes per day may be beneficial for people who are deconditioned (Garber *et al*, 2011). This is useful to consider for a fatigued patient group.

Limited available evidence of adherence to treatments and research procedures does not allow an appreciation of whether interventions are acceptable to patients. No qualitative data exploring this was found. Future RCTs should conduct nested qualitative research to explore patient experiences of participation. Long-term follow-up, treatment fidelity and safety data and cost-effectiveness data should be presented in future research reports to aid decisions regarding implementation in clinical practice. Future PA interventions for managing fatigue also need to consider how they might ensure long-term maintenance of PA.

3.4.1 Limitations of the evidence

The main limitation of the Cochrane review of exercise for CFS was the lack of studies suitable for inclusion (Edmonds, McGuire and Price, 2004). The authors acknowledged that the limited evidence base restricted the precision of the results. This

review was last assessed as up-to-date in May 2004 and a new version of the review was reported to be underway in 2010 (Edmonds, McGuire and Price, 2004). However, a more recent high quality RCT (White *et al*, 2011) and a meta-analysis (Castell, Kasantzis and Moss-Morris, 2011) confirmed the effectiveness of GET-based interventions.

The Cochrane review for exercise for CRF included many more studies (Cramp and Byron-Daniel, 2012). Consequently, heterogeneity in terms of intervention parameters was greater. Many RCTs in both CFS and CRF had small sample sizes, with insufficient power to detect changes in study outcomes. Similarly, a lack of follow-up data limited understanding of longer term changes. The need for trials with longer follow-up periods is evident.

Blinding of participants and some research personnel, such as therapists, is not often possible in trials of exercise interventions. However, efforts to blind other personnel such as outcome assessors were poorly reported. Some authors claim that use of self-reported primary outcome measures contributed to risk minimisation (White *et al*, 2011), but it is not clear whether investigators or study personnel were present when these measures were completed. Participants may feel obliged to report more favourable outcomes if they are being observed by an assessor or therapist.

There was a lack of trials where placebo controls received similar attention and time from research or therapy staff as those in the intervention arm. Some reports have acknowledged this as a limitation (Powell *et al*, 2001, Cramp and Byron-Daniel, 2012, Andersen *et al*, 2013). This may introduce systematic bias in favour of the intervention arm. For example, contextual intervention effects such as attending a treatment session, might in themselves increase PA and reduce fatigue regardless of the intervention content.

Lastly, none of the evidence reported the use of HBC theory to enhance PA uptake and maintenance. Although pragmatic rehabilitation included a CBT-based patient education component, this was reportedly directed at addressing negative illness beliefs rather than specifically promoting PA behaviour change (Powell, Edwards and Bentall, 1999).

3.4.2 Limitations of the review

Evidence discussed in this review was predominantly based on the findings of two Cochrane systematic reviews (Edmonds, McGuire and Price, 2004; Cramp and Byron-Daniel, 2012). This was a deliberate decision as the Cochrane collaboration has renowned expertise in conducting high quality reviews using rigorous methodology, thus enhancing the trustworthiness of the findings. Reliance on these reviews means that only RCTs and controlled clinical trials have been identified and discussed. Although this study

design provides the best estimate of intervention effectiveness (Glasziou *et al*, 2001), other important findings may be missed. For example, qualitative literature exploring patient experiences and opinions regarding acceptability of such interventions will not be included. An attempt to identify such literature did not yield any results in CFS or CRF. It would be useful to undertake a mixed methods systematic review to address this issue. To avoid a gap in this type of evidence in future research, patients' views about the acceptability of interventions should be sought during development and testing.

The decision to only explore fatigue management interventions where a published Cochrane review exists means that potentially useful evidence from other long-term conditions, such as MS, has been ignored. However, the high quality RCTs reviewed in CFS and the large number of studies contributing to analyses in CRF was felt to provide sufficient information on the effectiveness of PA for managing fatigue in long-term conditions.

3.5 Conclusion

The evidence for the effectiveness of PA for managing fatigue in CFS and CRF is sufficient to warrant the development of a similar intervention for managing RA fatigue. Aerobic exercise, delivered using a GET approach, seems to be particularly beneficial although long-term outcomes are currently unclear. The addition of a behavioural component based on HBC theory may enhance uptake and maintenance in the longer term. In recognition of the importance of maintaining changes in PA and exercise behaviour, it is useful to investigate whether HBC interventions are currently used for promoting PA in RA. Chapter 4 presents a systematic review of the literature to explore existing evidence for the effectiveness of HBC interventions for promoting PA in RA.

Chapter 4: A systematic literature review of interventions promoting physical activity in rheumatoid arthritis

Chapter 3 identified evidence for the effectiveness of PA interventions for improving fatigue in long-term conditions. Available follow-up data indicated that effects were short-lived, suggesting a need for interventions that incorporate BCTs to improve engagement with long-term PA. This chapter explores the use of interventions based on HBC theory for promoting PA in people with RA. The review considers PA promotion for all people with RA, not only those with fatigue. The findings of a systematic literature review designed to summarise and appraise research investigating the effectiveness of these interventions are presented. The structure of this review was based on the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Liberati et al, 2009) and the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011).

4.1 Background

4.1.1 Description of the condition

A description of PA in RA was presented in chapter 1, identifying physical inactivity as more prevalent in RA patients compared to the general population (Sokka *et al*, 2008). Clinical guidelines for managing RA recommend regular exercise to improve general fitness and function, reduce bone loss and manage cardiovascular risk factors (Luqmani *et al*, 2009, NICE, 2009).

Evidence for the benefits and safety of exercise in RA has been summarised in systematic reviews (Hurkmans *et al*, 2009, Baillet *et al*, 2010, Baillet *et al*, 2012). Cardiorespiratory aerobic training and resistance training are recommended as routine practice. Furthermore, high-intensity progressive resistance training may have the potential to modify cardiovascular risk factors (Lemmey *et al*, 2009). However, benefits of exercise and PA in the longer term (>12 months) are unclear, as the majority of studies have not included long-term follow-up (Baillet *et al*, 2012, Knittle, De Gucht and Maes, 2012). Those that have, reported that participants were no longer exercising at follow-up (for example, Lemmey *et al*, (2012)).

One of the biggest challenges facing health and exercise professionals is helping people to engage in suitable PA, and supporting them to continue PA in the long-term.

Engagement and maintenance is difficult for most people, but may be particularly difficult for people with long-term conditions who have pain and other physical and psychosocial limitations (Wilcox *et al*, 2006, Jack *et al*, 2010).

4.1.2 Description of the intervention

Assisting people to change their health-related knowledge, attitudes and behaviour is crucial for helping them to stay healthy. Behaviour patterns are closely related to a person's environmental, financial and social circumstances. Attempts to change behaviour need to take these factors into account (NICE, 2007a). HBC has been defined as *“the shift from risky behaviours to the initiation and maintenance of healthy behaviours and functional activities, and the self-management of chronic health conditions”* (p.245, Nieuwenhuijsen *et al*, 2006).

Interventions to promote PA behaviour change may be explicitly based on HBC theory or may employ cognitive or behaviour change strategies to enhance engagement with and maintenance of PA. Provision of information alone is not included in this definition of HBC interventions.

4.1.2.1 Models and theories of behaviour change

Many theories exist for changing behaviours. Models that seek to explain the thoughts and feelings associated with a health-related behaviour are particularly useful for HBC (Abraham *et al*, 2008). These include social cognition models and stage-based models. Concepts of self-efficacy (Bandura, 1977) and perceived behavioural control are frequently incorporated into social cognition models to examine predictors and precursors of behavioural action (Browning and Thomas, 2005). Common social cognition and stage models used in PA behaviour change are outlined below:

Social cognitive theory (Bandura, 1986, Bandura, 1998)

SCT builds on Bandura's self-efficacy theory (Bandura, 1977). A central concept of SCT is that self-efficacy expectations determine the initiation, effort and sustainability of coping behaviour (Bandura, 1977). According to Bandura (1977), self-efficacy is the belief that one can carry out a given behaviour in order to achieve a desired outcome or goal. A person's self-efficacy for a behaviour, such as PA, is dependent on their performance accomplishments (mastery), vicarious experiences (modelling), verbal persuasion and physiological states (emotional response). Although Bandura (1977) proposes that self-efficacy has a strong influence on behaviour, he does not claim that it is the sole determinant (Bandura, 1998). SCT proposes that goals, outcome expectancies and socio-structural barriers and facilitators, including environmental, political or economic factors, will also influence behaviour (Bandura, 1998). In this way, personal and social

determinants might affect well-being and contribute to self-regulation of healthy behaviours. The theory suggests that learning occurs in the context of a social environment.

Theory of Planned Behaviour (TPB) (Ajzen, 1991)

The TPB proposes that behaviour is determined by intentions to perform a behaviour and perceived control over that behaviour. Intentions are influenced by attitudes and beliefs towards that behaviour, social norms and perceived behavioural control. Attitudes are based on beliefs relating to consequences of behaviours and may be positive or negative. Subjective norms relate to the expectations of salient others, such as approval or disapproval, and the motivation to comply with this other person. Perceived behavioural control is a similar concept to Bandura's self-efficacy. This relates to beliefs about access to resources and opportunities to perform the target behaviour, and the importance placed on these factors for achieving the desired behavioural outcome (Abraham *et al*, 2008).

Stages of change/Transtheoretical model (Prochaska and DiClemente, 1984)

This stage-based model proposes that behaviour change occurs in ordered stages: pre-contemplation (no intention to change), contemplation (considering change), preparation (making small changes), action (actively engaging in behaviour) and maintenance (sustaining behaviour over time). Stages are not linear and a person can move back and forth between stages several times (Ogden, 2012).

Self-determination theory (SDT) (Ryan and Deci, 2000)

SDT is a theory of motivation and does not fit into the social cognition or stage models described above. Instead it distinguishes between two sources of motivation: intrinsic (autonomous) or extrinsic (controlled) (Deci and Ryan, 2008). Intrinsic motivation is comprised of three fundamental human needs: autonomy – the need to feel a sense of choice and volition with respect to health-related goals; competence – the need to understand how to attain health-related goals; and relatedness – the need to feel respected and cared for by practitioners and important others (Ryan and Deci, 2000, Sheldon, Williams and Joiner, 2003). Ryan and Deci (2000) note that a key difference between SCT and SDT is the distinction between autonomous and controlled behaviour. That is, although someone may develop high self-efficacy for a behaviour that they feel coerced into doing, they are more likely to spontaneously engage in a behaviour that satisfies their interest or enjoyment (Ryan and Deci 2000, Deci and Ryan 2008). Although SCT addresses competence in the form of self-efficacy, Ryan and Deci (2000) criticise this as presenting an oversimplification of sources of motivation.

4.1.2.2 Techniques for changing behaviour

A taxonomy of BCTs has been developed to classify recognised, evidence-based BCTs (Michie *et al*, 2011, Michie *et al*, 2013). This aids identification of BCTs employed in interventions when HBC theory is not specified. Some evidence exists for the use of specific BCTs for promoting PA in healthy populations, for example, self-monitoring of behaviour, goal setting, providing feedback on performance, and review of behavioural goals (Michie *et al*, 2009a). Such HBC interventions and BCTs may be useful for promoting PA in RA.

4.1.3 How the intervention might work

NICE has produced guidance for behaviour change recognising that interventions have the potential to alter patterns of disease (NICE, 2007a). This suggests that interventions need to address individual beliefs, attitudes, intentions and knowledge and skills linked to the intended behaviour (*Principle 1: planning interventions and programmes* (NICE, 2007a)).

Self-management programmes are often associated with behavioural interventions and health promotion programmes, and it has been suggested that they should place an emphasis on patient-generated, problem focused and action-orientated approaches (Lorig and Holman, 2003). The effects of self-management have been attributed to an increase in self-control amongst participants, in line with theoretical models such as Bandura's self-efficacy theory (Bandura, 1977). Techniques to increase motivation and self-efficacy, including cognitive behavioural approaches, are likely to support behaviour changes required to improve activity levels in patients with RA (Knittle *et al*, 2011, Dures *et al*, 2012, Lee *et al*, 2012).

As mentioned in chapter 1, specific theoretical bases have been recommended for self-management and behaviour change in rheumatic diseases (Iversen, Hammond and Betteridge, 2010, Zangi *et al*, 2015). For example, Iversen and colleagues (2010) recommended that self-management interventions should be based on SCT or CBT. Interventions based on CBT seek to modify behaviour through an active, structured approach that recognises patterns of disordered thinking initiated by an individual's internal thoughts and feelings (Sage *et al*, 2008).

4.1.4 Why it is important to do this review

It is currently not known whether HBC interventions or BCTs to promote PA in adults with RA are effective at increasing uptake and encouraging long-term adherence to PA. There is lack of consensus regarding the best way to engage people with RA in PA. Therefore this review was required to evaluate the available evidence to inform

development of a PA intervention, to direct future research and to identify implications for clinical practice.

4.2 Objective

To evaluate the effect of interventions incorporating HBC techniques on the uptake and maintenance of PA in adults with RA

4.3 Methods

4.3.1 Study Design

A systematic literature review was designed and carried out to address the study objective. A systematic literature review is an appropriate means of identifying, appraising and synthesising existing research evidence using rigorous methodology based on a pre-defined protocol, such as that used by The Cochrane Collaboration (Higgins and Green 2011). A protocol for this review was developed by the candidate and reviewed by the research supervisory team prior to commencing the literature search.

4.3.2 Criteria for considering studies for this review

Study eligibility was considered based on the following inclusion criteria:

4.3.2.1 Types of studies

The design of included studies was restricted to RCTs. This is considered the most appropriate design to provide evidence of effectiveness of an intervention and provides greater confidence for the minimisation of the risk of bias (Jackson and Waters, 2005, Glasziou *et al*, 2001).

4.3.2.2 Types of participants

RCTs of adults with confirmed RA (Arnett *et al*, 1988) were included. Studies involving participants without a confirmed diagnosis of RA were excluded, as were studies where RA data were not reported separately. Including these would have reduced the accuracy of data related to RA, and the results would not have been specific to the target population.

4.3.2.3 Types of interventions

HBC interventions that aimed to address PA were included. HBC interventions were defined as any intervention based on behaviour change theory or that employed specific BCTs as defined by a published taxonomy (Michie *et al*, 2011, Michie *et al*, 2013).

Interventions that provided information only or did not use techniques designed to influence and change PA health behaviours were excluded.

4.3.2.4 Types of outcome measures

Studies reporting PA as a primary or secondary outcome measure were included in the review.

4.3.3 Search methods for identification of studies

Relevant biomedical and allied health electronic databases were selected (box 4.1) and searched for publications from 1990 to November 2014. Searches were restricted by publication date because up until the early 1990s aerobic exercise was considered to be potentially harmful, and to exacerbate signs and symptoms of RA (Minor, 1996, Sokka *et al*, 2008).

Box 4.1: Electronic databases used in the systematic review

MEDLINE Allied and Complementary Medicine (AMED) Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus Cochrane Controlled Trials Register (CENTRAL) EMBASE PsycINFO SportDiscus Science Citation Index

A comprehensive search strategy was developed with assistance from a specialist subject librarian at the University of the West of England and adapted for each database (table 4.1). Searches used medical subject headings where applicable, and keyword searches, with an RCT filter applied (Higgins and Green, 2011). Search terms from a previous Cochrane review for RA were adapted (Cramp *et al*, 2013b). Keywords for the intervention were adapted from a taxonomy of BCTs (Michie *et al*, 2011).

Table 4.1: Search strategy

-
1. exp rheumatoid arthritis
 2. ((rheumatoid or reumatoid or revmatoid or rheumatic or reumatic or revmatic or rheumat* or reumat* or revmarthrit*) adj3 (arthrit* or artrit* or diseas* or condition* or nodule*)).tw.
 3. 1 or 2
 4. exp exercise/ or exp motor activity/ or exp sport/ or exp physical fitness/
 5. Physical* activit* or Exercise* or Walk* or Cycl* or Swim* or gym* or Aerobic exercise* or Yoga or Tai chi or Physical exercise* or Sport* or fitness or Fitness level* or Activity level*
 6. 4 or 5
 7. Cluster* randomi#ed control* trial
 8. randomized controlled trial.pt.
 9. controlled clinical trial.pt.
 10. randomized.ab.
 11. placebo.ab.
 12. drug therapy.fs.
 13. randomly.ab.
 14. trial.ab.
 15. groups.ab.
 16. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
 17. exp animals/ not humans.sh.
 18. 16 not 17
 19. exp self care/ or exp health promotion/ or exp health behavior/ or exp motivation/
 20. Behaviour or behavior or behaviour change\$ or behavior change\$ or health behaviour change\$ or health behavior change\$ or self management or self care or Health behaviour or health behavior or health promotion or approval or normative behaviour or normative behavior or goal setting or action planning or barrier identification or problem solving or graded task\$ or goal\$ or successful behaviour or successful behavior or shaping or self-monitoring or past success or behavioral performance or behavioural performance or feedback or prompts or cues or behavioural contract or behavioral contract or social comparison or social support or role model\$ or self talk or facilitat\$ or motivat\$ or imagery or fear or reward\$ or coping planning or time management or stress management or emotional control or motivational interviewing or behaviour\$ therapy or behavior\$ therapy
 21. 19 or 20
 22. 3 and 6 and 18 and 21
-

* and \$ were used to identify all words beginning with the stem; # denotes wild card for alternative spellings

Initial searches were carried out between 1st and 7th November 2012. AMED, CINAHL Plus, PsycINFO and SportDiscus were searched using EBSCO search engine, and MEDLINE and EMBASE were searched via OVID. Searches were updated on 7th November 2014 using the same search engines, with the exception of MEDLINE which was searched via EBSCO.

Only English language reports were included, as translation facilities were not available. Evidence suggests that language-restricted systematic reviews and meta-

analyses do not result in significant bias in estimates of intervention effectiveness (Moher *et al*, 2000, Juni *et al*, 2002).

Grey literature, including conference proceedings and abstracts from ACR, British Society of Rheumatology and EULAR, were searched to identify research that may have been presented ahead of full publication and to reduce publication bias. Theses from the UK and Ireland were searched using EThOS (Electronic Theses Online Search) and Index to Theses databases. Failure to identify and include trials through searching grey literature can overestimate the effectiveness of the intervention, as positive findings are more likely to be published as full text journal articles (Higgins and Green, 2011). Other relevant reports were identified through snowballing. This describes the process of finding missed papers through bibliographic searches of reports identified for inclusion in the electronic search (Glasziou *et al*, 2001).

4.3.4 Data collection and analysis

4.3.4.1 Selection of studies

Studies identified in the searches were imported into RefWorks web-based bibliographic management software (www.RefWorks.com) and duplicates were removed. The candidate screened titles and abstracts to identify research reports that potentially met the inclusion criteria. Full text papers were obtained for these reports. Where it was not clear from the abstract whether a paper should be included, or where the abstract was not available and the paper could not be excluded on title alone, full reports were retrieved. If full reports were not available authors were contacted to request raw data. Following the screening of remaining full text publications any uncertainty or ambiguity regarding inclusion of a study was discussed with a second reviewer (Fiona Cramp).

4.3.4.2 Data extraction and management

The candidate retrieved data from included publications and recorded these on a standardised data extraction form (appendix D). The following details were retrieved: study details (including objectives, study design, recruitment, inclusion and exclusion criteria); sample size (including sample size calculation); participant characteristics (age, gender, diagnosis, co-morbidities, ethnicity, disease duration); intervention description (treatment and comparison, duration); adherence to the intervention; outcome measures including time point; and adverse events.

4.3.4.3 Assessment of risk of bias in included studies

The Cochrane risk of bias tool was used to assess methodological quality of included studies (Higgins and Green, 2011, Higgins *et al*, 2011). This domain-based

evaluation tool involves subjective assessment of the validity of a study. This enables judgement as to whether the reported treatment effect can be considered representative of the true effect of the intervention (Liberati *et al*, 2009).

A range of tools is available to help assess the quality of RCTs, such as the Critical Appraisal Skills Programme tools (www.CASP-uk.net) and the Oxford quality scale (Jadad *et al*, 1996). However, the use of quality scales or checklists is discouraged by Cochrane as these over-emphasise reporting of the study rather than conduct of the research (Higgins and Green, 2011). The Cochrane risk of bias tool was chosen as Cochrane has renowned expertise in the area of systematic reviews. The tool has been described in chapter 2, section 2.3.3.3.

Risk of bias was assessed in the same way as in chapter 2, except for 'selective outcome reporting' and 'other sources of bias'. In this review risk of bias for selective outcome reporting was judged as low if all pre-specified PA outcomes were reported, high if not all pre-specified outcomes were reported or unclear if these was insufficient information. Other sources bias considered group contamination evidenced by control participants performing PA, differences in monitoring of attendance and/or PA or exercise participation in both groups, significant imbalance in PA between groups at baseline, financial incentives for participation and stopping the trial early. Risk of bias was judged as low (study appears free from other sources of bias), high (at least one important risk of bias identified), or unclear (there is a potential risk of bias but there is insufficient information to make a clear judgement). Evidence that provided justification for the decision was recorded. Data extraction and quality appraisal was repeated by a second reviewer (Fiona Cramp) for two studies to check consistency and accuracy. Discrepancies were subsequently discussed, informing the process for the remaining studies.

4.3.4.4 Measures of treatment effect

The central estimate (mean) and standard deviation for PA outcome measures were recorded. Where SMDs were reported these were also recorded. Interpretation of the effect size has previously been described in chapter 3, section 3.2.1.

It was decided *a priori* that a meta-analysis would not be performed, as it was expected that studies would include both subjective and objective measures of PA. It would not be appropriate to combine these data, the lack of consistency in the way in which data were recorded and reported would not allow a meaningful meta-analysis. Also, the intention of the review was not to identify an overall effect but to explore which HBC interventions or BCTs might be optimal. A narrative summary would allow more in-depth comparison of intervention components that might be considered for inclusion in future PA interventions.

4.4 Results

4.4.1 Results of the search

Seven studies were identified for inclusion. An additional study was identified through snowballing (van den Berg *et al*, 2006). Two studies were identified that were linked to included studies providing further data (Hurkmans *et al*, 2010b, Sjöquist *et al*, 2011). A summary of the study selection process including numbers of studies screened is presented in figure 4.1. Characteristics of excluded studies are presented in table 4.2.

4.4.2 Description of studies

A description of the included studies is presented in table 4.3.

4.4.3 Participants

A total of 1,157 participants with RA were entered into the eight studies, with 562 randomised to receive an intervention and 595 to a control arm. The number of participants completing the studies (intervention and control) ranged from 55 (Brus *et al*, 1998) to 191 (Brodin *et al*, 2008). For six studies, RA diagnosis was determined according to ACR criteria (Arnett *et al* 1987). Of the remaining studies one reported confirmation of RA diagnosis by a clinician (Lorig *et al* 2008) and the other reported a diagnosis of RA but did not say how it was confirmed (John *et al*, 2013). Mean age ranged from 49 (Taal *et al*, 1993, van den Berg *et al*, 2006) to 65 (Knittle *et al*, 2013) years old, with four studies reporting a mean age within the fifth decade. Disease duration was reported for five studies and varied from 21 months (Brodin *et al*, 2008) to 12.7 years (Mayoux-Benhamou *et al*, 2008). Another study reported mean disease duration as 11.6 for intervention participants and 14.09 for controls, but did not specify the unit of measurement (months or years) (John *et al*, 2013). Other demographic variables such as employment status, education and ethnicity were inconsistently reported.

Figure 4.1: Flow diagram showing study selection process

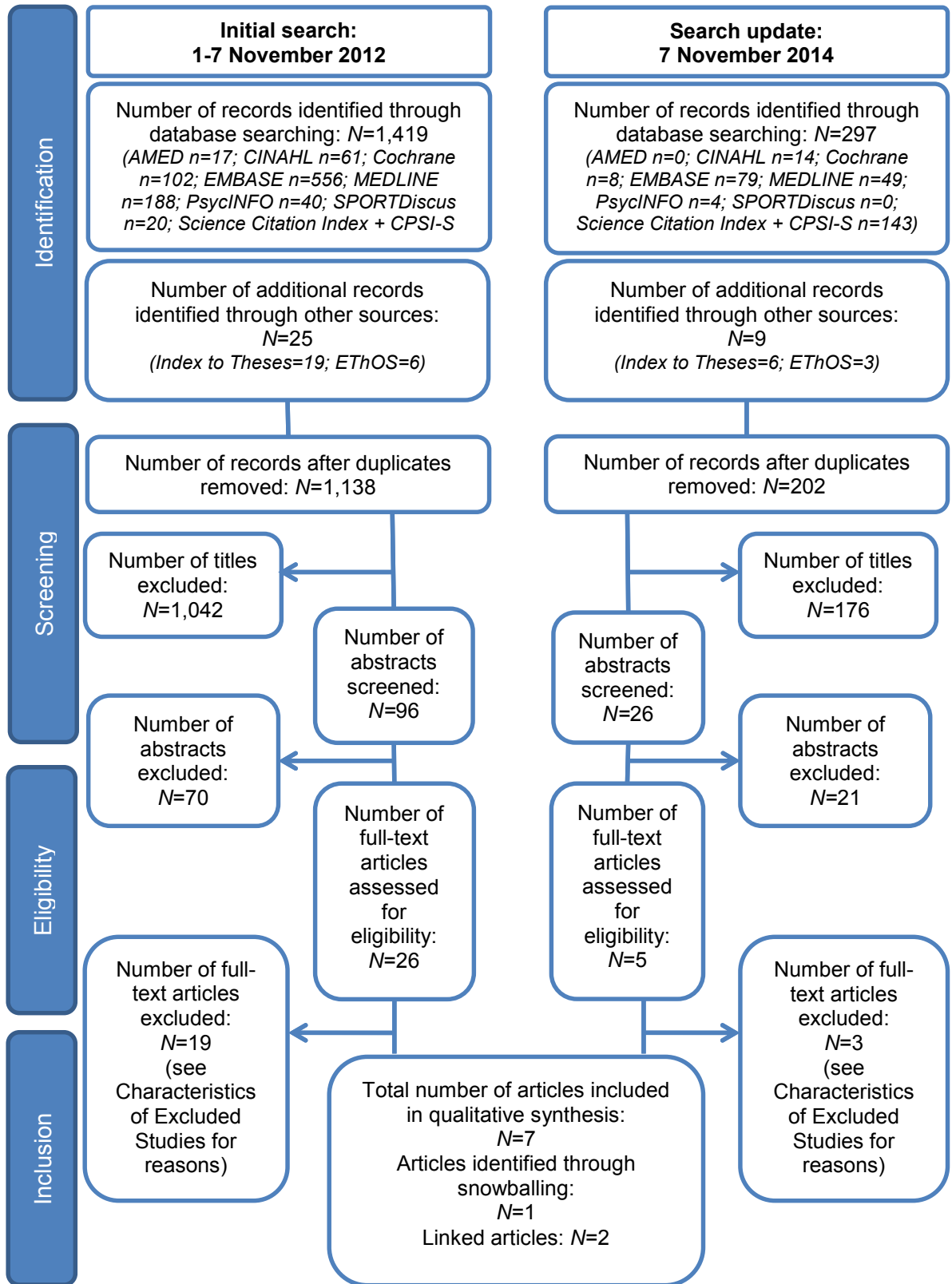


Table 4.2: Characteristics of excluded studies

Lead author, (year)	Reason for exclusion
Arvidsson, (2013)*	Not specific RA population, no PA outcome measure
Barlow, (2000)	No PA outcome measure
Barsky, (2010)	No PA outcome measure
Baruth, (2011)	Not an RCT
Braun, (2006a)	Conference abstract. Authors contacted. No response.
Breedland, (2011)	No PA outcome measure
Chang, (2014)*	RCT protocol only
Ehrlich-Jones, (2011)	Not an RCT
Feinglass, (2012)	Not full study report. Authors contacted. No response
Freeman, (2002)	No PA outcome measure
Fries, (1997)	PA not reported separately for RA
Froehlich-Grobe, (2004)	Not specific RA population
Hammond, (2008)	No PA outcome measure
Laforest, (2008)	No PA outcome measure
Lindroth, (1995)	No PA outcome measure
Lindroth, (1997)	No PA outcome measure
Lorig, (2005)	Not specific RA population
Mattukat, (2014)*	Not specific RA population
Nour, (2006)	PA not reportedly separately for RA. Authors contacted. No response
Sjöquist, (2010)	Not an RCT
Swardh, (2009)	Conference abstract for linked study (Sjöquist, 2011)
Van den Berg, (2007)	Not an RCT

*=identified in updated search November 2014; PA= physical activity; RA= rheumatoid arthritis; RCT= randomised controlled trial

4.4.4 Interventions

Included interventions are summarised in table 4.3.

Promoting PA was the primary aim of the intervention in one study investigating the use of a web-based individualised training programme (van den Berg *et al*, 2006). A second study investigated the effect of a motivational interviewing and self-regulation coaching intervention on autonomous motivation, self-efficacy and PA levels in sedentary RA patients (Knittle *et al*, 2013). PA was specified as the primary outcome in both studies.

Table 4.3: Description of included studies

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Study aim	To investigate the effect of a PA coaching programme on perceived health status, body function and activity limitation	To consider effects of patient education on compliance with sulphasalazine therapy and PA and effects on health	To evaluate the effects of a cognitive behavioural patient education intervention on modifiable CVD risk factors	To examine effects of the intervention on autonomous motivation, self-efficacy and PA in sedentary RA patients	To examine 6 and 12 month health status, health behaviour, self-efficacy and healthcare utilisation outcomes	To assess compliance with HEP and leisure PA recommendations	To examine effects of participation in group education on health status, behaviour, self-efficacy and outcome expectations	To compare effectiveness of an individualised versus general training internet-delivered PA intervention to promote PA
Primary outcome measure	EuroQoL VAS to assess current health state	Not identified	HDFQ-RA to assess knowledge of heart disease in RA	SQuAsH to assess leisure-time PA	Not identified	Not identified	Not identified	Proportion of patients meeting Dutch PA recommendations
HBC theory	Not specified	SCT	CSM, TPB, Stages of Change	Unclear. Possible use of Self-efficacy theory and/or SDT	Self-efficacy theory	Not specified	SCT	Not specified

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
PA outcome measures	Self-reported frequency of low, moderate and high-intensity PA	Self-reported frequency and duration of exercise per week	Attitudes, perceived behavioural control and behavioural intention to increasing PA IPAQ to assess participation in PA	SQuASH to assess leisure time PA (minutes per week) Number of days per week performing >30 min moderate-intensity PA Self-efficacy for PA questionnaire TSRQ (for autonomous motivation for PA)	Stanford Patient Education Research Center health-related behaviour measure for aerobic exercise (minutes per week) and stretching and strength exercise (minutes per week)	Baecke questionnaire for usual leisure-time PA Self-reported mean weekly number of exercises	Performance of exercises (times per week) Self-efficacy for performance of exercise	Proportion of patients meeting PA recommendations (as above) Total days per week of moderate or vigorous PA PA measured by Actilog activity monitor

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Description of intervention	Coaching to encourage healthy PA Tests of body function performed every 3 months to encourage adherence to goals	Education programme including information on RA, training in proper execution of physical exercises Encouraged to plan treatment regimens and make contracts regarding intentions	Cognitive behavioural education programme Exploration of beliefs about CVD Role of lifestyle modification discussed	Educational session plus MI and SR coaching Week 1: Education about PA in RA, recommended guidelines and tips to increase PA Week 2: MI Week 4 and 5: SR coaching Weeks 6, 12, 18: Telephone follow-up	Internet-delivered ASMP Access to interactive, web-based instruction and discussion centre, including tailored exercise programmes, exercise logs, self-management strategies, action planning	Class education and HEP Including information about RA management, guidelines for PA, advice to address barriers to exercise, access to aquatic and relaxation training classes	Education programme including contracting, goal setting and feedback, self-management and problem-solving, information on RA and treatment	Internet-delivered weekly individualised PA programme Advice regarding adopting PA as part of lifestyle Self-management strategies for pain and fatigue management, joint protection, energy conservation
Duration of intervention	12 months	8 months	8 weeks	5 weeks	6 weeks	8 weeks	5 weeks	12 months

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Number, duration and frequency of sessions	Unclear Continuous telephone support for 1 week then monthly support thereafter	4 x 2 hour meeting in month 1 Additional meeting in month 4 and 8	Week 1-4, week 8: 2.5 hour, 1 x weekly	Week 1: 1 x education session Week 2: 1 x MI, 45 mins Week 4 & 5: 2 x SR coaching, 40-60 mins, weeks 4 and 5	1-2 hour sessions, at least 3 x weekly	8 x 5 hour sessions, 1 x weekly	5 x 2 hour sessions, 1 x weekly	Tailored PA programme performed at home on 5 days per week Face-to-face group meetings every 3 months
Mode of delivery	Individual coaching by PT	Face-to-face group programme Partners of patients invited to attend	Face-to-face group programme delivered by rheumatology registrar	Face-to-face group education delivered by PT Individual face-to-face MI delivered by trained PT Individual face-to-face SR coaching and telephone follow-up delivered by rheumatology nurse	Internet-delivered	Face-to-face group delivery by MDT	Face-to-face group education delivered by rheumatology nurses, PTs or social workers	Internet-delivered home based PA programme Weekly supervision by email from experienced PT

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Control intervention	Access to usual PT including patient education and organised exercise max 2 x weekly	Brochure regarding RA with information on medication, physical and occupational therapy	Factual information leaflet about CVD Waiting list control	Education session plus list of local arthritis organisations and exercise classes	Usual care Sent \$10 Amazon.com certificate for each completed assessment	Usual care plus booklets with HEP and leisure PA recommendations	Referred to PT	Internet-delivered general PA training programme without individual tailoring or feedback
Adherence to intervention	Not reported	Attendance not reported	Not reported	94.7% received MI and SR	Intervention group: Mean log-in of 31.6 times (SD: 24.5) over 6 weeks (range 1 to 220)	Intervention group: Attendance rate for education = 97.8%; Compliance rate for HEP = 15.8% (6 months post-baseline), 11.8% (12 months post-baseline) Control group: Compliance rate for HEP = 4.8% (6 months), 4% (12 months)	81.4% attended all 5 sessions	Intervention group: 55% individualised training group using website at 12 month follow-up Control group: 7% general training group using website at 12 month follow-up
Study endpoint (from baseline)	12 months	12 months	6 months	32 weeks	12 months	12 months	14 months	12 months

Lead author, (year)	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux-Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Results for PA outcome (intervention versus control)	No significant difference between groups in reaching healthy PA pre- or post-intervention	No significant difference Significant increase in time spent on physical exercise between baseline and 3 months for interventions compared with controls ($p<0.05$)	Significant improvements in attitudes ($p=0.01$; small effect: 0.10), perceived behavioural control ($p=0.04$, very small effect: 0.06) and behavioural intention ($p<0.001$, small effect: 0.16) to increase PA. No significant change in PA (IPAQ raw data not reported – authors contacted but unable to provide data)	Significant improvement in leisure time PA ($p=0.022$; small effect: 0.29); days per week with >30 min PA ($p=0.016$; medium effect: 0.75); autonomous motivation ($p=0.001$; medium effect: 0.51); self-efficacy for PA ($p=0.008$; small effect: 0.47) Significantly greater proportion of patients meeting PA guidelines ($p=0.049$)	No significant results for PA outcomes at 6 or 12 months after baseline	Significantly greater compliance with HEP ($p<0.0001$) No significant effect for compliance with leisure PA (significant effect at 6 months only ($p=0.0001$)) Data for intervention and control not reported separately for Baecke questionnaire	Significant beneficial effects for performance of physical exercise ($p<0.01$) No significant difference in self-efficacy for performance of PA	Significantly greater mean days per week of vigorous PA ($p<0.05$; medium effect: SMD 0.5, 95% CI 0.2 to 0.9) No significant change in objective PA data

ASMP=Arthritis Self-Management Programme; CI=confidence interval; CSM=Common Sense Model; CVD=cardiovascular disease; HBC=health behaviour change; HDRQ-RA=Heart Disease Fact Questionnaire Rheumatoid Arthritis; HEP=home exercise programme; IPAQ=International Physical Activity Questionnaire; MDT=multi-disciplinary team; MI=motivational interviewing; PA=physical activity; PT=physiotherapist; RA=rheumatoid arthritis; ROM=range of movement; SCT=Social Cognition Theory; SD=standard deviation; SDT=self-determination theory; SMD=standardised mean difference; SQuAsH=Short Questionnaire to Assess Health-Enhancing PA; SR=self-regulation; TPB=Theory of Planned Behaviour; TSRQ=Treatment Self-Regulation Questionnaire; VAS=visual analogue scale

One study investigated the effect of coaching patients to healthy levels of PA on changes in health status, body function and activity limitation (Brodin *et al*, 2008). Two studies reported investigating exercise compliance (Brus *et al*, 1998, Mayoux-Benhamou *et al*, 2008). Another study evaluated the effects of a cognitive behavioural patient education intervention on risk factors for cardio-vascular disease (John *et al*, 2013). The remaining studies examined the effect of an internet self-management intervention (Lorig *et al*, 2008) and group-based education (Taal *et al*, 1993) on health status, health behaviour (including PA), and self-efficacy.

Control participants received usual care in five studies (Taal *et al*, 1993, Brus *et al*, 1998, Brodin *et al*, 2008, Lorig *et al*, 2008, Mayoux-Benhamou *et al*, 2008). The control arm received general training, as opposed to individualised training in one study (van den Berg *et al*, 2006), and in another they attended a one-off group education session that included information about PA in RA (Knittle *et al*, 2013). Control participants in the final study received a factual information leaflet about cardio-vascular disease (John *et al*, 2013).

4.4.4.1 Use of health behaviour change theory and behaviour change techniques

Two studies (Taal *et al*, 1993, Brus *et al*, 1998) reported that their interventions were based on SCT (Bandura, 1986). Lorig *et al* (2008) referred to Bandura's self-efficacy theory (Bandura, 1977). Knittle and colleagues (2013) alluded to self-efficacy theory, as well as SDT to address autonomous motivation (Ryan and Deci, 2000), although it was not clear if either theory was used as a basis for the intervention. Another study reported the Common-Sense Model (Leventhal, Brissette and Leventhal, 2003), TPB (Ajzen, 1985) and Transtheoretical Model (Prochaska, DiClemente and Norcross, 1992) as the underpinning theories (John *et al*, 2011, John *et al*, 2013). The development of this last intervention has been described in detail elsewhere (John *et al*, 2011).

The remaining studies did not mention specific theory but included BCTs in their interventions (van den Berg *et al*, 2006, Brodin *et al*, 2008, Mayoux-Benhamou *et al*, 2008). A summary of BCTs explicitly used in included studies is presented in table 4.4. The most commonly used techniques were instruction on how to perform the behaviour (n=7), information provision (n=6), goal setting (n=5), problem-solving (n=5), feedback (n=5) and self-monitoring (n=5).

Table 4.4: Behaviour change techniques employed in included studies

BCT	Brodin, (2008)	Brus, (1998)	John, (2013)	Knittle, (2013)	Lorig, (2008)	Mayoux- Benhamou, (2008)	Taal, (1993)	van den Berg, (2006)
Action planning		X		X	X			
Behavioural contract		X					X	
Behavioural practice/ rehearsal			X			X		
Body changes (relaxation)					X	X	X	
Feedback	X	X		X	X			X
Focus on past success				X				
Goal setting	X	X	X	X			X	
Graded tasks	X			X				
Information about RA and health consequences of PA	X	X	X	X		X	X	
Instruction on how to perform the behaviour	X	X		X	X	X	X	X
Motivational interviewing			X	X				
Problem solving	X		X	X	X		X	
Prompts/cues				X	X			
Review goals	X			X				
Reward progress			X	X				
Self-monitoring of behaviour	X		X	X	X			X
Self-talk					X			
Social comparison			X	X				
Social support (emotional)					X			
Social support (unspecified)			X	X	X			X

BCT=behaviour change technique, defined according to BCT taxonomy v1 (Michie et al, 2013)

4.4.4.2 Mode of delivery

Of the eight studies included in the review, two investigated individualised internet-delivered programmes (van den Berg *et al*, 2006, Lorig *et al*, 2008). Another two studies took a coaching approach, with one considering an individualised coaching programme with ongoing telephone support (Brodin *et al*, 2008) and another using a motivational interviewing and coaching intervention with telephone support (Knittle *et al*, 2013). The remaining four studies used group-based education programmes (Taal *et al*, 1993, Brus *et al*, 1998, Mayoux-Benhamou *et al*, 2008, John *et al*, 2013), one of which specified inclusion of an additional home-exercise programme (Mayoux-Benhamou *et al*, 2008).

4.4.4.3 Length of intervention and frequency, duration and number of sessions

Intervention length and frequency, duration, intensity and number of sessions was variable. The length of interventions ranged from five weeks (Taal *et al*, 1993, Knittle *et al*, 2013) to 12 months (van den Berg *et al*, 2006, Brodin *et al*, 2008). Face-to-face intervention sessions differed in duration from 40 minutes (Knittle *et al*, 2013) to five hours (Mayoux-Benhamou *et al*, 2008) and were delivered from once weekly (Taal *et al*, 1993, Mayoux-Benhamou *et al*, 2008, John *et al*, 2013) to every few months (van den Berg *et al*, 2006).

4.4.1.4 Intervention adherence

Intervention attendance was reported for three studies. Of 27 intervention participants randomised to education, 22 (81.4%) completed all five sessions (Taal *et al*, 1993). In another study, 36 (94.7%) of 38 intervention participants received motivational interviewing and self-regulation coaching (Knittle *et al*, 2013). The third study reported the attendance rate for the education programme as 97.8% (Mayoux-Benhamou *et al*, 2008). One study investigating an internet-based programme reported mean log-in times as 31.6 visits (SD 24.5) over the intervention period (Lorig *et al*, 2008). Another study comparing two internet-delivered programmes reported that of 77 intervention participants 42 (55%) were still using the website at the end of the intervention, compared with 5 (7%) of 75 control participants (van den Berg *et al*, 2006).

4.4.5 Outcome measures

Across all studies 81% of intervention participants and 84% of the control arm participants were reported to have completed all assessments. All studies used self-reported PA outcome measures, and one used accelerometry (van den Berg *et al*, 2006). Most self-report PA outcome measures were designed specifically for the study therefore reliability and validity data for the measures were not available. Mayoux-Benhamou *et al* (2008) used the Baecke questionnaire for leisure-PA (Baecke, Burema and Frijters, 1982).

Study authors reported that this has been validated in French (see Mayoux-Benhamou *et al*, 2008). Outcome data for this questionnaire were not presented separately for intervention and control arms.

Knittle (2013) used the Short Questionnaire to Assess Health-Enhancing Physical Activity (Wendel-Vos *et al*, 2003). The authors report that this instrument is “fairly reliable and reasonably valid” when assessed in healthy adults (18-65 years old) (pp.1169, Wendel-Vos *et al*, 2003). Self-efficacy for PA was measured using an 18-item questionnaire (Bandura, 2006). The Treatment Self-Regulation Questionnaire (Levesque *et al*, 2007) was used to measure autonomous motivation. Reliability and validity data for RA have not been identified for these outcome measures.

Lorig (2008) measured aerobic exercise using a validated health-related behaviour measurement tool developed by the Stanford Patient Education Research Center (2014). However, validity and reliability in a specific RA population are not known. The International Physical Activity Questionnaire (IPAQ) (Craig *et al*, 2003) was reported as an outcome measure by John *et al* (2013), but data were not presented in the results.

Three studies recorded the percentage of patients meeting guidelines for healthy PA (van den Berg *et al*, 2006, Brodin *et al*, 2008, Knittle *et al*, 2013). The first of these reported Dutch PA guidelines as at least 30 successive minutes of moderate-intensity PA on at least five days per week, or 20 successive minutes of vigorous-intensity PA on at least 3 days per week (van den Berg *et al*, 2006). The other studies defined guidelines as at least 30 minutes of moderate-intensity PA on most days of the week (Brodin *et al*, 2008) or on five days per week (Knittle *et al*, 2013).

4.4.6 Adverse events

Only one study reported that there were no adverse events associated with the intervention (Knittle *et al*, 2013). It is unclear whether adverse events occurred in the remaining studies.

4.4.7 Risk of bias in included studies

A summary of the risk of bias in included studies is presented in table 4.5. Assessment of the risk of bias was based on published material only.

Overall, two studies met three criteria (Mayoux-Benhamou *et al*, 2008, Knittle *et al*, 2013), three studies met two criteria (van den Berg *et al*, 2006, Lorig *et al*, 2008, John *et al*, 2013), and three met one criterion (Taal *et al*, 1993, Brus *et al*, 1998, Brodin *et al*, 2008) out of six for low risk of bias. The percentage risk of bias for each domain across all studies is presented in figure 4.2.

Table 4.5: Risk of bias in included studies

Lead author, (year)	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance and detection)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Brodin, (2008)	+	-	?	?	-	?
Brus, (1998)	?	?	?	-	-	+
John, (2013)	+	+	-	?	-	?
Knittle, (2013)	+	+	?	+	?	-
Lorig, (2008)	?	?	-	-	+	-
Mayoux-Benhamou, (2008)	-	+	?	?	+	?
Taal, (1993)	?	?	?	-	+	?
van den Berg, (2006)	+	?	?	-	+	-

+ = low risk; ? = unclear risk; - = high risk

4.4.7.1 Random sequence generation and allocation concealment (selection bias)

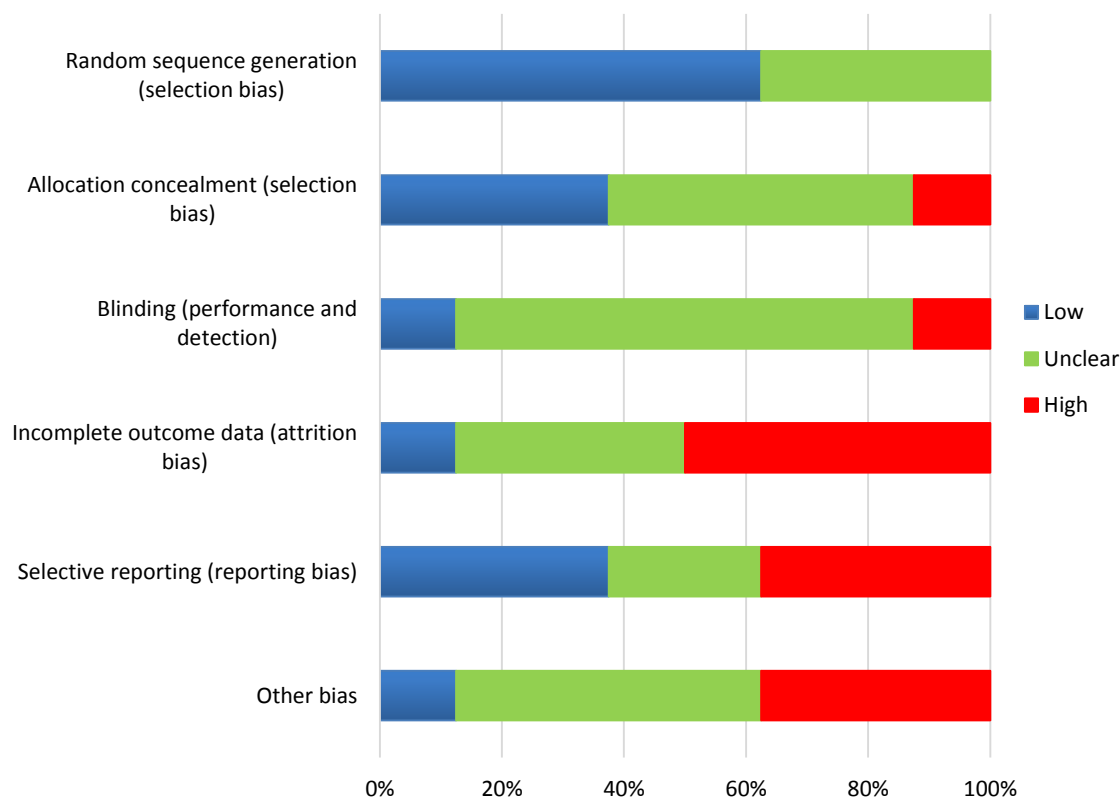
Only two studies provided sufficient information to be judged low risk of selection bias (table 4.5). Randomisation was performed by computer-generated random numbers in both studies (John *et al*, 2013, Knittle *et al*, 2013). Three studies reported allocation concealment. Methods included allocation by an independent researcher not involved in data entry or analysis (John *et al*, 2013, Knittle *et al*, 2013) and use of sealed opaque envelopes (Mayoux-Benhamou *et al*, 2008). Sequence generation and allocation concealment was not reported for three studies (Taal *et al*, 1993, Brus *et al*, 1998, Lorig *et al*, 2008). Allocation concealment was poorly reported by van den Berg (2006) and was considered high risk in the study by Brodin (2008) because study personnel could foresee group assignment.

4.4.7.2 Blinding (performance and detection bias)

Poor reporting of blinding of participants and study personnel in the majority of studies (n=6) prevented clear judgement of the risk of performance bias. The remaining studies reported that participants could not be blinded to the intervention (Lorig *et al*,

2008) or used a non-blinded study design (John *et al*, 2013). These were judged as high risk of performance bias.

Figure 4.2: Risk of bias as percentages for included studies (n=8)



Detection bias was judged as low risk in four studies reporting blinding of outcome assessors (Taal *et al*, 1993; Brus *et al*, 1998; Brodin *et al*, 2008, Mayoux-Benhamou *et al*, 2008). Poor reporting in other studies prevented accurate assessment of detection bias (Taal *et al*, 1993, Lorig *et al*, 2008, John *et al*, 2013, Knittle *et al*, 2013).

4.4.7.3 Incomplete outcome data (attrition bias)

Four studies were judged at high risk of attrition bias due to missing data, 'as-treated' or 'per-protocol' analysis performed or poorly described methods for imputing data in intention-to-treat analyses (Higgins and Green, 2011). Risk of attrition bias could not be judged in three studies where reasons for loss to follow-up were not reported (Brodin *et al*, 2008) or reporting of attrition or exclusions was insufficient (Mayoux-Benhamou *et al*, 2008, John *et al*, 2013). The remaining study was judged at low risk of attrition bias as they reported intention-to-treat analyses, although they used the last outcome carried forward method to impute data, which may introduce further bias (Knittle *et al*, 2013).

4.4.7.4 Selective reporting (reporting bias)

Three studies were judged at low risk of reporting bias (van den Berg *et al*, 2006, Lorig *et al*, 2008, Mayoux-Benhamou *et al*, 2008). One study did not use or report the same outcome measures specified in the trial protocol (Brodin *et al* 2008). Three studies had selective reporting of outcomes (Brus *et al*, 1998, Mayoux-Benhamou *et al*, 2008, John *et al*, 2013). These were judged at high risk of reporting bias. Another reported the trial registration number with the Netherland Trial Register but the protocol could not be accessed (Knittle *et al*, 2013) therefore risk was judged as unclear.

4.4.7.5 Other sources of bias

Only one study was judged at low risk of bias as specified for this review (Brus *et al*, 1998). Of the remaining seven, three were at high risk and four at unclear risk of bias from other sources. Reasons for judgements are presented in table 4.6.

Table 4.6: Reasons for judgement of the risk of other sources of bias

Lead author, year	Risk of other sources of bias	Reason for judgement of risk of bias
Brodin, 2008	?	Possible contamination – control arm had access to physiotherapy including education and organised PA. Uptake not reported
Brus, 1998	+	Low risk of other bias
John, 2013	?	IPAQ data not reported therefore baseline differences in PA not known
Knittle, 2013	-	Differences in monitoring of PA between groups as intervention arm completed exercise diaries
Lorig, 2008	-	\$10 Amazon vouchers for control participants only
Mayoux-Benhamou, 2008	?	Possible contamination – control arm had access to physiotherapy. Uptake not reported
Taal, 1993	?	Possible contamination – control arm referred to physiotherapy but details of treatment unknown
van den Berg, 2006	-	Both groups received PA intervention

+ = low risk; ? = unclear risk; - = high risk

IPAQ = International Physical Activity Questionnaire; PA = physical activity

4.4.8 Main effect of interventions on physical activity

The effects of interventions on PA outcomes are shown in table 4.3. Of six studies measuring self-reported PA levels, three demonstrated significant beneficial effects of the intervention on PA outcome when compared with the control arm at the study endpoint. Of these, one reported greater performance of physical exercise (times per week) ($p < 0.01$) (Taal *et al*, 1993), one reported significant greater frequency of vigorous PA (days per week) (van den Berg *et al*, 2006) and one reported a greater proportion of intervention participants meeting PA guidelines of at least 30 minutes per day on five days per week ($p = 0.049$) (Knittle *et al*, 2013). Knittle *et al* (2013) also reported significant improvements in leisure time PA ($p = 0.022$, small effect 0.22), self-efficacy for PA ($p = 0.008$, small effect 0.47) and autonomous motivation for PA ($p = 0.001$, medium effect 0.51). John *et al* (2013) noted greater improvements in attitudes ($p = 0.01$, very small effect 0.10), perceived behavioural control ($p = 0.04$, very small effect 0.06) and behavioural intention ($p < 0.001$, small effect 0.164) to increasing PA for intervention participants compared with controls at six months.

Two studies investigated the effect of an education intervention on PA compliance (Brus *et al*, 1998, Mayoux-Benhamou *et al*, 2008). One of these demonstrated a short-term improvement in the amount of time spent on PA ($p < 0.05$) in the intervention arm compared with controls at 3 months post-baseline, but this was not significant at 12 months (Brus *et al*, 1998). Another study reported significantly greater compliance ($p < 0.0001$) with a home exercise programme for intervention participants compared with controls at 12 months after baseline (Mayoux-Benhamou *et al*, 2008). However, although statistically significant, the mean compliance rate for intervention participants was poor (11.8%; SD 25.5%). Compliance with leisure PA in the same study was significantly increased in the intervention arm compared with controls only at 6 months after baseline ($p = 0.0001$). The difference between groups was not significant at 12 months.

Long-term PA outcomes were available for two studies (van den Berg *et al*, 2006, Brodin *et al*, 2008) at 12 months after the study endpoint. Neither demonstrated a significant difference between intervention and comparison arms (Hurkmans *et al*, 2010b, Sjöquist *et al*, 2011).

4.5 Discussion

This review aimed to evaluate the effectiveness of interventions using HBC theory and/or BCTs on the uptake and maintenance of PA in adults with RA. Eight studies were included that investigated HBC interventions and used a PA outcome measure, providing data for 1,157 people with RA. There was a large degree of heterogeneity amongst HBC interventions, with differences in content, length and frequency of sessions and duration of the intervention. HBC interventions employed a range of BCTs and methods of delivery, for example, web-based programmes, group education and individual motivational interviewing and self-regulation coaching.

Treatment effects for interventions varied. Some studies reported statistically significant short- to medium-term beneficial effects of an HBC intervention on PA outcomes at the end of the study. Long-term follow-up data demonstrated no effect 12 months post-intervention, although data were only available for two studies. The absence of long-term follow-up is not unique to RA. A systematic review of maintenance of behaviour change following PA and dietary interventions in adults reported that less than one third of included studies (n=29) included a follow-up assessment of 12 months or longer (Fjeldsoe *et al*, 2011).

PA-related cognitions were rarely measured, but some improvement was noted. Addressing cognitive determinants of PA, such as motivation may be key for improving PA in RA (Lee *et al*, 2012). Indeed, autonomous motivation has been associated with greater PA (Hurkmans *et al*, 2010a). Similar positive correlations have been noted for PA in RA for self-efficacy, health perceptions and previous PA levels, although evidence is limited, as few existing studies have explored these variables (Larkin and Kennedy, 2014). It has been recommended that measurement of these constructs of PA behaviour should be included in future research (Larkin, Kennedy and Gallagher, 2015).

Although HBC theory was specified or eluded to in five studies, it was unclear if or how theory was used to develop the interventions. An article describing the development of one intervention was available (John *et al*, 2011). This was based on the Common-Sense Model, TPB and Stages of Change (Transtheoretical Model). Improvements in PA-related cognitions associated with the TPB (attitudes, perceived behavioural control and intentions) were noted (John *et al*, 2013). However, PA behaviour was not changed. This is a common problem with social cognition models. While TPB provides an explanation for the causes of intentions, and therefore suggests potential cognitive determinants that might be targeted for behaviour change, it does not indicate how to change these cognitions (Abraham *et al*, 2008). A review of TPB-based interventions has suggested that

there is limited evidence demonstrating the usefulness of this model (Hardeman *et al*, 2002).

Self-efficacy theory or SCT was explicitly mentioned in three studies. However, the use of these theories in intervention development was unclear. While two measured self-efficacy for PA, no significant changes were observed. A recent review of the use of theory in interventions to change PA and dietary behaviour in healthy adults reported that interventions based on SCT or Stages of Change (Transtheoretical Model) were no more effective than interventions that did not report an underpinning theory (Prestwich *et al*, 2014). Unfortunately SCT is often not applied appropriately, with studies of interventions that claim to be SCT-based only assessing one or two components of the model, such as self-efficacy and outcome expectancies (Abraham *et al*, 2008). This offers a possible explanation for the apparent insufficiency of SCT-based interventions for affecting behaviour change. Indeed, Prestwich and colleagues (2014) reported that theory was rarely used to develop or evaluate interventions, noting large inconsistencies between application of theory and the effects of interventions.

Variation in terminology and the absence of a definition of BCTs is problematic when attempting to identify HBC interventions (Michie *et al*, 2011). However, use of a BCT taxonomy (Michie *et al*, 2013) helped to identify implicit use of BCTs in the included interventions. These were varied and inconsistent. Consequently, it is difficult to postulate what techniques might be useful for changing PA behaviour in RA, although three of the techniques commonly identified in the studies (goal-setting, problem-solving, self-monitoring of behaviour) have previously been reported as effective for promoting PA, albeit in healthy adults (Michie *et al*, 2009a, Bird *et al*, 2013).

Only two studies specified promotion of PA as the main aim (van den Berg *et al*, 2006, Knittle *et al*, 2013). The remaining interventions aimed to improve other variables such as overall health status, cardio-vascular disease risk factors and self-management rather than specifically seeking to change PA behaviour or PA-related cognitions.

PA outcomes varied and only three studies used a similar measure (percentage of participants meeting recommendations for healthy PA) (van den Berg *et al*, 2006, Brodin *et al*, 2008, Knittle *et al*, 2013). All studies used self-reported PA outcome measures. Self-reports of PA may be influenced by social desirability and social approval (Adams *et al*, 2005). Most of these were designed for the study, raising concerns regarding validity. One study (John *et al*, 2013) reported using the IPAQ, although it was not reported whether the full IPAQ or short form (IPAQ-SF) was used. Whilst this is a validated tool (Craig *et al*, 2003), and has been used in other RA studies investigating PA (Demmelmaier *et al*, 2013), an assessment of criterion validity has reported that the IPAQ-SF has limited use

as an accurate PA measure in patients with RA (Tierney, Fraser and Kennedy, 2014). Other validation studies have noted that IPAQ-SF overestimated PA levels by 46-173% when compared with objective measures (Lee *et al*, 2011). Where an objective PA measure was used no effects were demonstrated, despite differences in self-reported vigorous-intensity PA at the end of the study (van den Berg *et al*, 2006). This supports the suggestion that subjective measures may over-estimate PA.

Poor methodological quality for the majority of studies limits the trustworthiness of these results, making it difficult to determine the effectiveness of the included interventions for promoting PA in RA. For most, this was due to inadequate reporting making it impossible to rule out the risk of bias. The quality of reporting of the most recent study was higher than previous studies but methodological limitations, such as the underpowered sample size and short follow-up period, make it difficult to determine the effectiveness of the intervention for changing PA in the longer term (Knittle *et al*, 2013). Given the high percentage of unclear risk across all domains for the risk of bias tool (figure 4.2), the potential influence on treatment effect could not be predicted. However, it should be noted that blinding of participants in behavioural or exercise interventions is often not possible (Bourke *et al*, 2013), as discussed in chapter 2. Also, use of self-reported outcome measures means blinding of outcome assessors may not be meaningful. Whilst it is difficult to minimise performance and detection bias in these studies, attempts to address this were not reported.

Concerns regarding contamination were noted for three studies (table 4.6). Participants enrolled in such a study may seek to increase, or report to increase activity levels regardless of their arm allocation. In these instances it is not clear how much additional input was sought or received by control participants, which could underestimate the effectiveness of the intervention for increasing PA. Indeed, in one study control participants did increase PA during the study (van den Berg *et al*, 2006), although not in another (Brodin *et al*, 2008). Poor reporting by Mayoux-Benhamou and colleagues (2008) did not allow changes in PA over time to be determined.

Inconsistent reporting of characteristics such as disease activity and disability limits external validity of the findings, as it is not possible to determine if these are representative of the general RA population. Reporting of disease duration was also variable with some studies investigating early RA and others indicating a mean disease duration of several years. Comparison of data across these studies is difficult, as differences in baseline characteristics might influence the results. Likewise, where studies reported gender of RA participants, only 26% were male, indicating under-representation of men. As discussed in chapter 2, this is common for PA trials in RA. The mean age of

participants fell within the fifth and sixth decades, which is likely to be representative of the general RA population in the UK (Symmons, 2002). The small number of participants in all studies also limits generalisability of the findings. Sample size calculations were reported in five studies, but only one was sufficiently powered to detect change in PA outcomes (van den Berg *et al*, 2006).

A general limitation of research into PA interventions is that recruitment may be biased towards people who are interested in PA, or who are already more active. This has been discussed in chapter 2. This may underestimate the intervention effects if baseline PA levels are already above average for the population, or if motivation for PA is already high. One study excluded patients who met PA guidelines of 30 minutes of PA five times per week in an attempt to reduce recruitment bias (Knittle *et al*, 2013). Reasons for not taking part were not reported in most studies, although two recorded reasons for refusing consent. These included lack of motivation, work commitments and distance from home (Mayoux-Benhamou *et al*, 2008), and poor health or limited mobility, and scheduling or transport conflicts (Knittle *et al*, 2013).

4.5.1 Limitations of the review process

Initial searches carried out in November 2012 used Ovid to search MEDLINE databases. When the search was re-run in November 2014, it was noted that the database searches did not identify a known study that met the inclusion criteria. The MEDLINE search was re-run using EBSCO and the study was identified. The Ovid omission was queried with a specialist librarian who reported that, as the article of interest was e-published ahead of print, the citation was not available in Ovid. However, EBSCO receives content for MEDLINE directly from PubMed, which does index content ahead of print. Whilst it is possible that there were other unknown omissions in the initial search in 2012, any 'ahead of print' citations were likely to have been assigned to a print journal between 2012 and 2014, and would have been identified in the updated search. Nonetheless, it is important to consider this issue when selecting databases and their host search engines when conducting searches in the future.

Methods used to identify relevant studies were limited to English language, potentially missing relevant published data. However, it is likely that the majority of studies were published in English. Moreover, as mentioned in the methods, restricting the language does not appear to cause significant bias when estimating the effectiveness of interventions (Moher *et al*, 2000, Juni *et al*, 2002).

Hand-searching of journals was not performed which may have resulted in missing data, although most journals post-1990 are available in electronic format and would have been identified in electronic database searches. Only one reviewer ran searches and

screened titles for eligibility, increasing the chance of studies being missed from the review. Checking of data extraction and data synthesis by an additional reviewer was only carried out for two studies.

Finally, the search was limited to RCTs in order to determine effectiveness of the interventions of interest. By limiting the search in this way potentially useful evidence from non-randomised and qualitative studies may have been missed.

4.5.2 Other systematic reviews

A review exploring the same research question has recently been published (Cramp *et al*, 2013a). Only three studies in the current review were included (van den Berg *et al*, 2006, Brodin *et al*, 2008, Mayoux-Benhamou *et al*, 2008). This is likely due to differences in the search timeframe. The authors searched databases from 1998 to 2012 whereas the current review included articles published between 1990 and 2014. Therefore Cramp and colleagues (2013a) would not have found four of the studies in their search. It is not clear why the remaining study (Lorig *et al*, 2008) was not included. This might be explained by a more comprehensive search strategy to identify HBC interventions employed in the current review, based on a BCT taxonomy. Whilst previous authors reported searching for BCTs it is not clear how they were defined (Cramp *et al*, 2013a). The current review also has advantages as it used the Cochrane risk of bias tool instead of a quality assessment tool. As mentioned in section 4.3.4.3, Cochrane discourages the use of checklists as they place too much emphasis on reporting rather than conduct of the research (Higgins and Green, 2011).

Cramp and colleagues (2013a) concluded that individualised HBC interventions seem more effective than group interventions. This is misleading as it is based on weak evidence from only three studies. This is not supported by the current review, as there is insufficient evidence to make a judgement regarding the influence of intervention format. However, despite methodological and interpretative differences, both reviews highlight a lack of high-quality research investigating HBC interventions for promoting and maintaining PA in people with RA. Similarly, both recognise a need for use of validated and reliable subjective and objective PA outcome measures in future research.

Another recent narrative review has explored the use of HBC theory to promote PA in RA (Larkin, Kennedy and Gallagher, 2015). Although not a systematic review, this adds support to the current review findings, with authors noting a lack of appropriate application of HBC theory in many interventions, and limited evidence for success in changing long-term PA. A strength of the review was the use of a theory coding framework to aid examination of the extent to which interventions were theory-based. Four of the same studies as the current review were included (van den Berg *et al*, 2006, Brodin *et al*, 2008,

Mayoux-Benhamou *et al*, 2008, Knittle *et al*, 2013). However, lack of details regarding exclusion criteria mean it is not possible to determine whether other studies in the current review were identified and excluded in the narrative review (Larkin, Kennedy and Gallagher, 2015).

4.6 Conclusions

The current review shows a lack of evidence of effectiveness of BCTs for improving or maintaining PA in people with RA, confirming findings from previous reviews (Cramp *et al*, 2013a, Larkin, Kennedy and Gallagher, 2015). The small number and overall low quality of studies identified for inclusion makes it difficult to draw firm conclusions regarding the application of HBC interventions in clinical practice. There is a need for high quality research to determine the most effective theory-based interventions to increase and maintain PA in the RA population, with long-term follow-up to determine ongoing effects. This includes defining intervention parameters, including length and frequency of sessions, mode of delivery and intervention duration. Additionally, consistent use of valid and reliable, subjective and objective PA outcome measures is needed.

Factors identified in this review must be combined with lessons learnt from evidence in other long-term conditions (chapter 3) when developing a new intervention to support RA patients with modifying PA as a way of managing their fatigue. However, lack of consistency in existing interventions makes it difficult to determine what might work well in a real-world setting. Identifying key parameters of PA interventions used in clinical practice, including theory, content and delivery methods, was important to clarify this information. Combining existing evidence with practice-based knowledge and experience might offer a starting point for intervention design. Therefore, a qualitative exploration of HCPs' experiences of implementing and delivering such PA interventions was conducted. These experiences are presented in chapter 5.

Chapter 5: Exploring the experiences of health professionals delivering physical activity interventions for fatigue management in long-term conditions

Chapter 3 discussed existing evidence for the use of PA for fatigue management in long-term conditions. However, evidence of a theoretical basis for these interventions was limited. Chapter 4 highlighted a lack of evidence for the effectiveness of HBC interventions to promote PA in people with RA. The qualitative study reported in this chapter explored HCPs' opinions and experiences of delivering PA interventions for existing fatigue management programmes in long-term conditions, and aimed to identify any barriers and facilitators to implementation and delivery. Key components of the PA content of existing programmes were ascertained, and use of HBC theory or BCTs to facilitate PA behaviour change was explored.

5.1 Background

As discussed in chapter 1, fatigue is an important symptom of RA. The need for effective interventions to reduce the personal impact of fatigue for RA patients is evident. Meta-analyses have demonstrated that PA is effective for managing fatigue in long-term conditions such as CFS and cancer where these interventions are more established (Edmonds, McGuire and Price, 2004, Cramp and Byron-Daniel, 2012) (see chapter 3). Although the aetiology of fatigue in these conditions is likely to differ from that of RA, there may be important overlaps. Whilst these differences rule out the possibility of simply delivering existing programmes in RA, investigating PA interventions being used in these long-term conditions could provide valuable information regarding key structural elements, content and delivery, as well as identifying potential issues for implementation and delivery in clinical practice.

This study explored the use of PA interventions in established programmes for fatigue management in long-term conditions. Understanding how existing interventions work in practice, including practicalities and obstacles relating to delivery, is extremely useful for informing the development of novel interventions (Haines and Iliffe, 1995, Campbell *et al*, 2000), helping to pre-empt and identify potential pitfalls during the design phase.

5.2 Aims

The aims of this study were:

1. To identify and explore key components of the PA content of existing fatigue management programmes for people with long-term conditions.
2. To explore expert opinion regarding deliverability and acceptability of these programmes, including barriers and facilitators to implementation.

5.3 Methods

5.3.1 Research design

A qualitative approach was chosen for this study. Qualitative methods use a person-centred, holistic approach to gain knowledge and insight, and are a useful means of answering questions relating to clinical practice (Holloway and Wheeler, 2010). The MRC recommends use of interviews in the exploratory phase of developing complex interventions to improve health (MRC, 2000, MRC, 2008).

Semi-structured face-to-face interviews were carried out as they were considered an appropriate method to gain insight into the individual experiences of participants (Fossey *et al*, 2002). This type of data cannot be fully captured by quantitative means, which ignore the subjective and contextual elements of the research (Holloway and Wheeler, 2010). Qualitative interviews aim to examine the interviewee's beliefs and attitudes shaped by their own framework of meaning (Britten, 1995).

Alternative methods for collecting these data include use of focus groups or consensus methods (Jones and Hunter, 1995, Kitzinger, 1995). However, the candidate wanted to minimise the consensus effect of groups, whereby an individual may appear to agree with the strongest person so as to conform to the dominant view. In this scenario, less-confident participants may not voice their alternative opinion, with their silence assumed to infer agreement rather than fear of dissent (Sim, 1998). Therefore, individual viewpoints would not be captured as effectively in a group setting.

Telephone interviews offered an alternative to face-to-face interviews. It could be argued that these would have been more appropriate given the small number of geographically spread recruitment sites, being less time consuming and resource intensive for both the participant and researcher (Rubin and Rubin, 2012). Telephone interviews also have the advantage of obtaining an immediate response with improved anonymity for participants (Holloway and Wheeler, 2010). However, visual cues and non-verbal information are lost and there is a lack of opportunity to develop a researcher-participant relationship (Rubin and Rubin, 2012). Given the limited experience of the

candidate, it was felt that face-to-face interaction would be important to obtain rich data from participants.

5.3.2 Identification and sampling

The University of the West of England Faculty of Health and Life Sciences Research Ethics Committee granted ethics approval for this study (HLS/12/11/139). HCPs delivering PA components of fatigue management programmes in long-term conditions were invited to take part.

Fatigue services were identified through internet searches and known contacts. The candidate contacted services for CRF and CFS to determine whether PA was included in their fatigue management programmes. Lead clinicians for PA were identified. Further participants were sampled by snowballing, whereby potential interviewees identified other experts in their field who may have relevant experience in the subject area (Teddlie and Yu, 2007). Research and development approval was obtained for each National Health Service (NHS) site where potential participants were employed. Individual sites and services are not named in this account in order to protect anonymity of the participants.

A purposive sampling strategy was used to recruit participants. This allowed the candidate to deliberately choose a sample identified as having relevant knowledge, expertise and experience to address specific purposes related to the research question (Teddlie and Yu, 2007, Holloway and Wheeler, 2010). The target sample size was six to ten participants. As this was an exploratory qualitative study no formal sample size calculation was required, and the intention was not to reach data saturation.

Potential participants were provided with an information sheet and reply slip explaining the purpose of the study (appendix E). They were encouraged to ask questions and the candidate clarified any issues prior to taking consent. Those who agreed to take part were asked for verbal permission to collect pre-interview information including demographic data and programme details, such as the structure and content of their fatigue management programme. Data were collected on a case report form (appendix F) and returned to the candidate either in advance via a pre-paid envelope or at the time of the interview. Participants were asked if they were willing to share any programme information booklets. If they were unable to provide this information before the interview it was discussed at the start.

5.3.3 Data collection

Interviews took place in a meeting room at the participants' place of work at a time that was convenient for them to minimise disruption to their clinical work. At the start of the interview the candidate introduced themselves as a doctoral research student with a

background as a clinical physiotherapist. Reflexivity is a key consideration in qualitative research (Mays and Pope, 2000). Explicit acknowledgement of potential influences on the researcher and the research process is an important means of ensuring transparency and confirmation of the results (Finlay, 2002, Shenton, 2004). The candidate needed to demonstrate awareness and sensitivity to the role that personal experience, previous assumptions and intellectual biases may play in shaping data collection and interpretation (Mays and Pope, 2000).

Decisions regarding the disclosure of the candidate's professional background were made prior to commencing data collection. As the participants were therapists themselves, the way that they responded to questions may have differed if they knew the interviewer had the same professional background (Richards and Emslie, 2000). For example, they may be more willing to give fuller explanations and use more technical language rather than giving a basic description of the phenomena in lay terms. This may enhance the richness of the data or, conversely, participants may make assumptions about the interviewer's experience that result in less detailed accounts being provided. The candidate needed to be aware of this to ensure that appropriate, probing questions were asked to obtain a full and rich explanation that added value to the data.

The interview process was explained and there was an opportunity to ask questions. Each interviewee was advised that they could stop the interview at any time. Written consent was requested prior to commencing the interview. Interviews were based on a topic guide (box 5.1) and were 45 to 60 minutes in duration. They were audio-recorded and transcribed verbatim. Transcripts were checked for accuracy and all names of people and places were anonymised to protect confidentiality.

5.3.3.1 Topic guide and questionnaire development

A topic guide and questionnaire were developed through consultation with the supervisory team and PRPs. As suggested by Braun and Clarke (2013), initial questions were generated following a discussion session with team members, and were designed to elicit information from participants that would help to answer the research question.

Box 5.1: Interview topic guide

Part A: Background information and clinical role

- Tell me about the origins of this fatigue management programme, e.g. who designed and developed it?
- Are you aware of any theoretical basis underpinning the programme? What do you understand by this? How does that work in practice?
- When you started delivering this programme did you have any previous training or experience of running this type of programme?
 - Do you have any clinical supervision or support to run the programme?
 - Do you think any health professional could deliver this programme? Would they need any additional specific training?

Part B: Delivery and acceptability of the physical activity (PA) component

- How do you describe the programme to service users?
- Tell me about the PA component of the programme
 - What is your understanding of PA and how do you describe this to service users? What words do you use?
 - Do you distinguish between exercise and PA?
 - How do you feel the PA component works?
 - What works well or not so well? Why?
- How do service users receive the PA component?
 - Do people engage with it easily?
 - How do you motivate people? How do you help people maintain motivation after the programme?
 - What is the uptake/dropout rate like? Do people give reasons why they drop out?
 - Do you know if people maintain activity afterwards?
- How and when do you assess fatigue during the course of the programme?
- How do you evaluate the programme?
- Is there any follow-up to the programme?
- What do you think about the administration and referral process? Who can refer to the programme?
- Can you tell me more about how the programme is delivered?
 - Is there anything you would change?
 - What are the greatest challenges to delivering the programme?
 - What would you recommend to others wishing to set up a similar programme?
 - What is the best tip you would like to pass on?

Part C: Close

- Are there any issues that we have not talked about that you would like to raise?
- Thank you very much for your time and valuable contribution to the study.

Prompts: During the interview the researcher may use the following prompts to explore certain aspects in more detail:

Could you tell me more about that? Can you describe that for me? Can you give me an example? How did that make you feel? Why did you do that? What do you think about that?

Various issues were discussed during development. Opening questions for the topic guide were designed to be broad and neutral, to put participants at ease at the start of the interview (Braun and Clarke, 2013). Question sequencing was carefully considered to provide a logical flow to data collection. Questions were grouped into two sections: background information and clinical role; and delivery and acceptability of the PA

component. PRPs assisted with the wording and construction of questions to ensure that rich and useful data would be obtained. A list of prompts was included to assist the candidate with eliciting further detail and exploring certain aspects in more depth where applicable.

A pilot interview was conducted with a member of the supervisory team and observed by an experienced qualitative researcher from the University of the West of England. This allowed the candidate to test and refine the questions, and to practice their interviewing technique, thus greatly enhancing confidence prior to actual data collection. Further refinement of the topic guide was carried out after initial data collection, through reflection and discussion with the research team.

5.3.4 Analysis

5.3.4.1 Interview data

Data were organised and analysed using thematic analysis (Braun and Clarke, 2006). Thematic analysis is not tied to any epistemological position and is therefore appropriate for a pragmatic mixed methods approach. Although it may be criticised as an ‘anything goes’ approach, Braun and Clarke (2006) argue that this is advantageous, as it is not constrained or limited to a specific methodology. In fact, they propose that thematic analysis should be considered a method in its own right.

A hybrid thematic approach of deductive and inductive analysis was used for this study (Fereday and Muir-Cochrane, 2006, Dures *et al*, 2012). Deductive (or theoretical) thematic analysis is driven by pre-existing theory related to the researcher’s analytic interest, whilst the use of inductive thematic analysis facilitates identification and analysis of novel themes that do not fit into a pre-existing framework (Braun and Clarke, 2006). A taxonomy of BCTs was used as the deductive framework (Michie *et al*, 2013) to identify behaviour change strategies being used by HCPs. Drawing the deductive and inductive analyses together gives a richer explanation and understanding of the topic under exploration. The final report is a combination of the two analyses (Fereday and Muir-Cochrane, 2006).

Initially content analysis was considered as an appropriate systematic analytic procedure. This would allow the candidate to check the frequency of occurrence of categories identified in the literature as being key components of the phenomenon of interest (Joffe and Yardley, 2004). However, a criticism of this method is that by simply counting frequency, the context of the category is lost and the meaning may be removed. Joffe and Yardley (2004) suggest that thematic analysis is preferable, as it still provides a

systematic approach and allows for an analysis of the frequency of codes whilst retaining their meaning within a contextual setting.

To ensure rigour, two transcripts were independently analysed by a member of the supervisory team with expertise in the field of qualitative research, and a PRP. The three sets of analyses were discussed and common codes agreed. This helped to establish objectivity and provide some distance between the candidate and the data (Meyrick, 2006).

5.3.4.2 Hybrid thematic analysis process

Analysis was based on Braun and Clarke's (2006) six phase approach to thematic analysis and the hybrid approach of Fereday and Muir-Cochrane (2006).

1. Reading and familiarisation

This phase involved the candidate becoming immersed in the data in order to gain a thorough understanding and appreciation of the depth and breadth of the content of each interview (Braun and Clarke, 2006). The candidate began to look for patterns and meanings across the data during this stage.

The first interview was transcribed by the candidate, whilst subsequent interviews were professionally transcribed. In all instances the first step in the familiarisation process was to listen to audio files to ensure that the transcripts retained their intended meaning. Transcripts were read and re-read, with points of interest highlighted and notes made identifying initial thoughts and ideas about the data.

The first three transcripts were read thoroughly prior to conducting subsequent interviews. This allowed the candidate to reflect on the interview process and review early data in order to modify and refine the topic guide. This iterative approach ensured that any interesting data obtained in these initial interviews could be explored further with future participants.

2. Initial coding

Coding was approached both deductively and inductively.

Deductive thematic analysis

Firstly, deductive codes were systematically applied to the data. Each transcript was explored for examples of each code, as defined in the BCT taxonomy (Michie *et al*, 2013). This theoretically-derived taxonomy was used to identify BCTs being described by participants, particularly where they did not explicitly name the techniques. The taxonomy includes a code for each BCTs with a description and example. This was used as the coding manual, as recommended by Fereday and Muir-Cochrane (2006). Segments of data that fitted a BCT description were selectively coded and copied into a framework in

Excel (Microsoft Office 2007). An example of the deductive framework is presented in appendix G. Coded data were re-checked and coded using the computer-assisted qualitative data analysis software Nvivo 10 for Windows (QSR International, 2012) as a data management tool.

Inductive thematic analysis

Following completion of deductive coding for BCTs, transcripts were coded inductively and both data- and researcher-derived codes were generated. Inductive thematic analysis sought to extend and complement the deductive codes (Dures *et al*, 2012) and to look for additional themes not related to BCTs. Codes were predominantly descriptive and aimed to reflect the semantic meaning of the data, staying close to the content and original meaning as intended by participants (Braun and Clarke 2013). Nvivo was used to manage inductive codes.

Hybrid analysis

Deductive and inductive codes were combined prior to theme development.

3. Searching for themes

In this phase of analysis the candidate started to organise similar codes into broader categories. These categories, or themes, were grouped around a central organising concept reflecting programme design. The combined inductive and deductive codes were grouped together and re-grouped into different themes and subthemes several times during this phase of the analysis.

4. Reviewing potential themes

Once an initial set of candidate themes had been developed these were reviewed and refined to represent a summary of the data. A review of the original research question and objectives of the study helped to focus the analysis during this phase.

During this stage the candidate started arranging themes into groups of similar issues, assisted by the use of an online mind-mapping tool, Mindomo (www.mindomo.com; accessed September 2013). Reviewing candidate themes helps to reflect on the overall message portrayed by the data set and to check that this is in line with the original meaning intended by participants (Braun and Clarke, 2006). Creating thematic maps and networks assisted the visualisation of relationships between codes, themes and subthemes.

5. Defining and naming themes

Themes were defined according to the aspects of the data that they represented and how they related to other themes and subthemes. Names were devised to capture the sense of what each theme was about (Braun and Clarke, 2006, Braun and Clarke, 2013).

6. Producing the report and finalising analysis

This phase aimed to tell the story of the data and is evidenced by data extracts taken directly from the transcripts. This included interpretation of the data in relation to the original research question.

5.3.4.3 Questionnaire data

Questionnaire data were inserted into a spreadsheet in Microsoft Excel (2007). Numeric data were analysed using descriptive statistics and free text responses using thematic analysis as described above.

5.3.5 Ensuring quality

The “quality” debate in qualitative research is extensive and far-reaching, spanning the entire epistemological spectrum from positivist quantitative to naturalist qualitative research paradigms. As a result, various strategies for ensuring trustworthiness in qualitative research projects have been presented (Mays and Pope, 2000, Shenton, 2004, Meyrick, 2006). Reflexivity and independent analysis to enhance rigour and quality have been touched upon in sections 5.3.3 and 5.3.4 respectively.

Other techniques, such as triangulation and providing a clear, transparent account of data collection and analysis procedures, are useful approaches for ensuring quality (Mays and Pope, 2000). Findings from this study have been triangulated with data from a review of the literature related to PA for fatigue management in long-term conditions (chapter 3). This process enabled verification of findings and helped to improve the quality of intervention development (Meyrick, 2006).

5.4 Results

5.4.1 Participants

Eight fatigue service providers were identified and staff approached. Two services were ineligible as they did not offer a PA intervention and staff delivering a third service did not respond to the candidate’s enquiries. Ten HCPs were subsequently invited to participate in the study from five different health services (four NHS trusts and one private organisation). Nine people agreed to take part. All participants were female with age ranging from 33 to 53 years (mean: 42.8). Participant demographics are presented in table 5.1.

Table 5.1: Participant demographics

ID	Profession	Clinical role	Time since qualification (years)	Length of time running PA programme (years)
001	PT	PT	16	3.5
002	OT	OT	23	3.5
003	PT	PT	15	1.5
004	PT	Senior PT, CFS service	29	3
005	PT	Clinical specialist PT	32	8
006	PT	Clinical specialist PT	14	7 months
007	OT	Providing activity management and GET	12	7
008	Exercise physiologist	Graded exercise therapist	11	2.5
009	CNS	Team leader, fatigue service	30	8

CFS=chronic fatigue syndrome/myalgic encephalitis; CNS=clinical nurse specialist; GET=graded exercise therapy; ID=participant identification code; OT=occupational therapist; PA=physical activity; PT=physiotherapist

5.4.2 Programme information – questionnaire data

Data from the programme information section of the pre-interview questionnaire are presented in table 5.2. Eight fatigue management programmes were described (two participants were delivering the same programme) targeting palliative care conditions where patients experience fatigue and breathlessness (for example, CRF, chronic obstructive pulmonary disease and lung disease (n=3)), and CFS and other fatigue syndromes (n=5). For group programmes, minimum reported group size ranged from 1 to 8 patients and maximum from 8 to 12 patients. Detailed programme information was discussed during the interviews and is presented in the thematic analysis in section 5.5.

Table 5.2: Questionnaire part 2: Programme information

ID	Long-term condition(s)	Group or individual	Min group size	Max group size	How is PA included?	Other components	Length of programme (weeks)	Number of sessions and frequency	Number of sessions of PA, and proportion of session dedicated to PA
001 [§]	Any palliative care patient with fatigue and breathlessness	group	1	10	FAB: Weekly gentle warm-up, one session dedicated to exercise education	Prioritising and planning, sleep, diet, breathlessness, thinking traps (CBT)	6	6 sessions, 1 x weekly	6 sessions; 5-10 mins per session. One session dedicated to exercise
002 [§]	Cancer, COPD, heart failure, lung fibrosis	group	1	10	FAB: Weekly gentle warm-up, one session is dedicated to exercise	Planning, pacing and prioritisation, nutrition, breathlessness management, CBT, sleep management	6	6 sessions, 1 x weekly	1 x hour session, and 5-10 mins for all other 5 weeks
003	Any - palliative care	group	1	*	Circuits, Pilates, FAB	FAB – making the most of every day, nutrition, breathlessness, sleep, CBT	Circuits/ Pilates: 9; FAB: 6	9 or 6 sessions, 1 x weekly	Circuits/Pilates - 1 hour weekly. FAB - 1 whole one hour session and weekly 10 mins
004	CFS	both	8	12	Mostly educational	Relaxation, BR control, activity management	10	no specific number	1 to 20 sessions
005	CFS	group	6	8	Weekly sessions of 30-60 mins	Activity management (OT), CBT (clinical psychologist)	10	10 sessions, 1 x weekly	10; 30-50%

ID	Long-term condition(s)	Group or individual	Min group size	Max group size	How is PA included?	Other components	Length of programme (weeks)	Number of sessions and frequency	Number of sessions of PA, and proportion of session dedicated to PA
006	Adult CRF	both	*	10	*	Goal setting, activity analysis and management, mindfulness, CBT, acceptance and commitment therapy, sleep hygiene	6	6	*
007	CFS, fatigue syndromes	individual	n/a	n/a	GET, body mechanics and ergonomics	Activity analysis, sleep, pacing, goals, relaxation and mindfulness, setback management	52	14 sessions, 1 x fortnightly	
008	CFS, fatigue syndromes	both	4	8-10	ADL & exercise	Sleep, relaxation, goal setting	up to 52	14 sessions, fortnightly, then every 4-6 weekly	8
009	CFS, fibromyalgia	*	*	*	*	*	*	*	*

*ADL=activities of daily living; BR=breathing rate; CBT=cognitive behavioural therapy; CFS=chronic fatigue syndrome/myalgic encephalomyelitis; COPD=chronic obstructive pulmonary disease; CRF=cancer-related fatigue; FAB=Fatigue and breathlessness group; GET=graded exercise therapy; ID=participant identification code; n/a=not applicable; PA=physical activity; *=missing data; §=participants delivering the same programme*

5.5 Thematic analysis of qualitative interviews

Four main themes and several subthemes were identified that describe and explore various aspects of programme structural components, implementation components, theoretical approaches and intervention outcome. Supporting quotations are identified by participant identification number.

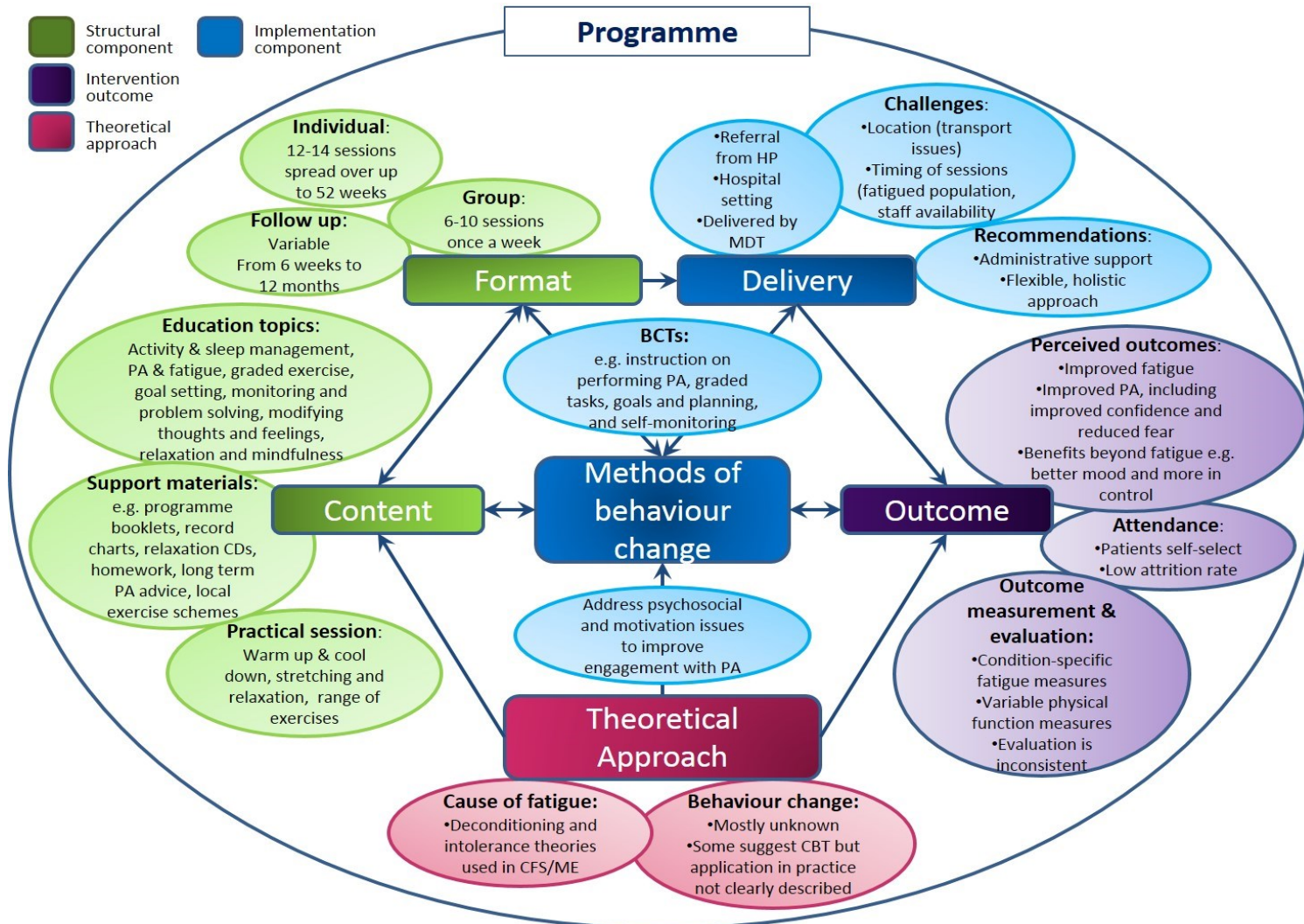
Of a possible 93 BCTs in the deductive framework (Michie *et al*, 2013), 26 were identified, defined and coded across the nine interviews. These are presented in table 5.3 in descending order of the number of sources in which they were coded. The deductive and inductive codes were combined and analysed together as a hybrid analysis. The relationship between resultant themes and subthemes is illustrated in figure 5.1.

Table 5.3 Behaviour change techniques coded by deductive analysis

BCT number and name, as defined by Michie <i>et al</i> (2013)	Number of interviews coding BCT
4.1 Instruction on how to perform the behavior	9
8.1 Behavioural practice or rehearsal	9
9.1 Credible source	9
3.3 Social support (emotional)	8
12.6 Body changes	8
1.1 Goal setting (behaviour)	7
1.2 Problem solving	7
1.5 Review behaviour goal(s)	6
2.3 Self-monitoring of behaviour	6
6.1 Demonstration of the behaviour	6
8.7 Graded tasks	6
3.1 Social support (unspecified)	5
4.3 Re-attribution	5
8.6 Generalisation of target behaviour	5
1.4 Action planning	4
2.4 Self-monitoring of outcome(s) of behaviour	3
11.2 Reduce negative emotions	3
2.6 Biofeedback	2
5.4 Monitoring of emotional consequences	2
1.6 Discrepancy between current behaviour and goal	1
2.2 Feedback on behaviour	1
2.7 Feedback on outcome(s) of behaviour	1
9.2 Pros and Cons	1
15.1 Verbal persuasion about capability	1

BCT=behaviour change technique

Figure 5.1: Relationship between programme themes and subthemes



5.5.1 Theme 1: Programme structure

5.5.1.1 Format

This subtheme describes the programme mechanics. These are broken down into key elements, such as group versus individual sessions, programme and session length and duration, session structure and programme follow-up.

Group versus individual sessions

Five programmes offered predominantly group sessions, and the remaining four were mainly individual, although two of these occasionally offered group sessions. Several positive aspects of group programmes were identified, including vicarious learning and sharing of experiences:

001: "the best thing about the group is that the patients get to share their own experiences,"

005: "I think people definitely do gain from um that [...], vicarious learning..."

The social support provided by these group sessions was felt to be a useful BCT to motivate patients and promote behaviour change.

Group programmes were individualised as much as possible, although this presented a challenge to HCPs:

006: "I think it's a great challenge but this is also what makes it interesting, that they are all at different levels,"

From a practical perspective groups were considered useful for managing the volume of referrals.

005: "...there are positive benefits to patients being seen in a group you know, as well as just the, sort of, logistics of handling the number of referrals"

However, group sessions were not appropriate for all patients and it was suggested that the option of individual therapy should be offered if necessary. Indeed, for some patients, particularly those with communication difficulties, one-to-one sessions may be more suitable:

001: "people who, um, have difficulty, a little bit more difficulty with hearing or communication that tend to engage less. [...] so sometimes you just need a one-to-one..."

Negative aspects of group sessions included a perceived lack of evidence for group programmes with difficulty meeting individual needs, a perception that some people do not like groups and thoughts that some patients may be brought down by others.

007: "I don't think the evidence base is as strong for groups"

007: "[groups] can't really be targeted to their needs."

004: "There's a lot of people who wouldn't come to a group [...] they don't like groups"

004: "Sometimes people bring each other down in a group."

Programme length, session frequency and duration

Programmes varied from 6 to 14 sessions spread over 6 to 52 weeks. Group sessions were generally held weekly over 6 to 10 weeks. Individual programmes offered 12 to 14 sessions spread over 52 weeks with sessions initially weekly or fortnightly, then extended to every six to eight weeks later in the programme to encourage self-management. Key format characteristics described by participants are presented in table 5.4.

Table 5.4: Group and individual programme characteristics

Characteristic	Group programmes		Individual programmes
	CRF	CFS	CFS
Total programme length	6-9 weeks	8-10 weeks	12-14 sessions spread over up to 52 weeks
Frequency of sessions	Once a week	Once a week	Initially every 1-2 weeks, frequency varies according to individual need
Duration of session	60-120 mins	120 mins	45-50 mins
Programme follow-up	Between 3-12 months		Between 6 weeks – 6 months after programme end
Duration of education component	5-60 mins	60 mins	45-50 mins
Includes practical session	Yes	Yes	No
Duration of practical session	10-120 mins	10-120 mins	N/A

CFS=chronic fatigue syndrome; CRF=cancer-related fatigue; N/A=not applicable

Session structure

Broadly speaking all sessions were structured to include an education and activity management component. Some group programmes also contained a practical element where patients had the opportunity to try some PA. The content of these sessions is presented in section 5.5.1.2.

Although some HCPs followed a fairly rigid programme structure, the importance of individualising the programme and allowing flexibility in the sessions was emphasised.

008: "Individualise the programmes, [...] tailoring it as much as possible to the person,"

Programme follow-up

Five of the eight programmes offered a follow-up session after the end of the programme. The timing, duration and delivery varied between sites. One group follow-up was reported at 3, 6 and 12 months, although this was not always applied consistently. For two group programmes individual follow-up took place within a month, with either group or individual follow-up at 6 months. People attending individual programmes tended to have a consultant or clinical nurse specialist review at least 6 weeks after therapy. Occasionally telephone follow-ups were offered for patients who found it hard to attend appointments in person.

5.5.1.2 Content

This subtheme describes education topics covered in the programmes. HCPs delivering a practical component also reported the structure and content of these sessions. In addition to content delivered within the sessions, all programmes provided a variety of support materials. These are described in this subtheme.

Education topics

Education topics related to activity management, goal setting, and physical (for example, PA, exercise and sleep) and psychosocial aspects of fatigue (for example, modifying thoughts and feelings, relaxation, managing setbacks).

Activity management

Activity management was an important element of most programmes. Some participants mentioned that patients had patterns of high activity followed by low or no activity, referred to as 'boom and bust'. Education sessions aimed to help patients recognise this pattern through analysis of their daily activities. HCPs also explained how inactivity could potentially exacerbate symptoms of fatigue using models such as the deconditioning cycle.

They helped patients to identify potential triggers for fatigue, and to consider the effect this might have on their activity levels.

007: “when I look at the deconditioning cycle with them and looking at how they need to make behavioural changes [...] and how the deconditioning can maintain their symptoms and make their physiological symptoms worse, that can be enough”

The re-attribution of beliefs about causality was useful for patients who believed PA would make their fatigue worse. This was seen as an important step in overcoming fear of activity and supporting patients to change their PA behaviour.

Some participants reported that activity analysis also required identification of different levels and types of energy expenditure.

007: “they’ll be asked to think about whether an activity is a high, medium or low energy and erm if it’s a cognitive, primarily cognitive or physically based”

Planning, pacing and prioritisation were discussed, with HCPs helping patients to plan their week and prioritise their activities so as to reduce the impact of fatigue on their daily lives. Several participants used action planning as a BCT. This included pacing activities as an effective way of preventing the boom and bust patterns identified by activity analysis.

002: “we talk about planning and pacing, erm, so I try and make them look at their week, look at their day [...] so they can plan through the week to sort of, have busy times and quieter times and if they have got a major busy thing coming up to maybe try and make them plan, you know, to have some good rest time...”

One participant emphasised that analysing activity took into consideration all activities of daily living and work activities, not just PA.

006: “... activity but also occupation, [...] in general sort of any activities throughout the day, not just ones that would make you short of breath.”

Goal setting and reviewing behaviour goals

Several participants assisted patients with identifying and setting appropriate PA goals to facilitate behaviour change. These goals were reviewed in subsequent therapy sessions.

005: “we look at, specifically, what goals did they set for themselves at the start of the programme, how have they done with those, um, and what are the, you know, what do they need to do next...”

Physical activity education

Education about PA generally included graded activity or exercise, the effects of PA and how to maintain PA in the longer term. GET was commonly used. This approach has been described in chapter 3, section 3.3.1.1. Positioning, balance and preventing falls were also mentioned as additional topics but were not commonly included.

All participants provided instruction on how to perform PA. Patients were encouraged to practice the behaviour between sessions. Where a practical component was included, behavioural rehearsal took place within the session. Participants used these techniques to encourage patients to engage in regular PA.

005: "I'm really taking them through the process of introducing exercise into their life going for regularity. It doesn't really matter too much what they do, but getting something as a, as part of a regular routine."

Participants advocated general PA, not just formal exercise. Patients were reassured that being active does not necessarily require specialist equipment or attending a gym. Generalisation of the target behaviour to any type of PA may facilitate behaviour change therefore patients were encouraged to integrate PA into their daily lives.

002: "... even going to the front door, to open the front door or getting up to go to the toilet through the day, that's, that's still doing some exercise,"

003: "So introduce to them the idea that any movement and activity can count, it doesn't have to be in the gym,"

Participants believed that some patients were not aware that PA is good for them. However, other patients were aware of the benefits but needed support and advice on how to get started and what type of PA they could do.

003: "a lot of people understand that exercise is good for them. Erm, they just struggle putting it into practice."

Type of physical activity

The type of PA varied. Participants emphasised that this should be the patients' choice. It was felt to be important that patients did something that was relevant and appealing to them.

004: "most people find [GET] easiest to do with walking, but sometimes people do it with housework, they use physical activity in the broader sense. [...] We give people the choice,"

006: "it's got to be something that appeals to them [...] for it to be done."

Although patients were encouraged to choose their activities one participant reported that there were times when exercise prescription was required.

008: "... if you're making a programme with them, a stretching programme or a strengthening programme then there is an element of prescription in that side of it because you've got to identify what exercises or what stretches would be most suitable for them"

Another participant reported encouraging aerobic activities, and others recommended stretching exercises as a gentle introduction to PA.

Frequency of physical activity

Some participants recommended that patients aimed to be physically active on a regular basis, at least on five days a week. One participant reported that exercises were to be performed three times daily.

005: "So, they're encouraged to exercise every day, the idea being that, hopefully, they'll then get at least, sort of, five days a week..."

009: "they do [prescribed exercises] three times a day, they do a daily walk,"

Intensity of PA

A small number of participants using GET reported advising patients to start from low- to moderate-intensity exercise. This was monitored using the Borg scale (Borg, 1982), enabling patients to self-monitor exertion as an outcome of PA.

006: "... talk about exercising at a moderate intensity and demonstrate that by use of the Borg Scale."

Graded activity and graded exercise therapy

Graded activity and GET were employed by several participants, particularly, but not exclusively those working in CFS services. This was reported to be evidence-based practice in this patient population. Graded tasks were an important BCT used by these participants.

The principles of GET formed an integral part of patient PA education for these programmes and was reported as three phases:

1. Establish a baseline for PA
2. Increase duration of PA
3. Increase intensity of PA.

Participants using a GET programme reported a strict systematic approach to each session.

GET aimed to increase PA without exacerbating symptoms of fatigue.

008: "it's still about trying to make sure that whatever is introduced doesn't have a negative impact on their fatigue so starting at a baseline in their activity, i.e. stabilising their normal activity and start setting a baseline of exercise that isn't going to exacerbate their fatigue."

Maintaining PA

The majority of participants reported discussing long-term PA with patients.

005: "we talk quite a bit at the end of the programme about, how are you going to maintain, you know, the improvements that you've made, and the, you know, what, what might there be out there, what could you do that would make it more fun? Can you find a group to join? Can you exercise with someone else? What might motivate you?"

Two participants mentioned links with general practitioner referral schemes and local leisure centres.

Sleep management

Education about sleep management was included in the majority of programmes and was considered an important part of therapy.

009: "the first thing I always do is talk about sleep, sleep is the most important thing to establish,"

One participant noted that addressing issues around sleep can be vital to enable some patients to attend the programme.

005: "If someone is sleeping all morning, [...], then it might be that part of their workup would be moving their getting up time back to enable them to attend the groups. So, sometimes, you know, we might see someone once or twice, um, around modifying their sleep before they start, so that they can manage to attend."

Sleep management was reported to include timing of sleep, encouraging a good routine and considering the impact of poor sleep. Participants believed that if they only looked at PA and ignored other contributing factors like sleep then they were less likely to see improvements in fatigue levels.

008: "if there are some major things that are happening you know that's contributing to the fatigue or impacting on the fatigue you can do everything within the physical activity side, but if they're only sleeping you know, if they're sleeping hideous hours, or if they're sleeping 4 hours or they're sleeping 12 or 14 hours, erm you know you're not going to make a big difference to the fatigue on its own."

Diet

One programme for CRF included a session delivered by a dietician discussing how energy levels can be influenced by diet.

002: "So we have a dietician that comes here, [...] diet is a huge part of, you know, if you don't eat well, then you're going to be tired anyway"

Modifying thoughts and feelings

Participants identified that there is an overlap with psychology when using PA for fatigue management.

007: "I think with fatigue, it's bio-psychosocial, and you have to be addressing all of those areas,"

Addressing psychosocial factors alongside PA education was considered crucial for sustained behaviour change.

008: "I mean the physical activity and the exercise side of it, on its own is really, really simple, [...] it's usually other stuff that are having an impact and if you don't address those, erm...."

INT: You can't make the changes?

008: Yeah, or well they're not sustainable, I think ... they can make short-term change but it's the long-term change, if you haven't looked at those things, you will see it come, you know 12 months' time actually because they didn't make those changes to the other things, they weren't able to sustain the exercise or the physical activity,...."

Participants suggested that several barriers to PA stemmed from patients' thoughts and fears that it would make their fatigue worse. Participants felt that this was a major issue that must be addressed.

001: "if they think "I'm going to fall, I know I'm going to fall" or, um, "I'm going to get so breathless I'm probably going to die" or "if I go for that walk and I'm not going to have enough energy to do my, err, dinner this afternoon", if they've got those which are, are blocking them, and er, however much you tell them it's the best thing for them to do, they're not going to engage with it, because they're, they've got other things that are stopping them. So you need to kind of explore those and address those."

Additional reassurance that PA was not going to cause damage was also an important aspect of education.

004: "we're trying to educate people to understand that it's not harmful."

In some instances participants felt these fears had been exacerbated by mixed messages and advice from other HCPs and from information on the internet telling patients it would make them worse and that they needed to rest.

005: *“they still have some anxieties, so they’ll say, well, I think it could be, but I am worried it’ll make me worse, because I’ve read stuff on the websites, and on the internet there’s a lot of stuff that’s very anti physical activity.”*

007: *“we hear that a lot, from other professionals, they’ve [patients] been told by other professionals to rest”*

Another perceived fear for patients related to the after-effects of PA the following day or a few days later.

008: *“ ... because of the worry that they’re going to have a set back and certainly within our CFS patients it’s not, it’s not always at that particular time when they’re doing something it’s the post-exertional fatigue two days later that is quite scary for them.”*

Psychosocial education aimed to look at these beliefs and fears and help patients overcome these obstacles.

Managing setbacks

Discussion about managing setbacks and how to manage if things did not go to plan were considered key topics by several participants. This involved identifying potential issues that might have interrupted progress with therapy, and prompting the patient to explore how they might manage this situation in the future.

007: *“if a patient comes in and they’ve had a sudden setback [...] we would look at where they are in that setback, look at setback planning and how to think about and learn from that setback.”*

This use of problem-solving was an important BCT employed by participants.

Relaxation and mindfulness

Most participants encouraged relaxation. This was either included as an education topic, or incorporated into the practical component.

009: *“... you know patients in general do not relax, people that are fatigued, think because they’re fatigued and doing nothing they’re relaxing and their body’s having down time, and it’s really not, because their mind is very wired.”*

Relaxation techniques were used alongside stretching and flexibility exercises to help patients prepare themselves for PA.

Several participants included mindfulness meditation in their programme. This was reported to be useful to reduce anxiety or depression, decrease the focus on symptoms and help minimise negative thoughts and emotions.

006: “[mindfulness] can work as a, as a rest in a way, and er, so instead of, of, of relaxation, you are focusing your mind on something and, and trying to let all the thoughts, the worrying thoughts or other thoughts that might come in, trying to let them go and focus on a ... on a simple thing which could be your breathing or, or some imagery.”

Practical sessions

Practical sessions were included in most group programmes, but not in individual therapy sessions. A number of positive aspects of doing PA within the session were identified, including providing a starting point for getting into PA, improving confidence and reducing fear of PA in a supportive environment.

008: “I think a lot can be gained by actually doing things in a session with someone that gives them an element of support and confidence”

Demonstration of PA within the practical sessions was considered a helpful BCT for improving motivation.

The type of PA included in practical sessions varied from gentle seated exercises to circuits based exercise. Some participants reported offering patients a range of exercises to choose from during this session. Many practical sessions also included a warm up and cool down, stretching and relaxation.

003: “they would do a 10 minute or so warm up, seated, and then about 40 minutes of stations of exercise around the gym and then a 5/10 minute cool”

The duration of the practical component varied (see table 5.4).

Support materials

Participants used a variety of support materials to accompany their programmes. The majority provided paper-based programme booklets or handouts, containing information covered in the sessions for patients to use as a reference.

004: “And we also give them a booklet we have here which explains it [the programme].”

Some programmes also had a manual for staff outlining the programme structure.

Activity analysis and planning was frequently supported by the use of activity diaries. These were used for self-monitoring PA.

002: *"I gave them all a sort of diary sheet so they could take it away and they could use it through the week to plan when they were going to do things"*

004: *"we get people to do an activity diary"*

Other materials included record sheets, exercise sheets to remind patients of the exercises they have done in the class and suggestions for exercise in the community.

005: *"For the exercise sessions, I give them, um, some sort of sets of diagrams of different stretches, um, lists of the circuit type exercises that they can do at home with no, or minimal equipment, ways to progress those, and the list of exercise opportunities in the community."*

A small number of participants reported providing patients with a relaxation CD to support the education topic and to encourage them to explore the topic further in their own time.

Some participants reported using a presentation when delivering the education sessions.

001: *"I do have a PowerPoint to try to keep me on track because otherwise [laughter] I can get a bit waylaid,"*

The majority of programmes included some form of homework, such as small tasks or goals to work on between sessions.

004: *"... and they've got homework, so they take stuff home, they've got some handouts, so the handout will talk about relaxation or something, and they go home, they practice it. You know, if it's about goal setting, they'll go home, choose some goals."*

5.5.2 Theme 2: Implementation

5.5.2.1 Delivery

This subtheme describes how programmes were accessed and delivered including referral and assessment process, location and setting, time of day and professional and staffing considerations. The theme is closely linked to theme 1, as it demonstrates how programme mechanics are implemented.

Accessing the programme

Access to programmes was via referral from either a member of the MDT, for example a therapist or clinical nurse specialist, from the general practitioner or from the medical consultant. None of the programmes accepted self-referrals from patients.

001: *"it's generally the nurses that will refer.... Or we might refer as physios."*

005: *"So, [general practitioner] referrals, um, and also consultant referrals"*

Assessment for eligibility for programmes ranged from minimal criteria with no assessment to detailed individual assessments.

001: *"they don't get assessed prior to coming to the group"*

002: *"the referral criteria is that it's for anybody that's got, that says that they are fatigued or breathless"*

004: *"we have a very detailed assessment, it takes about an hour and a half,"*

Some entry assessments examined patients' locus of control and readiness for change:

005: *"... in a short telephone appointment, it's more just sort of looking at, um, you know, sort of, how they view their condition and whether they're looking for someone else to cure them, or whether they think they're ready to start doing something about it themselves."*

007: *"... we ask the question do you have any concerns about making changes, and we look at sort of any psychological barriers or any thought processes that may impact on their readiness for change or fear, or worrying or anxiety or catastrophising at that stage."*

The assessment might inform the direction of therapy.

008: *"the therapy assessment with that, with the patient [...] determines whether they go to graded exercise or CBT."*

Most group programmes had closed entry points, although two were rolling programmes where patients could join at any time. The closed entry group programmes were run either at regular intervals or according to demand.

006: *"They run erm, as often as, you know, as, as they fill up essentially."*

Location and timing

Programmes were delivered in a hospital or clinic setting. This presented various access challenges for patients in relation to transport and travel arrangements. Some services had good hospital transport and parking facilities, but other participants believed that travelling to sessions was difficult for some patients, particularly given the level of fatigue that they were experiencing.

001: *"Transport and those sorts of practicalities are always difficult for, for quite a disabled population..."*

Two participants indicated that they would like see patients outside of a hospital setting for their therapy.

004: *“that’s our kind of ideal, is to take people out of the medical place, go somewhere where we can actually take people to do their activity.”*

007: *“I miss going into people’s homes and with the more severe people [...] being able to actually do some practical stuff with them at home”*

Conversely, another participant suggested that some patients liked the hospital environment.

009: *“patients loved coming into hospital or a treatment centre because it validates their condition again, it makes them feel important, and also gets them away from the home”*

The physical environment was particularly important if the programme incorporated a practical session, as this required adequate space and facilities.

005: *“setting is important. It, it would not be impossible, but it would be quite difficult if you’ve really only got a small room that’s geared up to people sitting.”*

006: *“Erm, if we’re thinking about the physical activity component, clearly if you see our room here, it’s quite limited what we can do in that there isn’t a lot of space and not room for equipment really.”*

Despite these challenges, it was acknowledged that being able to make the most of what was available was important.

008: *“... certainly I can deliver this [...] in the clinic room with a plinth is all I’ve got [sic]”*

Another issue closely linked to location and access was the time of day that sessions were held. This was believed to be especially pertinent for fatigued patients.

002: *“... patients they can’t get here for 10 o’clock in the morning. Getting here for 12 o’clock, when they do get here, is an effort. Some of them have been up since 6 getting themselves ready because they’re so tired [...] but if we did it in the afternoon they’d be too tired again so we’ve got this real [sic] small window.”*

006: *“... Erm, the getting up and going in the morning, as with many long-term conditions, can be a challenge so we wouldn’t have wanted to do one that started early in the morning.”*

The chosen time of day was also influenced by term-time dates, working hours and staffing availability. Location and timing were noted as key factors to consider when setting up new programmes.

Who should deliver the programme?

Various members of the MDT delivered the group programmes, including HCPs from different professional backgrounds. In general, physiotherapists delivered the practical component, whilst other therapists, such as a psychologist or OT, delivered the education topics. One group programme had a different clinician presenting each of the six sessions.

Individual programmes were usually uni-disciplinary. These participants had access to support from local clinicians.

007: "I'm a lone OT, so I go to another hospital I go to [...] where I meet with other OTs from [place] to discuss caseloads and patients etc."

When asked whether any professional could deliver a PA intervention for fatigue management, many participants felt that specialist knowledge and skills would be required. Several participants believed that different professionals should deliver their own specialist topics where possible. For example, one physiotherapist suggested that although any professional could probably deliver PA, physiotherapists were best placed to deliver GET:

004: "I know that physios are teaching psychologists to do graded exercise now. I think it also depends on whether the person has an interest or not. We have also exercise therapists – you know, sports science people – I think it depends really on the person. I think you can – anyone could do it – but I think the physios are best placed."

Other participants also felt that different professions might struggle to deliver the programme.

005: "I think it would be difficult for either a psychologist or an OT to confidently run a graded exercise session."

007: "So at a very basic level yes, probably a clinical nurse specialist could do it with support on a very, very general basis erm ... but the client group that we work with are complex so I would say no."

It was believed that post-graduate professional clinical experience was important for programme delivery. Although some participants acknowledged that therapy assistants could deliver the exercise component, one was unsure whether an assistant would have a high enough level of understanding to cope with the complexity of the patient population:

001: "These patients have got a high level of understanding of their disease, and to have somebody who doesn't have a high level of understanding of that particular area can really put you on the spot a little bit so if it, especially if there's an educational element I think that it does need to be a professional who's delivering it"

One participant felt that anyone could deliver the programme, as long as their training and educational needs specific to the client population were adequately addressed. This participant favoured a generic approach and development of a wider skill set to ensure that clients were treated holistically:

003: "it's a real decision to decide do you stay just very much within the boundaries of your profession or do you become more generic, become, get a wider skills base for the sake of the patient population that you're serving, erm, and I would probably favour the latter and say particularly in palliative care, that it's so, it needs to be so holistic,..."

Previous clinical experience

All participants in the study were senior HCPs with at least 11 years' experience (table 5.1). Most reported previous clinical experience in rehabilitation of people with long-term conditions, including pulmonary rehabilitation, chronic pain and elderly care rehabilitation.

One participant was a district nurse prior to getting involved in rehabilitation and fatigue management. She identified herself more as a therapist than a nurse, although she did not define how these roles differed.

009: "I started off as a District Nurse [...] and I got the job for the [programme name] that's what started me off [...] and then I've now become a therapist in the latter part, rather than a nurse if you like."

The majority of participants felt that programme delivery by a credible source such as HCPs with specialist experience was helpful for encouraging behaviour change.

005: "I think they gain confidence from thinking that you're somebody who's an expert."

Knowledge and skills

Knowledge and skills requirements for delivering the PA interventions were perceived as needing to be based on a sound understanding of the client population and knowledge about exercise, fatigue and psychosocial needs.

003: "...if your background was just in physical activity, I think there'd need to be some increased knowledge and understanding, erm, I guess knowledge base around what fatigue is, erm, that the, erm, kind of the side effects of living with a chronic or terminal illness. I guess if your background was just the clinical side of dealing with fatigue and not physical activity, your education, your knowledge needs would be around erm, how much to push someone physically, erm, what's a good combination of exercises to be doing..."

008: "the principles of [the programme] are very straightforward but the problem is that the patients are often more complex [...] so it's having an understanding not only of the physiological aspect of physical activity but you've also got an understanding of the psychological and you know the

biomedical aspects as well so I think that's where the complexity comes with it."

An appreciation of the complexity of fatigue was considered a necessity and was identified as an area for specific training by some participants.

003: "make sure that he's [generic therapy assistant] up to scratch with, for example, you know, what fatigue and what that could mean and the potential, if you push someone too much what would happen, rather than in a healthy population, if you push someone they might feel tired for a day or two then bounce back."

Other areas for training and skill development depended on the person's background. CBT techniques and approaches were reported to be employed by many participants. Some felt CBT skills training was essential for effective programme delivery.

009: "With the training, yeah, there's got to be an element of some sort of CBT training though, I think that's essential,"

Motivational interviewing was also considered a useful additional skill.

Not all participants delivering GET had received specific training.

004: "so there wasn't a specific training on graded exercise therapy."

Supervision

Most participants received clinical supervision and/or peer support to help them develop skills for running the programme. This was a helpful opportunity to discuss individual cases, problem solve and improve clinical decision-making.

003: "it's good to take stock and just to talk through individual cases, because they'll always be individuals for whom it might not be particularly working and you just need to make a clinical decision, erm, should they continue, should they stop, erm, should we get them doing one-to-one. Yeah so I think it's good to have the opportunity, if possible, just to discuss cases and discuss with other colleagues"

Several participants felt that specific psychology supervision was very beneficial.

009: "I think psychological supervision of some sort [...] They're good at being able to unpick all that stuff, the physical side I could do in my sleep, but the psychology sometimes, not too bad now, but sometimes I get worried, you know I think, and you talk to someone and they say yeah, you're right to be worried, they need to be referred on"

5.5.2.2 Methods of behaviour change

Deductive analysis identified a range of BCTs used by participants in their programmes (table 5.3). Many of these have been discussed throughout the previous themes. This subtheme describes suggestions for supporting patients with behaviour change, such as helping patients to engage with the programme and PA, using feedback and behavioural monitoring, addressing concerns with motivation and recognising psychological issues.

Supporting engagement with the programme

Educating patients about the value of PA and exercise was considered a key factor for helping patients engage. This is linked to physical education content presented in section 5.5.1.2. Ensuring that patients bought in to the programme and its principles before starting therapy further enhanced engagement. It was deemed crucial that patients believed in the programme and that it was their decision to engage.

009: "... you have to pick something with the patient to get them to believe in the programme and then they run it themselves because then they've got something invested in it."

Taking care to link goals and activities to patients' values further enhanced this engagement.

006: "it's very much around goal setting and, and erm, practical strategies, things that are linked with their values in life so that they see the point of doing it because otherwise we know that we can do a nice six week exercise programme and there's absolutely no carry on afterwards."

Some participants felt that engagement was about empowerment and that this should be supported by giving patients positive messages that they will improve.

001: "I think that, unless you give them that hope that this is going to change, this is going to make a difference, um, then it's quite difficult to buy in to."

Feedback and monitoring

A small number of participants reported providing feedback regarding PA performance. This either took the form of biofeedback, such as pedometers to measure step-count

006: "we've also got pedometers, erm, which we can give out"

or encouraging self-monitoring of the behaviour or verbal feedback and reflection from the HCP to reassure patients of their capability.

001: *“So, we’re just kind of introducing “how do you feel after that? Actually you managed to do it, you thought you couldn’t exercise but you managed to do something” and a little bit of reflection,”*

Patients were also prompted to monitor their PA through the use of activity diaries, (see section 5.5.1.2). Although this was a useful and popular BCT, one participant acknowledged that not everyone liked self-monitoring:

004: *“Some people do print-outs and, you know, sort of, like OCD, you know, gone mad, you know, of every amount of steps they use pedometers, and their ... So, whatever somebody likes. If somebody likes that kind of approach, I’ll go with it. Some people say, I just don’t like recording things ...”*

Motivational interviewing techniques

Some participants suggested that motivational interviewing could be a useful tool to improve motivation and engagement with PA.

004: *“I think doing some more motivational interviewing, that would be helpful.”*

It was also reported that motivational interviewing was helpful to address readiness for change before individuals attended the group (see section 5.5.2.1)

Recognition of psychological issues

Participants emphasised that PA programmes for managing fatigue overlapped with psychology.

007: *“...in facilitating those patients that are unable to shift because of the catastrophising or the worry or the anxiety or the symptom focussing [...], you have to run the psychology and the physical in parallel.”*

Participants felt that with appropriate training, such as CBT skills, they were able to address simple psychosocial issues. However, for some patients who found it difficult to engage, referral for specialist psychological therapy was required.

007: *“I’ve done psychology training, [...], you know just to look at how to address individuals that are stuck and how they’re not able to move forward [...] Erm if an individual early in therapy is at that point, it may be that we discuss moving them to cognitive behavioural therapy to look at addressing those issues”*

Mode of information delivery

Information delivery was reported to be interactive. Several participants emphasised that they tried to avoid telling patients what to do so that they could find their own solutions. Most participants reported trying not to be too prescriptive.

005: “we’re not telling them they need to do it, we’re hoping that they’ve made that judgement themselves.”

006: “absolutely avoiding the, the raised finger, ‘Oh you must, you really should do, this is ... this is what the evidence says’,”

This suggests that most participants were aware that they should avoid didactic information giving when facilitating self-management and behaviour change. However, a small numbers of participants believed that some information must be presented in a more didactic format.

001: “there are some things that I just do need to tell them. There is some information that I just need to get across, that will, I know will help them.”

5.5.3 Theme 3: Theoretical approach

This theme explores the underpinning theory of the programmes, as understood by participants. Some participants were unable to relate to the concept of a theoretical basis but instead reported that the programme was developed using current available evidence for exercise and fatigue in their client group. Several participants working with CFS patients made reference to the FINE and PACE trials (Wearden *et al*, 2010, White *et al*, 2011).

5.5.3.1 Theory of behaviour change

The majority of participants were unsure of the specific theoretical approach for their programme, with some not aware of any theory:

INT: “[is there a] theoretical basis underpinning the programme? [...]”
001: “No, I.... not that I know of. Don’t know.”

Others were uncertain, but identified CBT as the named approach. However, an explanation of what this meant to participants and how CBT might work in practice was not clearly established:

008: “No I wouldn’t know of a term, apart from the cognitive behavioural approach, [...], effectively we are looking at a behavioural cognitive restructuring...”

One participant mentioned a self-efficacy outcome measure, but SCT was not specified.

5.5.3.2 Theory of causal mechanisms of fatigue

Most participants working with CFS patients reported using models and analogies to explain the causal relationship between PA and fatigue to patients, for example, the

deconditioning model, rather than a theory of behaviour change. This suggested a bio-medical rather than bio-psychosocial approach. One participant working in CFS felt that this model provided an inadequate explanation for fatigue.

004: "we always say that [deconditioning model] to people, but actually some people are already doing quite a lot of activity, so it doesn't make sense."

5.5.4 Theme 4: Intervention outcome

Intervention outcomes, such as attendance rates, perceived fatigue and PA outcomes, outcome measurement and programme evaluation are presented in this theme.

5.5.4.1 Attendance

Programmes were generally perceived to be well received by patients, and participants reported good attendance.

006: "[...] we've had a couple of drop-outs but by and large people are very committed."

Some participants acknowledged that the high attendance rate was due to self-selection of patients prior to agreeing to attend, as those who agreed to join the programme were aware that it involved PA.

008: "by the time they come to us they've already chosen to engage in physical or look at physical activity or exercise as part of their rehab."

On the occasions when patients did drop out of the programme there was usually a good reason, such as illness, hospital appointments or bereavement.

002: "... people have hospital appointments, they have other things through the week or they've become less well"

One participant noted that, at times, patients find it difficult to engage with the programme or have negative views of PA, which might also result in them dropping out.

004: "I think I've had a couple of [...]. people who've come, and they're very anti [PA], and they don't usually stay for long."

Another reported that with pragmatic rehabilitation some drop out because they find it too structured.

009: "Usually [people drop out] because the programme is too rigorous, as in it's too structured"

5.5.4.2 Perceived outcome

All participants believed that overall, patients experienced positive improvements in their fatigue from attending the programmes. This might be through improved PA, improved mood or generally feeling more in control of their fatigue symptoms.

Several positive effects of PA on reported fatigue were noted.

001: "it helps them on an immediate level, to engage with the programme and to feel a bit more awake and to feel a bit more alive"

003: "what I see happening is people just changing that pattern of feeling tired from doing nothing and actually begin to feel positively tired, but also begin to get a bit more energy."

Beyond fatigue, improvements in PA and general physical well-being included less fear, physical improvements, increased confidence and better engagement with exercise.

001: "the fear of exercise is, has gone."

005: "I think it can give enormous confidence to feel, actually, that you can start to go from this place to this place, rather than being contained and controlled by your condition"

Activity levels were also thought to improve, although fitness may not have changed significantly.

005: "They're obviously not particularly fit and active, but I think what they do, get them a lot more active, just in the time that they're with us ..."

Improvements in psychological well-being were reported. Participants proposed that this could be due to an increased sense of purpose, or an overall psychological shift in patients' thoughts and beliefs about exercise.

003: "it becomes really down to quality of life and holistic, erm, really filling someone's day with meaning and purpose and doing things that they choose to do ..."

005: "... I don't think it matters too much if they're not continuing to exercise regularly every day, it's more about them being prepared to attempt something physical, which they might not have done in the past."

Additional benefits of the programmes included improved self-management and coping skills, allowing patients to feel more in control of their fatigue.

007: "people come in and they, they're controlled by the fatigue and it's, it's giving them something to do, you know something that they can, rather than just talking about how the fatigue is, they can actually go away, take a skill with them and feel that this is going to help me..."

Subjective reports received by participants suggest that patients felt much better at the end of the programme, with some finding it a life changing experience.

003: *“subjectively they continue to report feeling good for coming, and feeling good for coming to the gym and exercising...”*

004: *“Patients say, it’s amazing, it’s changed my life.”*

5.5.4.3 Perceived barriers to good outcome

Although programmes were felt to be beneficial overall, they were not without their challenges. One participant acknowledged that a lot of people find it hard to stick to the programme.

004: *“if you can stick to it, which a lot of people can’t, I think it works incredibly well, but it’s not easy for everybody to stick to.”*

Another participant felt that those who had experienced symptoms for longer struggled more,

007: *“you look at who improves and who don’t [sic], [...] individuals that have had fatigue for a lot longer period of time are more challenged, erm their maladaptive coping mechanisms are more engrained,”*

although increased severity of symptoms was thought to be associated with better outcome.

009: *“the people that have the worst levels of fatigue show the most improvement usually.”*

A common challenge was that other life factors could get in the way, for example, caring for children, making it difficult to sustain behaviour change.

007: *“individuals sadly that have young children are challenged because they don’t have much control over their environment.”*

Despite these challenges participants reported that very few patients said they felt worse afterwards.

008: *“I think there would only be a small minority that are in the much worse it would be well under 10% or 5% that would say that they’re a little worse, or even worse than that.”*

5.5.4.4 Long-term physical activity outcome

Participants were unaware of the long-term changes in PA levels following the programmes, as these were often not measured.

001: *“on a, a long-term level we haven’t actually measured, so we don’t know for sure if they’re starting to exercise more”*

5.5.4.5 Outcome measurement and programme evaluation

A variety of outcome measures were identified (table 5.5). Participants working with CFS patients used National Outcomes Database measures with all their patients. Several participants reported that they intended to measure fatigue and quality of life outcomes. The majority of participants also identified a physical outcome measure, although these were mostly for physical function rather than PA levels.

One participant included EQ-5D. They did not specify the three or five level version.

006: "...after much deliberation, EQ5D although we're not sure that it'll be sensitive to our intervention but we feel erm, we ought to for commissioning purposes where it's widely used"

Another participant reported an awareness of the financial cost of delivering some programmes. They commented that one of the biggest challenges to delivery was justifying the economics of a 12 to 14 week programme.

007: "... we could do with more sessions to be funded, certainly with the people that are more moderate in [fatigue] category, it may take up to session 8 or 9 to get on board, so that's not for everyone, so from an economical point of view."

Table 5.5: Outcome measures named by participants

Fatigue and quality of life measures	Physical function measures	Other
Chalder fatigue questionnaire*	SF36 physical functioning	SPIN (pre-programme)
HADS*	Sit to stand	Self-efficacy scale (name not recalled)
VAS pain*	6 minute walk	
CGI*	Static bike test (pre-programme)	
FACIT-F	Timed up and go	
QoL scale (name not recalled)	Functional reach	
EQ-5D	20 step test (reportedly from FINE trial)	

*CGI=Clinical Global Impression Score; EQ-5D=EuroQol-5 dimensions health outcome measure; FACIT-F=Functional Assessment of Chronic-Illness Treatment – Fatigue; FINE=Fatigue Intervention by Nurses Evaluation (Wearden et al, 2010); HADS=Hospital Anxiety and Depression Scale; QoL=quality of life; SF36=Short Form 36 Health Survey; SPIN=Social Phobia Inventory; VAS=Visual Analogue Scale; *=measure included in the Chronic Fatigue Syndrome national outcomes database*

One participant reported improvements in physical and fatigue outcomes following the programme.

005: "... there are significant, um, results on there [20 step test], so, yeah, that's good to have that, because it's useful to have at least one physical measure, I think, because otherwise everything else is self-report."

INT: "do they [fatigue measures] improve?"

005: "Yes, [...] But it does that thing where you get quite a lot of improvement post group, and then it just drops a little bit, but it doesn't drop anywhere back down near to the, um, the, the pre levels..."

Those using patient satisfaction surveys reported a good response. However, some felt patients were too polite and only provided positive feedback, making it challenging to make appropriate improvements to the programme.

002: "actually everyone was all so nice and positive about it, it was, they didn't want to upset anyone so they all filled it in, it was all lovely, or they didn't fill it in at all, so it actually didn't tell us anything, so we're still looking at how we can re-evaluate that."

The majority of participants reported difficulty with measuring outcome.

008: "[measuring physical outcomes] it's one of the areas that we unfortunately don't... I think is a bit of a weakness for us,"

They highlighted various issues relating to outcome measurement.

004: "we've always said our measures aren't very specific, and we needed to have some better measures really."

003: "it's harder to make it a priority with people because it feels, it can feel quite burdensome giving people questionnaires,"

008: "we don't tend to do a walk test regularly and the reason for that is location, erm in our clinic, we just don't have access to a gym"

Participants recognised this as an area for improvement.

001: "the issue continually comes up we need to be looking at outcome measures, we need to be measuring that this is making a difference, [...] we really, we really struggle to find a way of measuring it accurately,"

5.6 Discussion

This study explored the experiences and opinions of nine female HCPs each with over ten years' clinical experience. All participants were delivering PA interventions for fatigue management programmes in CFS, fatigue syndromes or cancer. Four themes were derived from the data, with several subthemes. These are illustrated in figure 5.1.

Structural elements of PA interventions varied between programmes (theme 1). Participants described a variety of formats for their PA interventions. Programmes were delivered as groups or individually, with considerable variation in total programme length, the number, frequency and duration of sessions and session structure. The lack of consistency in these parameters is unsurprising given the variable evidence-base for these programmes, identified in chapter 3. Group interventions described by participants tended to be shorter with more frequent sessions than individual programmes. However, the length of group sessions was often more than double that of individual sessions (120 versus 50 minutes). This was explained by the inclusion of a practical element in group programmes.

Participants identified several advantages to a group format, such as sharing experiences, vicarious learning and inclusion of a practical component that affords patients an opportunity to try PA in a safe environment. These findings are supported by previous qualitative research that noted that RA patients attending a CBT-based RA fatigue management programme valued sharing experiences and ideas for coping (Dures *et al*, 2012). The benefits of group interventions in relation to patient learning and behaviour change are advocated by SCT (Bandura, 1998). Participants delivering group interventions also identified practical advantages such as managing waiting lists. Despite these advantages, some participants made an important point that not every person will be willing or able to attend a group programme. Organisational flexibility was required to ensure individual options for treatment are available to those for whom group therapy is not suitable. Pre-intervention assessments described by some participants might be useful for identifying those individuals who would benefit from one-to-one therapy. Equally, care must be taken to ensure that group programmes are tailored to meet individual needs. This was recognised as a challenge for group delivery. The cost-effectiveness of interventions is also important to consider in the current commissioning climate. Unfortunately, few data are available regarding cost-effectiveness of PA interventions for managing fatigue in long-term conditions, as discussed in chapter 3, making it difficult for HCPs to make informed decisions regarding costs for service delivery.

Differences in format between programmes for CFS and CRF were evident, implying that interventions may need to be adjusted to meet the specific needs of each patient population. Variations between programmes included more focus on individual therapy in CFS programmes, with a strong educational element, whereas CRF programmes described in this study were delivered in groups often with a strong focus on practical PA. Some HCPs working in CFS services suggested that evidence for group programmes was weak for this patient population. However, this may reflect a lack of research investigating group programmes. None of the five GET studies included in a review of CBT and GET for CFS investigated group delivery (Castell, Kazantzis and Moss-Morris, 2011). Variation and lack of consistency in programme format in current clinical practice, both between and within long-term conditions, justifies the need to develop a specific programme for RA rather than simply delivering an existing programme.

Participants working with CFS patients made reference to PACE (White *et al*, 2011) and FINE (Wearden *et al*, 2010) trials as the basis of their programmes. These give guidelines regarding the number and frequency of sessions, with PACE recommending 15 sessions spread over nine months. Those participants offering individual sessions mostly followed these suggestions. However, two participants describing group sessions for CFS held weekly sessions over 10 weeks. There may be pragmatic reasons for adapting programmes for clinical practice, and participants emphasised the need for organisational flexibility when implementing such interventions. This adaptation for clinical practice may be viewed as an indication of evidence-based practice and practice-based evidence, where HCPs are combining their clinical expertise with the best available published evidence to achieve the best outcomes for patients (Sackett *et al*, 1996). However, there was no evidence that patients were involved in adapting the interventions. Therefore it is not known whether they matched patient preferences.

Provision of follow-up sessions for programmes was inconsistent. The effectiveness of follow-up is unknown and has previously been highlighted as an area for further investigation for self-management interventions in rheumatic diseases (Iversen, Hammond and Betteridge, 2010). Participants suggested that alternative modes of delivery, such as telephone follow-up could be considered, but evidence for optimal delivery is currently lacking.

Programme content was also varied, although several participants emphasised that only addressing PA was not enough to improve fatigue. Consequently, they advocated the inclusion of education topics related to both physical and psychosocial aspects of fatigue and PA. Participants reported that content was tailored as much as possible to individual patients to ensure that barriers to PA were addressed. As well as educating patients about

the benefits of PA, and how to make changes to activity levels, several programmes addressed fears and beliefs about exercise, problems with stress and disrupted sleep patterns. Negative beliefs, fear and uncertainty regarding PA are also barriers for people with RA (Law *et al*, 2010, Lee *et al*, 2012, Wang *et al*, 2014), supporting inclusion of these topics in a PA intervention for RA fatigue. Similarly, the inclusion of strategies for coping with sleep disturbance has been recommended following research investigating the role of discomfort and adequacy of sleep in RA fatigue (Goodchild *et al*, 2010).

A graded approach to PA was strongly advocated for managing fatigue in an attempt to avoid exacerbation of symptoms and minimise reinforcement of negative beliefs about the consequences of PA. This was predominantly used in CFS programmes, which was unsurprising given the focus of research in this area (chapter 3). This approach may also be useful in RA fatigue management, as fear of worsening fatigue symptoms is reported as a barrier to PA in RA (Wang *et al*, 2014). In light of potential fluctuations in symptoms, some participants emphasised the importance of discussing strategies for managing setbacks to ensure continued engagement with PA.

The inclusion of a practical element in group programmes was believed to be useful to allow patients to practice PA in a safe environment. Participants perceived increases in confidence with PA. Practical sessions allowed demonstration of specific exercises and feedback on performance to reassure patients that they were doing the right thing. Over half (57%) of participants (n=247) in a survey of RA patients' perceptions of issues regarding exercise and joint health expressed lack of confidence with performing PA (Law *et al*, 2013). Therefore the opportunity for practical rehearsal of PA within an RA fatigue management programme may be useful.

Programme content was frequently accompanied by support materials such as paper-based handouts and record sheets. The inclusion of activity diaries to support activity monitoring and action planning was considered valuable. Activity diaries have also been reported as a valuable self-monitoring tool in a CBT fatigue management programme for RA (Dures *et al*, 2012), suggesting that these might be useful to include for a PA intervention for RA fatigue. One service provided pedometers to support self-monitoring of PA. This might be a useful adjunct to an intervention. Pedometer-based interventions have significantly increased step-counts in adults with low activity levels (Baker *et al*, 2008), with step-counts maintained over 12 months (Fitzsimons *et al*, 2012).

Theme 2 highlighted a number of factors that might influence implementation of PA interventions in clinical practice. Programme delivery was variable. Many participants reported that they had developed their programmes according to available research evidence. However, much of the literature is inconsistent with no clear guidance as to the

exact number, length or frequency of sessions (see chapter 3). Clinicians are left to make pragmatic decisions about how to implement interventions in practice, taking into account resource issues such as staffing, including knowledge and understanding of concepts, room availability and administrative support.

Participants remarked that location and timing of sessions presented a challenge for fatigued patients who may be required to travel some distance to attend sessions. Travel and time constraints have previously been reported as barriers to participation in PA trials for RA (de Jong *et al*, 2004a, Vervloesem *et al*, 2012, Nordgren *et al*, 2014), and this is likely to be true for clinical practice. The location is also an important consideration for implementation, as it may affect the success of the intervention. Involving service users in intervention design may help to minimise these issues in future interventions (MRC, 2008). Participants did not provide any evidence of patient involvement in the design or implementation of the services in this study. It was highlighted that fatigued patients struggled to attend morning sessions, with implications for the time of day that sessions were offered. This is likely to be the case in RA, as symptoms are reported to be worse in the morning (Sierakowski and Cutolo, 2011).

Conflicting opinions were expressed regarding who should deliver PA interventions. Perceived issues regarding professional boundaries were apparent, with some participants seemingly unable to recognise the potential for cross-professional training and delivery. Some physiotherapists believed they were best placed to deliver GET, although not all had received specific training in this approach. Given that HCPs working in rheumatology, including physiotherapists, have expressed a need for further training in providing PA advice (Hurkmans *et al*, 2011), it is possible specific training would be required for RA clinicians. Physiotherapists in this study believed that with additional training they might be able to address psychological aspects of fatigue, yet did not appear to consider that a psychologist could be trained to deliver GET. Perceived protection of professional boundaries was not unique to physiotherapists, with participants from other professions also expressing concerns regarding the ability of different HCPs to deliver these interventions. The requirement for specialist staffing to deliver interventions has potential cost implications that may inhibit implementation in clinical practice. However, not all participants expressed these views. Some supported delivery by any person who had received appropriate training, including technical instructors. All participants agreed that anyone delivering the programme must have a detailed knowledge of the patient population and a thorough understanding of fatigue and PA. Importantly, access to supervision from within a specialist field, such as psychology, was considered invaluable by those HCPs utilising skills outside their traditional professional scope of practice.

Regardless of professional background, all participants recognised that telling patients to change their behaviour is not enough. Patient choice and decision-making were considered crucial for a successful outcome, particularly in the longer term. When deciding what type of PA to target, participants also advocated patient choice. Participation in an enjoyable activity has been demonstrated as consistently more predictive of intention to be active than an activity that is perceived as beneficial, as demonstrated in a TPB-based intervention to promote PA in adults at risk of type 2 diabetes (Hardeman *et al*, 2011). Although participants reported trying not to be prescriptive when delivering the programmes it is unclear from these data whether this was the case in reality. The use of PowerPoint presentations and information-giving by some may reflect a didactic approach.

Some participants recommended motivational interviewing as a useful skill for therapists delivering PA interventions. However, while they recognised that motivation is important it was unclear what strategies were employed to address this in the current programmes. Deductive analysis revealed that participants were using a number of BCTs to elicit behaviour change, even if they did not explicitly describe them. There were some commonalities between programmes in this study in terms of identified BCTs, with all participants providing instruction on PA and encouraging practice within or between sessions or both. All programmes were delivered by specialist clinicians. This was coded as a credible source, according to the BCT taxonomy definition of a health professional with expertise in their field (Michie *et al*, 2013). Beyond these dominant BCTs, there was inconsistency in application of the other methods identified and they were not firmly embedded in the programmes. BCTs appeared to be employed according to personal preference rather than a consistent approach underpinning the programme. Therefore their use may have arisen from tacit knowledge rather than specific training. The dominance of techniques relating to instruction and demonstration of PA may not be surprising given the perceived expertise of physiotherapy participants in exercise delivery rather than psychosocial approaches. It may be that BCTs are not acknowledged as specific techniques and therefore there is no evidence of their systematic application in clinical practice.

A systematic review of PA interventions in healthy adults suggested that the most effective components of successful PA interventions were self-monitoring and self-regulatory BCTs (Michie *et al*, 2009a). These included intention formation (action planning), goal setting, problem-solving and review of behavioural goals. Recent evidence also supports the inclusion of self-monitoring and intention formation techniques for

walking programmes in healthy adults (Bird *et al*, 2013). Although these BCTs were identified in this study, they were not used by all participants (table 5.3).

The lack of a systematic behavioural approach may have arisen from poor awareness of an underpinning theory, as demonstrated in theme 3. The absence of a sound theoretical basis may also contribute to the difficulty participants experienced with outcome measurement, as the theoretical approach will impact on choice of content, methods of behaviour change and potential outcome, as illustrated in figure 5.1.

Participants using GET identified PACE (White *et al*, 2011) and FINE (Wearden *et al*, 2010) trials as the basis for their programmes. Pragmatic rehabilitation used in the FINE trial is based on the theory that fear avoidance and chaotic sleep are perpetuated by inaccurate illness beliefs. However no specific behaviour change theory is evident. Similarly, White and colleagues (2011) report that the GET programme was based on deconditioning and exercise intolerance theories of CFS. These are theories of causality rather than a behavioural approach. Whilst the deconditioning model might help to explain how PA levels might mediate fatigue, it does not account for psychosocial issues that participants reported to be crucial to address in order to improve both PA and fatigue. Similarly, specific components of behaviour that might need to be considered to support PA behavioural change are not identified.

Findings suggest that some programmes may be based on CBT (Sage *et al*, 2008). This theory is more likely to explain how interventions might change PA behaviour. However, participants appeared to have difficulty articulating what they understood by CBT, what specific CBT techniques were used or how CBT worked in clinical practice. It is not possible to deduce from the current study whether CBT in these fatigue management programmes was being used primarily to explore and address psychosocial issues around fatigue symptoms, or to elicit a change in PA behaviour. It may have been used to influence both these outcomes, but this cannot be assumed from these data.

Theme 4 demonstrates that participants perceived considerable improvements in patient-reported fatigue following the programmes, including benefits beyond fatigue. This has also been seen following a CBT intervention for managing RA fatigue (Dures *et al*, 2012). However, objective data regarding attendance and outcomes were inconsistently measured. This was a common challenge for all participants. They acknowledged that improved programme evaluation and collection of measurable outcome data would offer support to their clinical judgement and evidence of good practice. This is particularly important for future commissioning of services. It may be that time and resource pressures make it difficult to prioritise outcome measurement, especially if patients are required to fill out lengthy questionnaires and HCPs need time and expertise to analyse

and interpret the data. Most participants attempted to collect fatigue outcome data. However, the absence of a consistent PA outcome measure meant that participants were not aware of the effect of the intervention on PA levels and PA-related cognitions. If interventions are attempting to address these cognitions, such as barriers and beliefs regarding PA it is important that these are measured (Larkin, Kennedy and Gallagher, 2015).

It was recognised that patients attending the programmes self-selected to take part in a PA intervention, suggesting a more motivated patient group. This is a common phenomenon for PA interventions and has been discussed in detail in chapter 2. It is important to recognise that these interventions are unlikely to appeal to everybody. It is possible that those who could benefit most, for example the most fatigued or most inactive, will not want to attend. However, it could be argued that this does not matter as patients have the right to make informed choices. So long as they are offered full and appropriate information they will be able to decide whether they wish to proceed with this type of therapy. It may in fact be counter-productive to include participants who are not ready to make changes to their PA. This was recognised by one service and hence readiness for change was assessed prior to enrolling on the programme. This might help to prevent disengagement with the intervention and avoid poor outcome.

5.6.1 Strengths and limitations

Use of qualitative interviews allowed the candidate to gain insight into the individual experiences of participants delivering PA interventions in clinical practice. This enabled a more in-depth exploration of the issues and challenges than would have been gained by quantitative methods. Although only nine participants were interviewed the sample was recruited from a range of fatigue services across England, therefore accessing different clinical experiences and ways of working.

Another strength was the use of a BCT taxonomy as a deductive framework to supplement the inductive thematic analysis. In the absence of underpinning behaviour change theory the taxonomy helped to identify recognised behaviour change strategies that might be useful for managing fatigue in RA.

Only those HCPs who were using PA for fatigue management were included in the study. This meant that the views of those who do not use PA, perhaps because they do not feel it is useful or appropriate for managing fatigue, were not explored. As a result the data presented in this account offer a biased view of this intervention.

Other limitations relate to the candidate's inexperience with interviewing. Occasional use of leading questions may have biased responses from participants. For example, asking whether there are benefits of PA for fatigue might initiate a positive response.

Instead a neutral question, such as what are the consequences of PA for fatigue might elicit a more balanced answer. Additionally, the use of prompts and further questioning to produce more detailed responses would have been useful at times. For example, further questioning about how CBT was applied in practice, including more specific techniques, and whether it was used for general fatigue management, or to address PA behaviours might have been useful.

5.7 Conclusions

This qualitative exploration of HCPs experiences identified a variety of approaches to providing PA interventions for fatigue management in long-term conditions, including both group and individual programmes of variable length. All programmes were delivered face-to-face but large differences in the number, frequency and duration of sessions were described. Although the structure and content of programmes varied, key findings included the use of GET and a need to address psychosocial and motivation issues relating to PA and fatigue. Several BCTs were identified and cognitive behavioural approaches were suggested but these were not firmly embedded within existing programmes. This may be explained by the absence of underpinning theoretical approaches to behaviour change.

This study highlighted potential challenges to implementing and delivering services, including accessing a suitable location to deliver practical PA, meeting training needs of staff, evaluating programmes and measuring outcomes. Organisational flexibility and adequate administrative support were identified as essential for addressing these challenges.

Having identified potential programme components, it was important to determine which, if any, of these would be suitable and relevant to include in a PA intervention for managing RA fatigue. Similarly, factors affecting implementation in a rheumatology setting needed to be discovered. Therefore, using data from this study as a starting point for suggested format, content and methods of delivery, the preferences of RA patients who might receive these interventions and rheumatology HCPs who might deliver them were sought in a series of focus groups. These are presented in chapter 6.

Chapter 6: Exploring patient and professional ideas to inform the development of a physical activity intervention for the management of fatigue in rheumatoid arthritis

Chapter 5 discussed the clinical use of PA interventions for managing fatigue in long-term conditions. HCPs gave ideas for programme structure and implementation, and raised issues regarding outcome measurement and evaluation. Lack of theory underpinning the programmes was noted but BCTs were identified. Data from these interviews informed the development of the study presented in this chapter. This study discussed and identified key components that might be included in a PA intervention for the management of RA fatigue, and explored ideas about its likely acceptability and potential implementation in clinical practice.

6.1 Background

Earlier chapters highlighted that few programmes currently exist to facilitate symptom management for people with RA fatigue. The potential utility of PA interventions to improve fatigue outcomes in RA has been recognised (chapter 2). Existing literature in other long-term conditions supports this concept, with some evidence of short-term effectiveness of PA interventions for improving self-reported fatigue (chapter 3). HCPs using PA interventions for managing fatigue in these conditions also support its use (chapter 5), suggesting that PA interventions may be beneficial in RA. However, the opinions of people with RA and rheumatology AHPs regarding the use of PA for managing RA fatigue are unknown. Gaining an insight into the attitudes, beliefs and behaviours of those individuals who might be receiving or delivering an intervention helps tailor it to the target population and is likely to increase the chances of its success (MRC, 2000, MRC, 2008).

6.2 Aims

1. To explore the views of RA patients and AHPs regarding the use of PA for fatigue management
2. To discuss and identify important content and key components of a PA intervention (as identified in phase 1) for inclusion in a fatigue management programme for RA, including type of PA and HBC approaches, who should deliver the programme, support materials, duration and location.

6.2.1 Objectives

Part 1 (patients):

1. To find out what support patients with RA would like to help manage their fatigue and how this should be delivered
2. To explore a range of delivery methods and key components of a PA intervention, identified in chapter 5, and discuss their acceptability for managing fatigue in RA

Part 2 (AHPs):

1. To explore the views of rheumatology AHPs regarding implementation and delivery of a PA intervention for managing fatigue in RA
2. To discuss ideas regarding suggested content (from part 1 data) of a PA intervention
3. To explore the practicalities, including facilitators and barriers to implementation

6.3 Methods

6.3.1 Research design

For part 1 and 2 of the study, focus groups were chosen to generate discussion amongst participants and encourage group interaction, allowing them to share their experiences of fatigue and PA in RA. The focus group format allows participants to debate particular questions while reflecting on their own experiences (Kitzinger, 2005). The group interaction allows participants to raise issues that are important to them individually and explore them as a group, thus generating new ideas and questions, and highlighting any concerns and priorities (Kitzinger, 1995). Group discussion was felt to be an appropriate means of exploring a wide range of views and producing ideas that might not be disclosed in a one-to-one interview (Kitzinger, 1995). Focus groups have been recommended for the exploratory phase of complex intervention development (MRC, 2000).

The patient focus groups continued into a workshop. During the workshop patients were presented with options for programme delivery and content that had been identified in interviews presented in chapter 5. Following brief discussion they were invited to vote for their preferred option. Although it could be argued that this was a consensus approach it did not employ more traditional consensus techniques such as nominal group or Delphi methods (Jones and Hunter, 1995). Moreover, the aim of the workshops was not to rate or rank items or gain agreement, but rather to establish a broader view of patient preferences and thoughts about the data presented, in order to inform further intervention development.

6.3.2 Identification and sampling

Ethics approval was granted for this study by the East Midlands National Research Ethics Service Committee (Reference 13/EM/0331) and the University of the West of England (HLS/13/08/107).

Participants were recruited using purposive sampling, as described in Chapter 5. As this was an exploratory qualitative study no formal sample size calculation was required. For both part 1 and 2, the candidate aimed to recruit two groups of four to eight participants. This number is considered typical for a focus group (Kitzinger, 1995). A larger group may result in unequal participation, with some people saying very little and others dominating the group (Finch and Lewis, 2003). It may also be harder for the moderator to manage if subgroups emerge and alter group dynamics. Equally a group of less than four might require more work from the moderator to stimulate discussion or challenge the group (Finch and Lewis, 2003).

The number of focus groups was chosen to include the opinions of different groups of patients and AHPs. Patient groups differed in relation to the rheumatology clinic they were recruited from. One was an inner city, research-intensive rheumatology clinic and the other a district hospital serving a sub-urban and rural population. AHP groups varied in terms of location, with one held in southwest England and the other in the Midlands. Each group included participants working at different NHS trusts, thus representing a range of experiences of working in rheumatology services.

6.3.2.1 Part 1

Adults (over 18 years old) with a diagnosis of RA as confirmed by a rheumatologist according to ACR criteria (Arnett *et al*, 1988), who had experienced self-reported fatigue at some point since their diagnosis, were invited to participate in this study. Patients were purposefully sampled to reflect a range of age, gender and disease duration. Patients attending the rheumatology outpatient clinics of two NHS trusts in southwest England

between September and October 2013 were screened for eligibility by a member of the healthcare team.

Those who met the inclusion criteria were introduced to the candidate or approached by a research nurse who explained the study. Potential participants had an opportunity to ask questions and clarify any issues that arose. They were given a participant information sheet and reply slip (appendix H) with a pre-paid envelope to take away. PA was not the main focus of the information sheet in an attempt to avoid recruitment bias to those who were interested in PA. It was important that the views of patients who were ambiguous about PA or did not like the idea of PA were also considered during development of the intervention. The candidate contacted patients who had agreed to take part and confirmed the date, time and location of the focus group and workshop.

6.3.2.2 Part 2

Specialist rheumatology AHPs or those with at least 12 months' experience working in rheumatology were invited to take part in a focus group. To encourage participation, a continuing professional development session was provided after the focus group. Initially only rheumatology physiotherapists were invited to participate as it was felt that they were most likely to deliver a PA intervention, and that it would be easier to approach one profession when recruiting. However, two OTs expressed an interest in taking part. On further consideration, and given the slow recruitment rate, it was agreed to extend the inclusion criteria to other AHPs working in rheumatology.

An advertisement (appendix I) was placed on the online rheumatology and musculoskeletal networks of the Chartered Society of Physiotherapy. In addition, the advertisement and participant information sheet were distributed via email lists to Chartered Society of Physiotherapy regional networks in the South West and South East of England and London, and to members of British Health Professionals in Rheumatology. Further participants were identified by snowballing (described in chapter 5). As for part 1, potential participants were provided with an information sheet explaining the purpose of the study (appendix J).

Focus groups were scheduled in Bristol and London, each following the same format. The London group was cancelled due to low numbers and was rescheduled and held in Birmingham.

6.3.3 Data collection

For part 1 and part 2, written consent was requested and obtained immediately before the session commenced. Participants were encouraged to ask questions and the candidate clarified any issues prior to taking consent.

6.3.3.1 Part 1

Two half day sessions were held with separate RA patient groups, each of which included a one hour focus group and a one hour workshop. These took place in meeting rooms at the hospitals where patients had been recruited.

The focus group was held first so that participants had the opportunity to discuss fatigue and PA and to become familiar with the concept of PA as a potential intervention for managing fatigue. Those who gave consent were asked for demographic information, such as age, gender, work status and duration of RA. These data were collected on a case report form (appendix K) and returned to the candidate at the time of the workshop. Each participant also completed the IPAQ-SF (Craig *et al*, 2003).

Following an introduction and explanation of the study proceedings, patients took part in the focus group. The groups were run by the candidate with a PRP as a second moderator and a note-taker from the research supervision team. The PRP was able to support and encourage patients during the discussion. Notes were recorded on a flip chart during the focus group.

At the start of the discussion everyone introduced themselves and explained their role, for example, whether they were a researcher or participant. Participants also reported the duration of their RA. The subsequent focus group discussion explored patients' views and experiences relating to fatigue and PA and was based on a topic guide (box 6.1). Focus groups were 50-70 minutes in duration. They were audio-recorded and transcribed verbatim. Transcripts were checked for accuracy and all names of people and places were anonymised to protect confidentiality.

Box 6.1: Part 1 topic guide

Views and experiences of fatigue

- How do you currently manage/have you managed your fatigue in the past?
- What advice have you received from health professionals about managing fatigue?
- At what point would you like to have help/information with fatigue management?
 Prompt: e.g. when you are having an episode of fatigue, or as a means of preventing fatigue?

Views and experiences of PA

- What does the term physical activity mean to you?
- Do you think of this differently from exercise?
- Would you/do you consider walking/household activities as PA?
- Have you ever been advised to consider exercise or physical activity to help with fatigue?
- What might stop you being physically active?
- What might motivate/help you to increase PA or to stay active?

Fatigue and PA

- Do you think there is a role for PA in fatigue management?
- What do you think the outcomes/benefits (if any) of PA might be in relation to fatigue management?
- How would you like to access help with PA for fatigue management?
 Prompt: e.g. through peer support, professional support?
- How would you like to receive information to support PA for fatigue management?
 Prompt: e.g. leaflets, online, digital versatile disc (DVD) or video
- Would you want to take part in some form of exercise or PA as part of a fatigue management programme?
- What might a PA fatigue management programme/intervention look like/how might it be delivered?
 Prompt: Where/how would you want this delivered?

Focus groups were followed by a coffee break before continuing with the workshop. After the break patients were presented with options for programme delivery and content, derived from interview data (chapter 5). A series of multiple choice questions were presented using TurningPoint interactive polling software (TurningPoint version 4.2.3, www.turningtechnologies.com) via Microsoft PowerPoint (2007). TurningPoint is a response system that allows the audience to respond to interactive questions using a hand-held keypad, known as a ResponseCard™.

Workshop questions and response options (appendix L) were read out by the candidate. Participants were asked to discuss their views and thoughts regarding the presented content, such as which components would be most useful and acceptable as part of an intervention for fatigue management in RA. They were supported by the facilitator and PRP. Any comments or issues concerning specific questions were recorded

in field notes. Any ambiguity or uncertainty about each question was clarified before the participants responded. Participants were asked to vote for the response that they most agreed with using the hand-held ResponseCard™ (RF Accessibility) keypad. The keypads communicate with TurningPoint software via a radio frequency receiver that is connected to the computer using a Universal Serial Bus portal. This interactive software allows real-time data collection, providing instant feedback to the audience. Individual responses remained anonymous.

If there were participants who had severe deformity of the hands as a result of their RA the handsets would be secured to a table using a reusable adhesive. Participants would then be able to press the buttons using the tip of a finger without having to simultaneously hold the device. In this way all participants would be able to take part.

Data from focus groups and workshops were collated and summarised prior to part 2 of the study.

Topic guide and workshop question development

As described in chapter 5, topic guide questions (box 6.1) were developed through consultation with the supervisory team and PRPs. PRPs assisted with the wording and construction of questions to ensure that rich and useful data would be obtained. A list of prompts was included in the topic guide to assist the moderator with eliciting further detail where applicable.

As for the interview guide in chapter 5, opening questions were designed to be broad and neutral, and sequencing was carefully considered to provide a logical flow to the data collection. Questions were grouped into three sections according to topic: views and experiences of fatigue; views and experiences of PA; and fatigue and PA.

Questions for the workshop (appendix L) were based on data gathered from interviews relating to the structure and implementation of a PA intervention (chapter 5). They were designed to gauge what key elements from current programmes in other long-term conditions should be included in a programme for RA. The questions were designed to allow patients to provide a real-time response via the interactive software system. An initial list of questions and responses was reviewed and refined by PRPs and members of the research supervision team.

6.3.3.2 Part 2

Focus groups with rheumatology AHPs took place in meeting rooms in Bristol and Birmingham. Written consent was requested immediately prior to the focus group. Those who consented to take part were asked to provide demographic information, such as age, gender and length of time working in rheumatology. These data were collected on a case report form and returned to the candidate at the time of the focus group (appendix M).

At the start of the focus group the candidate welcomed participants and explained the purpose of the session. Following an introduction and explanation of the study proceedings AHPs took part in a one hour group discussion based on a topic guide (box 6.2). The groups were moderated by the candidate and a second researcher from the research supervision team who also took field notes.

Box 6.2: Part 2 topic guide

Views on PA for fatigue management in RA

- What do you think about PA for managing fatigue?
- What do you think the outcomes/benefits of PA might be in relation to fatigue management?

Views on patients' ideas from part 1

Professionals will be presented with data from part 1 of the study

- How might these be included in a PA intervention for managing fatigue in RA?
Prompt: Check understanding of graded exercise therapy (GET)/graded activity (GA) if necessary. Do they know the difference between GA and progression?
- Is there anything else that would be important to include that is not included in these data?
- How might such an intervention be implemented?

Implementation of PA as an intervention for fatigue management

- How feasible would it be to deliver a PA intervention as part of your service?
- Who do you think would be most appropriate to deliver this intervention?
- What would be the key practicalities to consider, including barriers or facilitators to implementing this intervention?
- How confident are you about delivering this type of programme?
- How much time could be dedicated to delivering a programme?
Prompt: e.g. how many weeks should it run for? (Consider local trust policies)
- Do you have suggestions on how you might measure/monitor a person's changes in fatigue resulting from a PA intervention?

Data from part 1 of the study were presented to participants during the discussion using Microsoft PowerPoint (2007). These included key points raised in part 1 focus groups and patient responses to the workshop questions. Ideas about content,

acceptability to patients and AHPs, and implementation of a PA intervention for managing fatigue in RA were discussed based on these data.

Focus groups were 75 to 80 minutes duration. The discussions were audio-recorded and transcribed verbatim. As for part 1, transcripts were checked for accuracy and anonymised to protect confidentiality.

Part 2 focus group topic guide (Box 6.2)

As for part 1, questions were generated following discussion with the research supervision team and PRPs. Questions were grouped into three sections: views on PA for fatigue management in RA; views on patients' ideas from part 1; and feasibility of delivering a PA intervention for fatigue management.

6.4 Analysis

6.4.1 Demographic and IPAQ questionnaire data

Demographic and IPAQ-SF data were input into a spreadsheet in Microsoft Excel (2007). Numeric data were analysed using descriptive statistics. IPAQ-SF categorical scores for level of PA (1 – low, 2 – moderate, 3 – high) were calculated according to the IPAQ scoring protocol (IPAQ, 2005).

6.4.2 Focus group data

Focus group data were analysed using inductive thematic analysis as described in chapter 5. Two transcripts were independently analysed by two researchers from the supervision team (Fiona Cramp and Nicola Walsh) and one by a PRP (Maria Morris). The four sets of analyses were discussed with the supervision team and common codes and themes agreed.

6.4.3 Part 1 workshop data

Responses to workshop questions were collected via TurningPoint handsets and imported into Microsoft Excel (2007). Bar charts representing response data were generated in Excel and summarised narratively.

6.5 Results: Part 1

6.5.1 Participants

Participants were recruited from two NHS rheumatology outpatient clinics. At one site the candidate was directly responsible for recruitment. Thirty-three potential participants who attended clinics were screened for eligibility to take part in the study. Seven patients (21%) were ineligible as they reported that they had not experienced fatigue, and a further eight (24%) were unable to attend a focus group on the specified date. Of the remaining 18 patients, eight (31%) agreed to attend the focus group and workshop. However, two patients were unable to attend due to illness and one patient did not turn up on the day. Five participants attended the group.

Recruitment for the second group was conducted by a research nurse on site at the rheumatology clinic of a district general hospital. Eleven eligible patients were invited to take part. Of these, one refused (no reason given), one was unable to attend due to the time of the session, one did not return their reply until after the date of the focus group and another agreed but was unwell on the day. Therefore, seven participants attended this focus group and workshop.

Twelve patients (6 female) consented to take part in the study. Background information is presented in table 6.1.

Table 6.1: Part 1 patient participant information

ID	Gender	Age (years)	Disease duration (years)	Work status	IPAQ-SF score
010	M	66	4	Semi-retired	3
011	M	43	7	Receiving incapacity benefits	1
012	F	55	5	Student, Retired	3
013	F	53	4	Paid work	2
014	M	59	24	Retired	1
015	F	52	2	Paid work	3
016	M	62	25	Pension credit	1
017	F	56	5	Paid work	1
018	F	56	16	Retired, receiving incapacity benefits	2
019	M	64	3 months	Paid work	1
020	F	66	4.5	Retired	1
021	M	49	2	Paid work	3

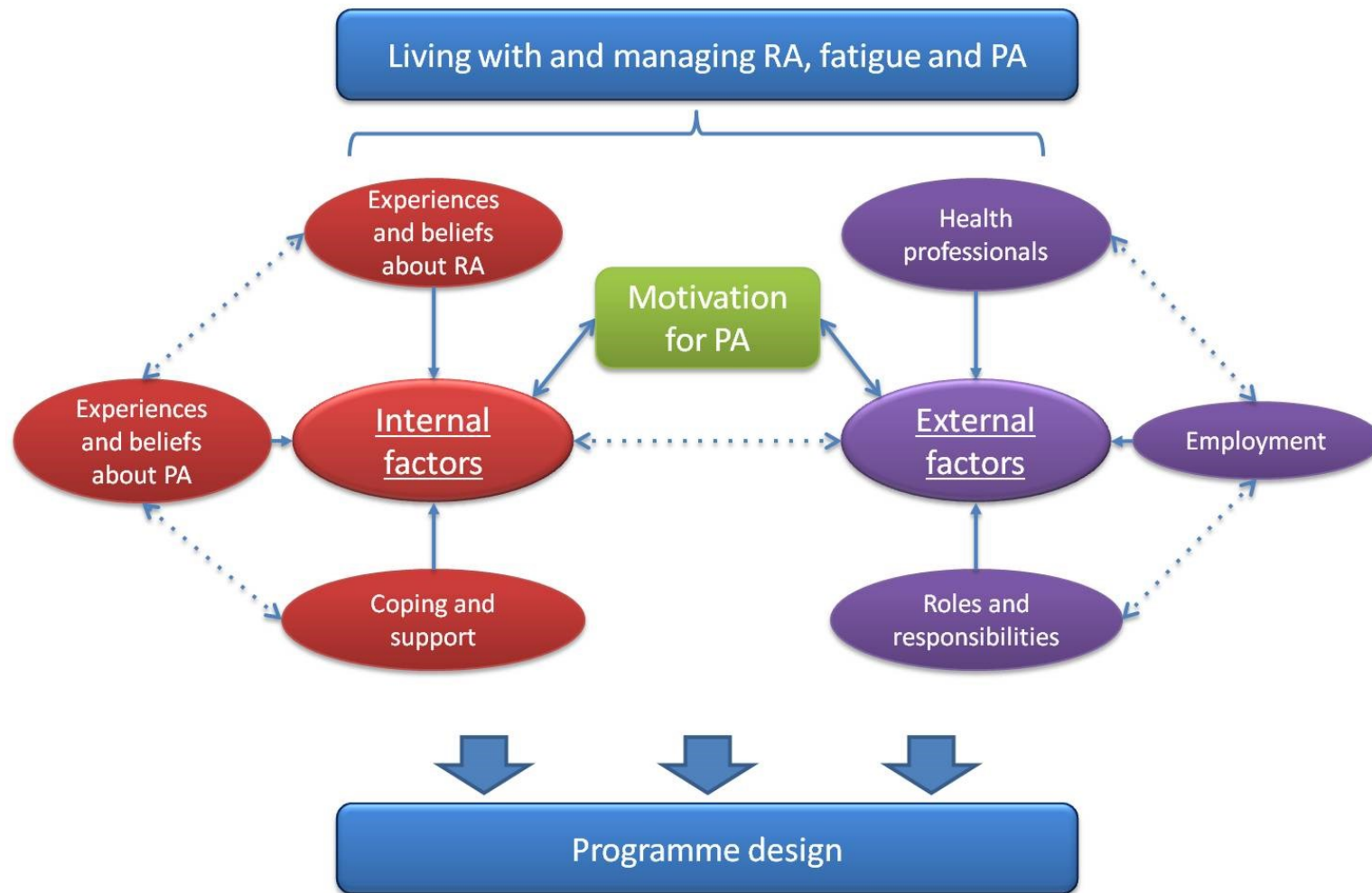
F=female; ID=participant identification code; IPAQ-SF=International Physical Activity Questionnaire short form; M=male

IPAQ physical activity level – 1. Low (not meeting criteria for moderate or high categories), 2. Moderate (half an hour of at least moderate-intensity activity on most days), 3. High (at least an hour of moderate-intensity activity over and above basal level of activity, or half an hour of vigorous-intensity activity daily)

6.6 Thematic analysis of patient focus groups

Three themes were identified from the analysis. Two core themes related to internal and external factors related to living with and managing RA, fatigue and PA. An additional third theme was associated with the effect that these factors might have on patients' motivation for PA. The relationship between these themes and their contribution to programme design is illustrated in figure 6.1.

Figure 6.1: Relationship between internal, external and motivation factors affecting life with and management of RA, fatigue and PA



6.6.1 Theme 1: Internal factors

The RA experience was different for each individual, but nonetheless the condition had a considerable impact on the daily lives of all participants. Participants described varying experiences of and beliefs about RA, fatigue and PA and the importance of self-management and support systems for coping with the condition. These factors influenced how motivated participants were to engage in PA, with those who had negative previous experiences or fears about PA being less motivated to take part.

6.6.1.1 Experiences and beliefs about RA

Physical consequences

Several participants reported that the overall impact of RA on their day-to-day lives was variable and unpredictable. Every day was different from the last, making it difficult to make plans or stick to daily routines.

014: "I wake up every morning and wonder which joint is going to be hard work today..."

Participants spoke about the physical consequences of RA, such as physical disability and difficulty with their mobility, with joints seizing up at various times of the day.

015: "I don't do anything when I get in from work though. I can't ... I'm very seized up."

They noted that it can be particularly difficult to get going in the morning, due to taking medications and symptoms often being worse at this time of day.

016: "I clam up in the morning when I wake up so that's the worst problem..."

Seizing up was also reported as a consequence of prolonged periods of sitting.

018: "... I would actually find it really painful sitting still after a while, and I think that was the hardest thing."

One man was concerned about trying to do PA as part of a fatigue management programme after sitting through an education session, as he would find it difficult to move.

011: "But I'm thinking like sat around now, I know I'm hardly going to be able to move when I get up in a minute [...] and I'm thinking I don't want to be doing any exercise after being sat around for a long period like that..."

Physical symptoms experienced by RA patients were potential barriers to PA, for example pain and joint deformities.

013: *"I think the pain stops me."*

014: *"Mine is my disabilities, that's what stops me doing anything, is the actual physical disabilities...."*

One man specifically referred to foot pain as a limitation to walking.

010: *"My left foot at times is excruciating to walk on."*

Fatigue was confirmed as a big problem, although it was often not clear whether participants could differentiate fatigue from other symptoms such as pain. Whilst some felt able to predict the onset of fatigue, others could not tell when fatigue might occur.

013: *"Every time I tried to do something I just had to lie on the sofa, I was just completely zonked, I never had anything like that before. [...] I don't recognise when I'm going to be like that..."*

014: *"So fatigue, I don't know what fatigue is because fatigue hits you more when your pain is a higher level perhaps, than a lower level."*

Some patients reported that at times fatigue was so severe that they were unable to keep awake.

016: *"... I can start walking along and fall asleep with my eyes shut, that's how bad I get sometimes."*

However, sleep often did not reduce fatigue.

014: *"... even when you're asleep and you sort of get up tired, worse than you were when you went to bed sometimes."*

Fatigue was cited as a barrier to PA.

MOD: *"... what might stop you being physically active, what do you think might be the main thing?"*

020: *Fatigue.*

021: *Fatigue, yeah."*

Psychosocial impact of RA

Alongside the physical symptoms of RA, participants spoke of the considerable psychosocial impact, suggesting that it was equally significant. This included low mood, depression and frustration. Some participants expressed that they occasionally had difficulty accepting that they were no longer able to do the things they used to do. One man reported that he had attempted suicide as a result of having RA.

021: *"I think depression is a big problem with it. I don't mind admitting in front of everybody I've had an attempt on my life in the last twelve months because of it."*

Some participants reported psychological barriers to PA such as fear of pain and damage to joints.

010: *"It's the fear of the pain for me."*

013: *"... sometimes I don't do things because I worry, I know it's going to hurt."*

Participants discussed how they often feel like they fail with PA, especially if they have previously experienced a flare up of the disease as a result of exercising.

011: *"The minute you mentally make yourself kitted up ready to do it [PA] and then you fail at the first hurdle."*

013: *"And it's horrible failing."*

011: *"Then you just spiral down to just giving it up, then you might give it a couple of days, and try it again, and then yeah."*

014: *"You try as hard as you can until you can't."*

021: *"I tried swimming and it caused flares in my shoulders. So I went to see the doctor about it and they said try an exercise bike for a minute a day, and that used to set off in my knees."*

The fear of failing with PA was demotivating and distressing for patients, exacerbating psychological symptoms of RA such as feelings of frustration and low mood.

011: *"...when you're having a bad period, where you can't do things, you don't accomplish stuff, and when you're failing at stuff, that puts you in a blue mood anyway."*

Patients suggested that it might be helpful to have advice about how to cope with these aspects of RA and fatigue.

018: *"I mean it's quite a depressing, um, condition to have, you get so impatient with yourself [...] and I get really, really cross with myself, I wouldn't say depressed [...] but I get cross, you know, impatient and think, "You stupid, useless ..." Um, so sometimes possibly something [in the programme] to address that."*

6.6.1.2 Coping and support

Self-management and coping

The importance of self-management was acknowledged during the discussions.

012: "I think that's something patients need to be educated about the fact that, you know, it's not all down to the consultants and health professionals, that we need to take a certain amount of responsibility for ourselves and trying to find out, um, what's out there and what is there to support us. "

However, fatigue self-management techniques reported by patients were variable and inconsistently applied. Several participants reported that they were aware of pacing as a potential self-management strategy, but it was not clear whether they made effective use of this technique in their day-to-day lives.

012: "...the occupational therapist I saw at the time, um, told me about pacing, which was something I, um, struggled with and do still struggle with to a certain extent."

Some expressed a lack of knowledge about self-management skills to manage PA.

011: "I didn't think there was any way of forward planning [PA] like that."

Several participants appeared to use stoicism as a coping strategy for managing their RA. They expressed resignation that they had no other choice but to carry on regardless due to external demands, such as caring roles and responsibilities.

016: "I mean I've got to look after my mother, I mean she's an old lady now, so you can't give up yourself even though you might be bad, I'm looking after my mother.

015: Because other people are relying on you, aren't they?"

Only two participants employed exercise as a coping strategy.

012: "I was recommended to, um, try exercising and I actually ... which is why I went to the aqua class and I did actually find that that helped..."

018: "... I make myself get up and move and do things. Er, I've been a big swimmer and walker and if I can, I ... you know, I will swim because I actually find that exercise is energising"

Preferred support systems

Many patients reported that their main support came from a spouse or family member, but this was not always the case. Some felt that their family did not understand their condition, and one lady (018) found her family too protective.

016: "But my family think that there's nothing wrong with me.

020: Mine are like that actually, because they can't see it, they don't ... they think I'm as fit as when I was working and I haven't worked for the last 14 years."

018: "... sometimes they [family] will go for overkill, when actually I just need to be allowed to get on with it myself."

A number of participants also reported a lack of understanding from other friends and colleagues due to the invisible nature of RA.

015: "Because people can't always see arthritis, people think, from the outside, you look quite ... sorry, I don't use the word 'normal', but that's how it looks..."

Peer support was considered extremely valuable. Consequently, participants reported that they would prefer group delivery of a fatigue management intervention. Written or online materials would be inadequate as they would omit the opportunity for interaction and discussion with fellow patients as well as HCPs. This was considered key for problem solving and learning.

021: "... I'd rather have face-to-face or in a group because then you can all talk about your experiences, like we're doing now [...] and like if you were to tell me to do something to help my fatigue I can say, "Hang on a minute, I can't do that," whereas if you give me a brochure or a DVD, I can't talk to that."

There was also support for a practical component, although there was some concern that it would be difficult to individualise PA in a group setting.

011: "... everyone is individual aren't they and everyone's different, and when it's generalised and put to people you should be doing that or you shouldn't be doing that, I think everyone should find their own level and be able to do that and I don't think you'll do that in a group."

It was felt that a choice of exercises with different levels and progressions might help to ensure everyone is able to work at their own pace.

MOD: "...would you prefer to have sort of a range [of exercises] to choose from?

021: Yeah, different levels as well, so you've got something that's really, you know, simple and you can progress."

6.6.1.2 Experiences and beliefs about physical activity and exercise in RA

Definitions of physical activity and exercise

Not all participants were clear about the difference between PA and exercise, with some interpreting them as the same thing. When asked about PA, many assumed they were being asked about exercise. This was problematic for some, who saw a change in PA as a requirement to fit extra exercise into their day.

011: "I've probably thought of that or interpreted it differently as having to try to do some more exercise rather than just walking to the kitchen, walking to the bathroom, coming back and being mobile like that."

021: "I've got a problem in understanding the difference between my job, which is very physical, and exercise. To me, they're both the same, in my mind's eye, so if I'm doing that for eight or nine hours a day, do I want come out and do [exercise] for another couple of hours."

Others did differentiate between PA and exercise, viewing PA as keeping mobile and exercise as something more challenging.

014: "I won't call it exercise, I would say keeping yourself mobile"

018: "I would say I would want to think that my pulse was going up a bit and I was breathing a bit harder"

MOD: So you would think of [PA] as different from exercise?

018: Yes, I would think of exercise as being something a bit challenging."

One participant reported that for her the distinction was important as she believed that PA worsened her fatigue, whereas exercise improved it.

012: "I can do physical activity, something that is strenuous that is going to cause me fatigue, but doing the aqua class doesn't cause me fatigue, it makes me feel better."

Physical activity experiences and beliefs

Participants acknowledged that they were less physically active due to the physical and psychosocial impact of RA. They expressed uncertainty about what type of PA or exercise they should or could do. One man who was newly diagnosed believed that he could not return to the gym until he had seen a physiotherapist.

011: "... I've taken on stuff where they say, 'You shouldn't be doing that, you shouldn't be doing this and that,' and I haven't done it and I think I could have been doing it, and then I spoke to a doctor only a couple of weeks ago [...], and they're saying, 'Oh no, no, you can do that'.. "

019: "I'd like to get back into the gym, but I'm waiting to see the physio, which is December. Until then, I can't get back ..."

For some individuals joint surgery and physical disabilities restricted their options for the type of PA.

010: "The surfing I also can't do now because of getting the wetsuit on and off. I've had a tendon reconstruction for my forefinger there, and I still haven't got power back to be able to tug a wetsuit and boots"

018: "I used to love going out on a bike, but I can't actually manage the, um, handlebars and brakes,"

PA undertaken by participants varied. Some activities were seen as part of daily life, such as walking the dog, doing the housework or gardening,

010: "I take a walk for the paper every day without fail..."

020: "I've got a little dog and I have to take her for a stroll..."

while others undertook more structured exercise, such as daily mobility exercises provided by a physiotherapist or attending hydrotherapy. These were generally undertaken to maintain mobility rather than manage fatigue.

012: "I was given exercises to do by my, um, physiotherapist and, um, I do them, well more or less religiously every day, because I know that by doing those exercises I'm keeping my joints mobile."

Some participants mentioned that an unwelcome consequence of RA and inactivity was weight gain. This was felt to exacerbate psychological factors associated with RA, such as low mood and reduced motivation for PA.

011: "I'm gaining weight and I'm feeling really lethargic and don't feel very good in myself, like I've got no get up and go to do anything."

015: "I can't maintain my weight now since I've had arthritis. [...] Weight's a very difficult one, which gives depression, I'm afraid to say"

Advice on weight management was suggested as an education topic to include in a PA intervention, as it was noted that this can help improve engagement with PA.

MOD: "... anything else that really must ... that you think is really important [to include in a PA programme for fatigue management]?"

018: Weight management.

015: It's a nightmare.

017: It is, yeah.

018: [...] Um, yeah because also I find the activity helps to keep my weight down, um, and ... but then because my weight is down the activity is easier, um, that sort of thing.”

Perceived benefits of PA

Participants identified several benefits of PA that might be motivators. These ranged from physical benefits, such as raised general fitness, increased muscle strength and improved cardiovascular fitness, to psychosocial gains, such as increased social interaction, maintaining independence and building confidence.

011: “I reckon [PA] raises your level of confidence, your social activity with other people...”

MOD: “... what do you think the outcomes or the benefits of physical activity might be for fatigue management?

014: [...] Not got to rely on other people to do everything for you.

MOD: So keeping that independence?

014: Yeah.”

Several participants reported direct experience of feeling generally better, more alert and less fatigued after performing PA or exercise.

018: “I mean also, [PA] makes you mentally more alert and I think that tends to sort of, um, stave off fatigue a little bit and there’s the sort of feeling of achievement as well, if you’ve done it, you know.”

6.6.2 Theme 2: Motivation for PA

Participants reported various other motivating factors for PA including being creative, getting outside and enjoying the sense of achievement.

020: “I try and do a bit of gardening

015: Yeah, I do.

018: It’s creative that, isn’t it.

020: [...] But it is rewarding, yeah, you can see actually that you’ve done things, it is good.”

It was suggested that determination and a positive attitude play an important role in motivation.

MOD: “Any other things that might help motivate you, [...]?”

012: Having a positive attitude I think.”

MOD: “Can you think of anything else, [...] you think could be helpful for increasing your activity, [...]?”

017: Just determination, I’d say.

020: Yeah, that’s a big thing, keep going.”

However, some participants felt that a positive attitude did not prevent the frustration of trying and failing with PA or with managing fatigue in general.

010: *“The positive attitude, great, but when you try to do something and you fail...”*

011: *“It wears you down.”*

014: *“I’ve got the most positive attitude going and it don’t help me none, none of it. Not for fatigue.”*

External factors such as the physical environment also affected motivation and participation in PA. For example, the water temperature of many swimming pools was often too cold for RA patients wishing take part in water-based activities.

012: *“For me, well what stops me at the moment I haven’t been to aqua since this time last year and I stopped because of the temperature of the water was too cold, so that makes my joints feel bad and then I can’t really exercise.”*

Despite participants’ beliefs that PA had potential benefits for their overall well-being, barriers such as these made it difficult for them to engage in PA or exercise. Participants made suggestions for improving motivation to attend PA programmes, including better pain management and fixed appointments.

There was some support for concessionary benefits to facilitate long-term motivation and increase opportunities to engage in PA, such as exercise prescription and support with equipment such as footwear.

018: *“It would be useful if there were some, some more concessionary benefits or the [general practitioner] could sort of ... I know sometimes they can prescribe things, but it’s not universal, is it? [...] I know there’s Weight Watchers and things like that available, but, er, you know, something to go swimming with, you know, er, or help with walking boots.”*

6.6.3 Theme 3: External factors

This theme relates to external factors associated with living with and managing RA fatigue that might influence motivation for PA. These include advice received from HCPs and issues associated with employment. Although an external factor, roles and responsibilities are discussed in subtheme 6.6.1.2 above as these subthemes were felt to be inextricably linked within the discussions.

6.6.3.1 Health professionals

Participants reported a lack of knowledge and understanding about fatigue, with few seeking professional advice and support for managing this symptom. Advice that was received usually related to pacing activities. Advice regarding PA was generally aimed at improving physical function rather than managing fatigue. Participants therefore frequently

sought support from family members or other patients for managing their RA and fatigue, with peer support considered to be particularly valuable.

Fatigue management

Patient discussions indicated that advice from HCPs for fatigue management was variable and often limited. Two participants recalled receiving general RA advice early in their diagnosis through attending a patient education programme. These education sessions were thought to be helpful and did include some advice about fatigue. However, several participants reported that they have never received advice about managing fatigue from a HCP.

*MOD: "... have you received advice from health professionals about managing this tiredness and if so, what sort of advice have you received?
010: None at all. [...] I just wasn't aware that there was any of this."*

*MOD: "What about advice from health professionals about fatigue management?
015: This is the first time for me here."*

Participants expressed limited knowledge of the support available for fatigue management, with one reporting this as an incentive to participate in the current study.

015: "...this is basically why I've come today to see what can be done and what's going to be done."

Further discussion indicated that many had received advice about pacing activities, although the delivery and quality of this information varied from just being given a leaflet to having one-to-one sessions with an OT.

*MOD: "... how much information have you had in relation to that [pacing] [...]?
015: Just pace yourself.
021: Just pace yourself, here's the booklet."*

Specific fatigue information and engagement in homework provided in one-to-one sessions were reported to be more helpful than group advice or more general information.

*012: "...it was the one-to-one that I really got a better understanding of it [fatigue] because I was actually given a sheet, um, to chart, I think it was every hour, high energy, low energy, rest and that actually was quite an eye-opener, and it was having that to take away and do that actually made me more aware of how to manage it.
MOD: So that was more helpful than just being told general information?
012: Yeah, yeah, and than in a group."*

For one participant, the lack of advice and support was justified by the belief that the rheumatologist's role was to provide medical management, suggesting that patients may not know where to seek appropriate support for their fatigue.

015: "Mention [fatigue] to the doctors and consultant, but they're mainly about drugs, aren't they, and keeping it at bay and I suppose, you know."

One group suggested that despite good support in early RA there is a lack of ongoing professional support for patients with established disease, leaving these patients feeling abandoned and demotivated.

014: "... in the early stages of RA, we've probably been prodded towards that way [to attend patient education programmes], yeah?"

011: Yeah.

014: But once the illness has sort of taken over your life and been with you for half your life....

011: You're left on the shelf.

014: You've got to get on with it."

It was believed that regular contact with HCPs would improve motivation and confidence for managing RA.

011: "I think just the having advice, having contact quite regularly with the hospital or whatever would improve your state of mind, and how you feel ... it's like you're being monitored, and you're thinking, well yeah I can do that, if they're saying try and do this, and do that, and do the other, that will motivate you more than not hearing from anyone for six months..."

Consequently, although most participants felt that a programme would be most useful in the early stages of RA, there was also support for follow-up advice.

011: "I think preventative, yeah, early on, early doors and that, but also to be reminded of it every so often, because you tend to forget yourself."

PA advice has function as the focus

Advice regarding PA and exercise generally related to maintaining joint mobility and physical function through keeping active, or referral to physiotherapy or hydrotherapy.

MOD: "...have you been advised to do exercise or activity for fatigue?"

017: No, I mean physio has suggested exercise for certain parts of my body that are not working properly ..."

Only one participant had been advised to exercise to help reduce their fatigue.

012: "... when I was, um, first trying to get over this fatigue because at that stage I was spending so much time in bed just sleeping, and I was sleeping. The physiotherapist said that actually, you're not helping yourself and exercise is the thing that will help, um, to you know, to alleviate that..."

There was overall agreement amongst participants that there is a role for PA in managing fatigue in RA. The majority expressed an interest in a PA intervention to support this, with the exception of one man who felt that he would not benefit from attending a programme having had RA for so long.

MOD: "Is that something you'd want to do? Take part in exercise as part of managing fatigue?"

[...]

010: Yeah, yeah, if it's going to lead to something that will enable me to exercise in a more friendly way and is not going to cause pain then yeah, definitely.

014: I don't think I'd gain anything more from that now, I would have 10 or 20 years ago."

Participants were keen that any programme or advice to increase confidence with PA should be delivered by someone they considered an expert, although expert was not defined.

013: "I think anything where an expert is telling you it's okay to do, is the right thing to do and it can help you is good."

Support materials were also considered useful to supplement an intervention. Participants felt that these should be available in multiple formats to meet different preferences, for example a DVD for those who prefer audio-visual to written materials.

012: "A DVD is a good idea, online because there will be some people that that would be their preferred method, um, and leaflets, that's my preferred method because online is just no good."

6.6.3.2 Employment

Several participants reported having to give up work, either permanently or temporarily, due to their RA. This was reported to have a significant impact on their mood and general well-being, with some participants expressing a sense of loss and ongoing struggle to accept this change in their identity.

011: "..., it's a long ongoing battle where you've had to forget your old life, what you used to do, I've given up work and stayed home [sic]."

012: "... for me personally, I found [fatigue] a danger when I stopped work and I felt quite low about not being able to go to work,..."

Some participants reported that they were still working, although their experience of support from managers and employers was highly variable. One lady reported that her employer was extremely supportive, whilst others described a lack of understanding at work.

021: *“Um, so you go to my employer, explain to them, “I’ve got to pace myself.” They turned around to me and said, “You can’t do your job, there’s the door, that’s it.” ”*

Two participants had physically demanding jobs, leaving them with little energy and making it difficult to prioritise any PA outside of their working day.

021: *“... exercise is the last thing on your mind when you get in from work.”*

015: *“I don’t do anything when I get in from work though. I can’t ... I’m very seized up.”*

Dealing with RA and fatigue in the workplace was an important issue for these participants.

015: *“How would you implement that [fatigue management] in the workplace though? How would you ... I’d like to ask people how would you do that? How does that work?”*

The time of day that a programme might run was also discussed. It was emphasised that this should be carefully considered for those who work, as it was unlikely that they would be able to attend during working hours. Evening or holiday sessions would be preferable.

014: *“All this making appointments and coming to groups and all, that’s all fine, but the time element is more important than all your meetings. [...] Things have got to be done to make it easy for people to come.”*

015: *“So I’d be thinking hopefully during an evening or during a holiday time or something, for me personally, but then there’s others that can’t do that so you’ve got to take that into consideration.”*

Although participants who were working acknowledged that they might find it difficult to get to evening sessions, they felt that the peer support might motivate them to attend.

015: *“I suppose that’s encouragement, like you say, if you think, “I’m going there tonight, I’m meeting all of my friends who’ve got RA, we all chat together, we do exercise together, it’ll be all ...” you know. It’s a social event, but with like-minded people like yourselves, which I think is so paramount, to be honest.”*

6.7 Workshop data

After a coffee break, participants took part in the workshop, during which questions derived from HCP interview data (appendix L) were presented and discussed. Responses for questions where participants had to select one preferred answer are shown in figures 6.2 to 6.21. If participants indicated more than one response or their preferred response was not presented this was discussed and recorded in field notes. For three questions multiple topics were presented and participants chose one option from ‘yes’, ‘no’ or ‘don’t mind’ for each topic (tables 6.2 to 6.4). All figures and tables present combined responses from both focus groups (n=12).

Figure 6.2: Location for programme delivery

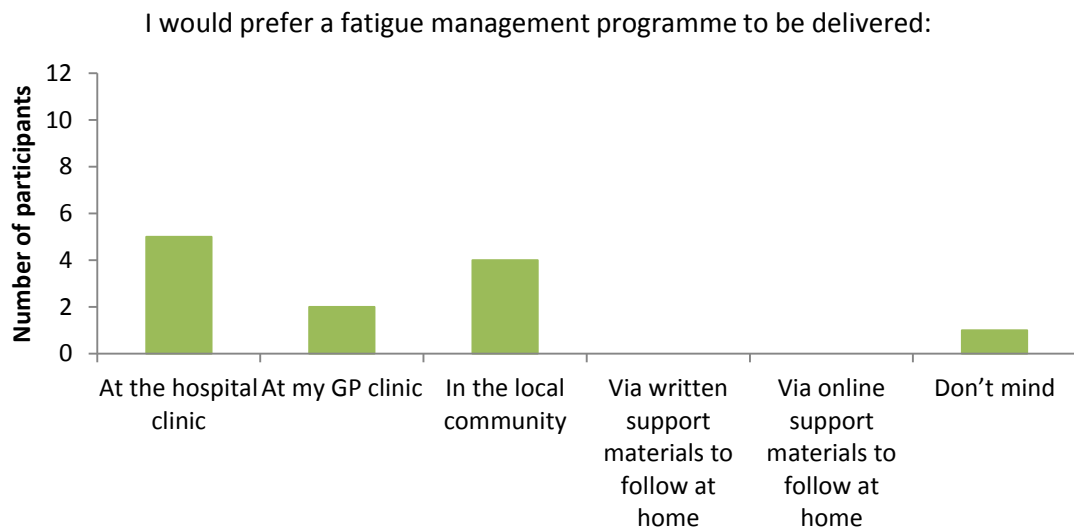


Figure 6.3: Programme referral route

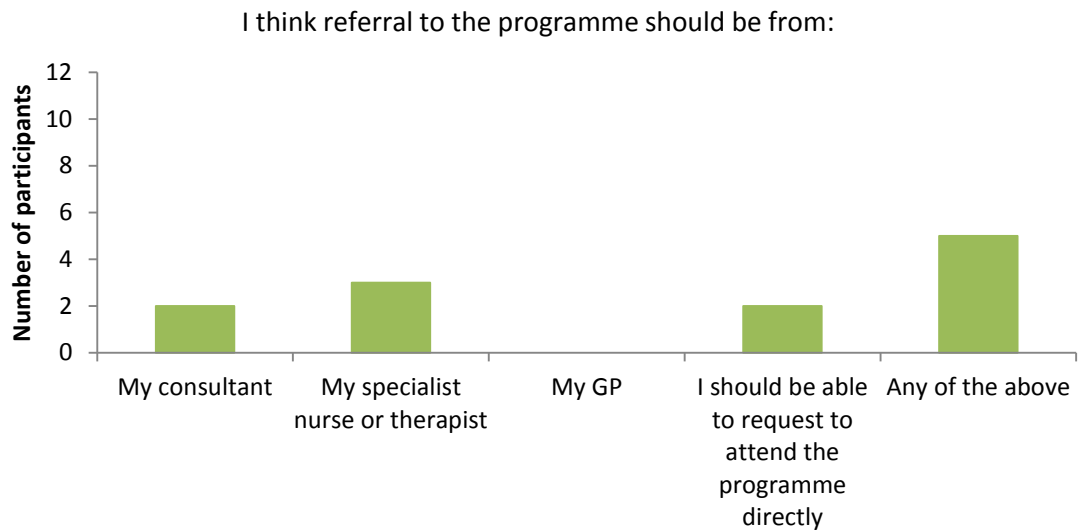


Figure 6.4: Pre-programme assessment

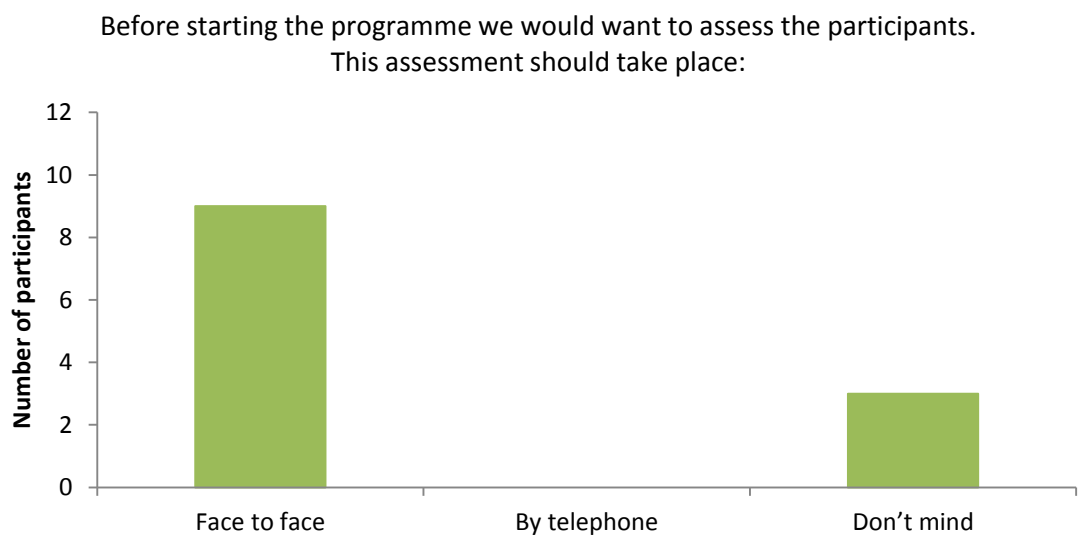


Figure 6.5: Programme length

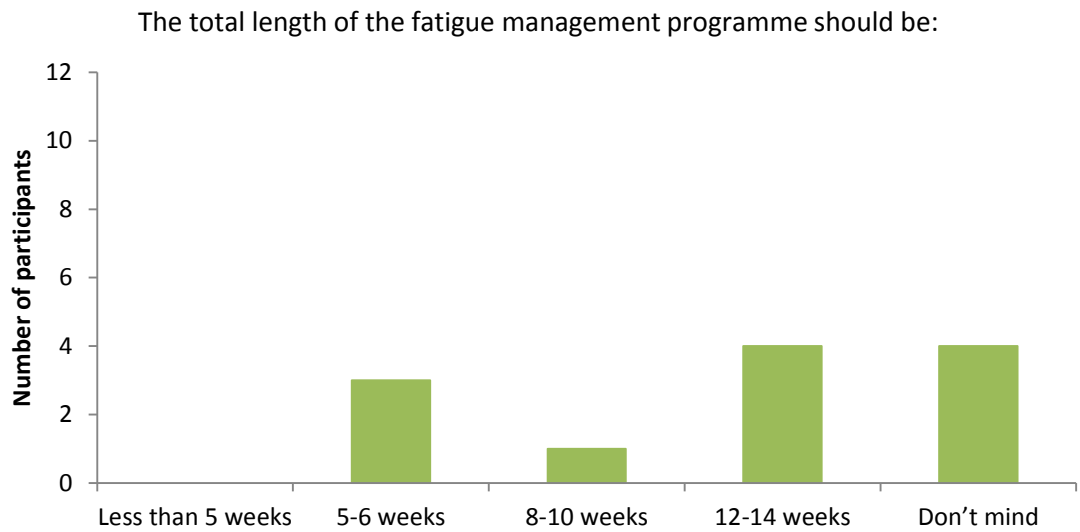


Figure 6.6: Importance of travel arrangements

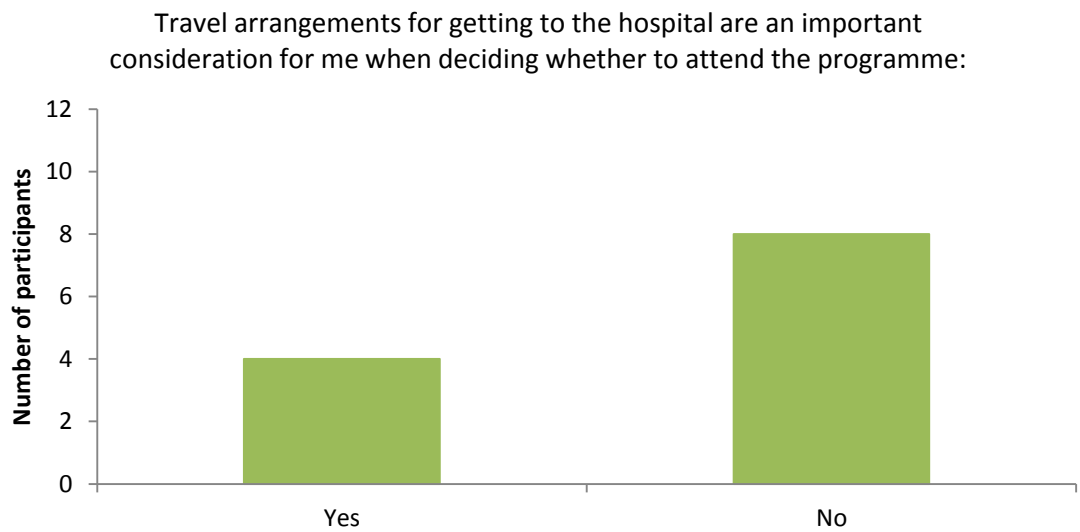


Figure 6.7: Transport requirements

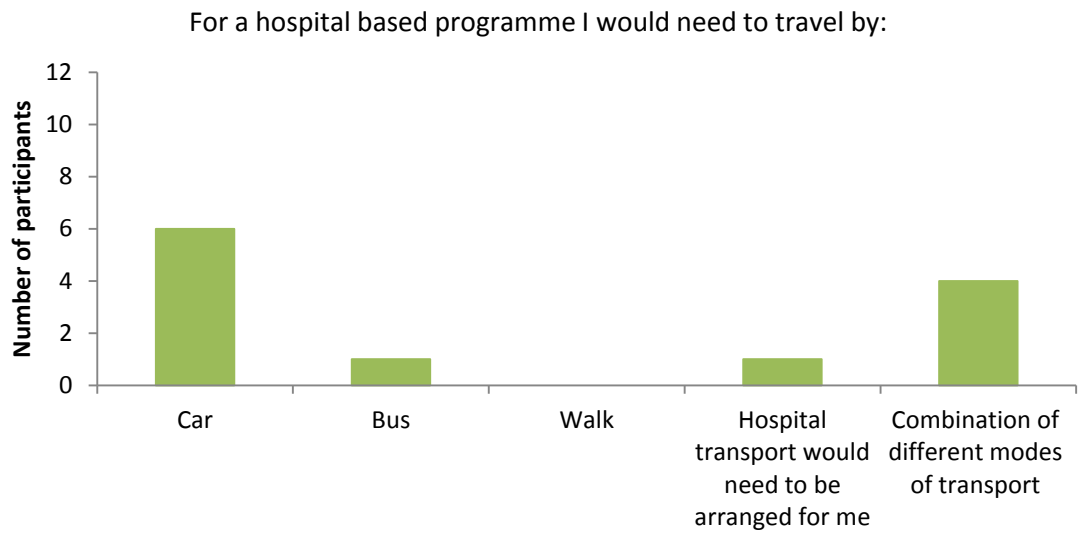


Figure 6.8: Attendance arrangements

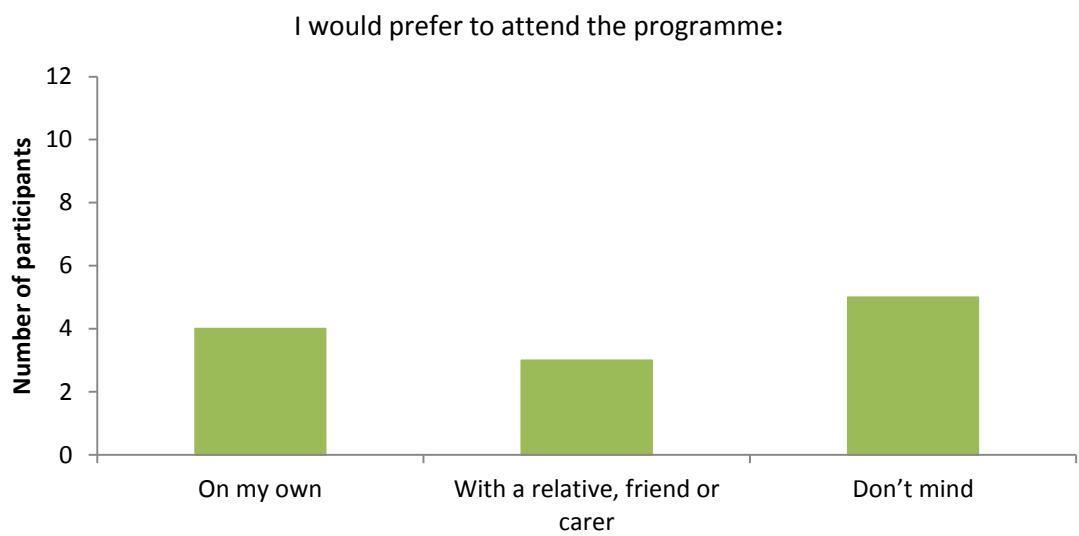


Figure 6.9: Frequency of sessions

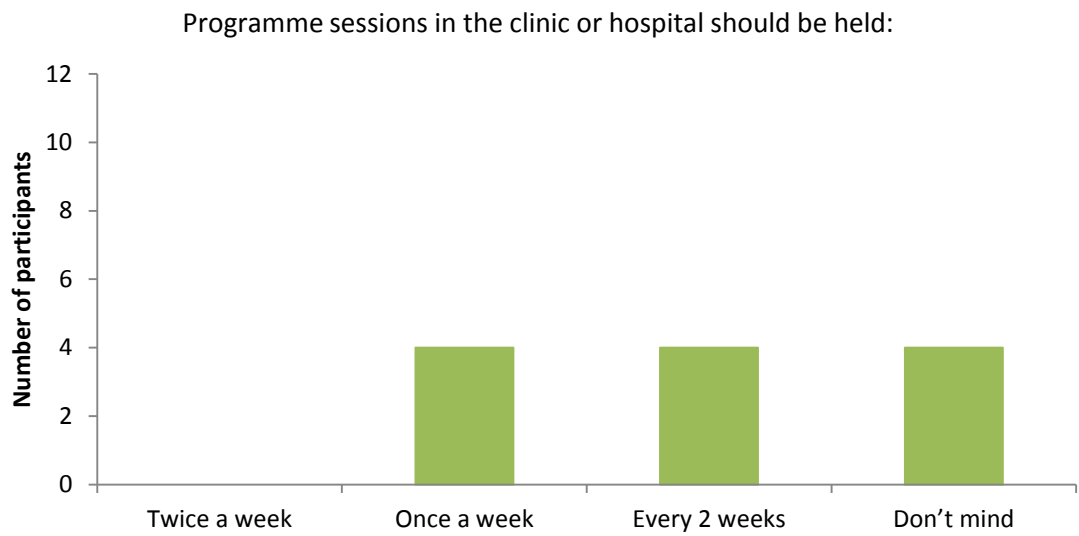


Figure 6.10: Delivery format

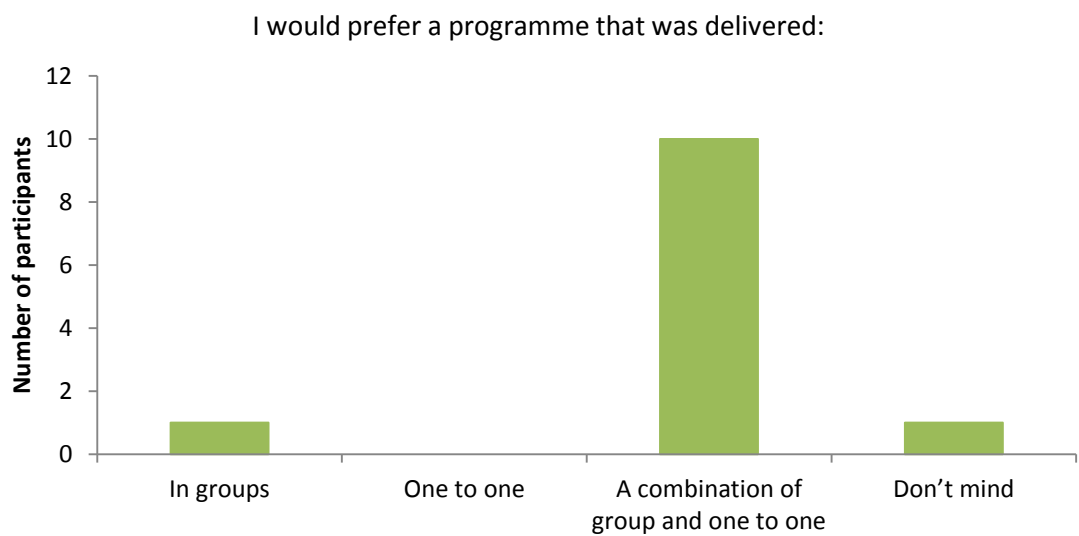


Figure 6.11: Session duration

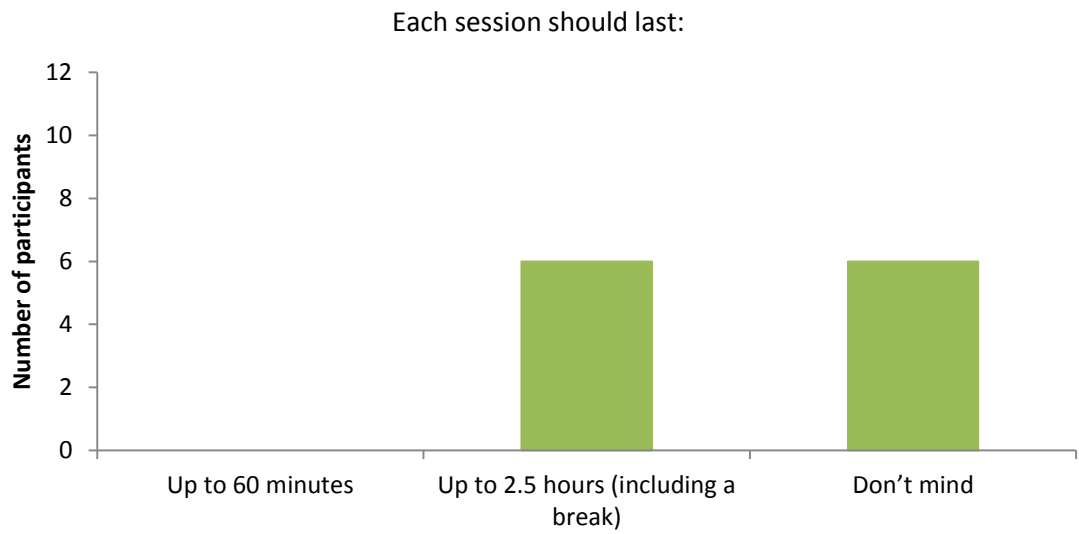
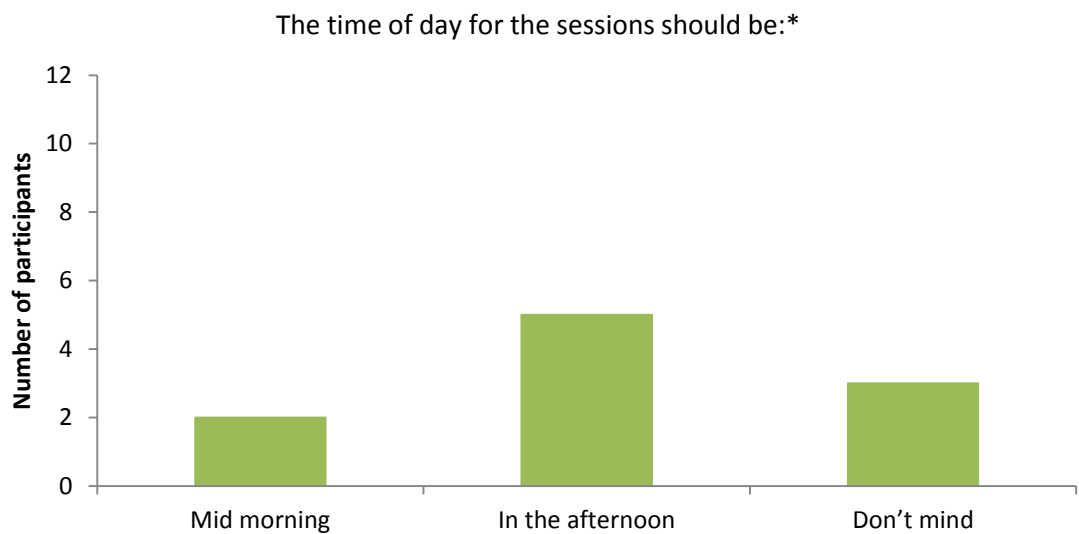


Figure 6.12: Time of day



**Two participants did not respond because they would be unable to attend either of these times as they are during the working day*

Figure 6.13: Session structure

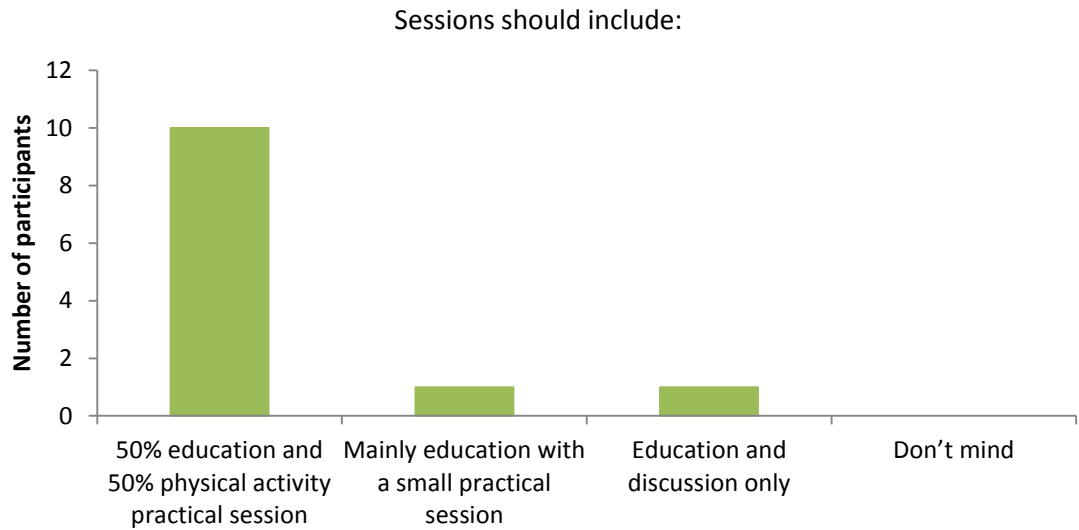


Figure 6.14: Programme tutor

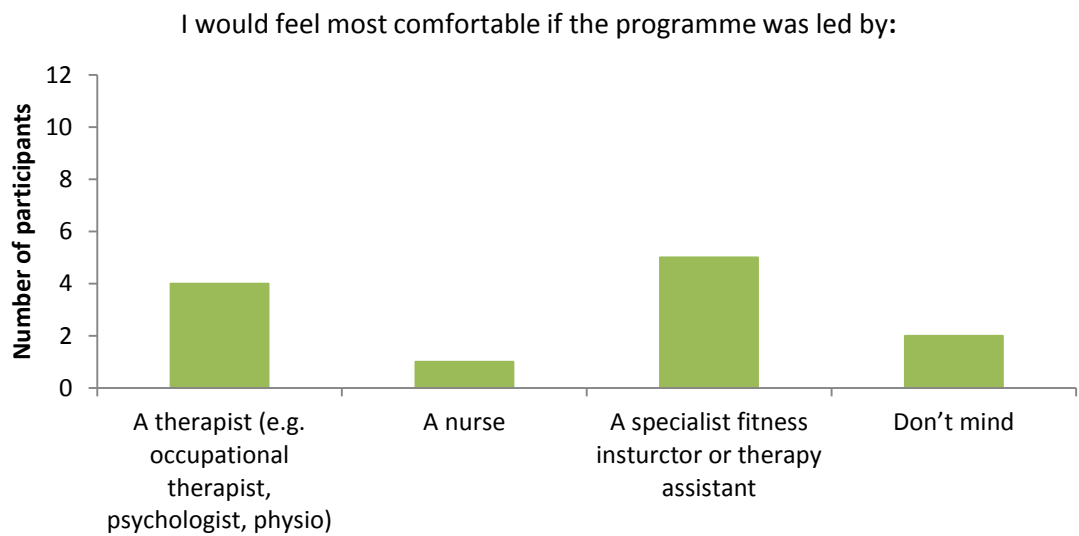


Figure 6.15: Inclusion of homework tasks

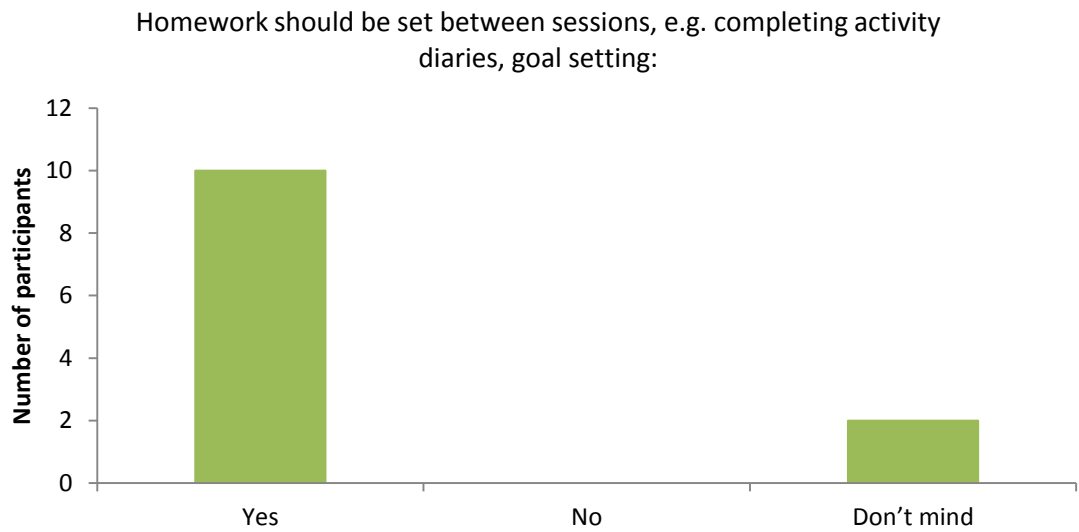


Figure 6.16: Programme follow-up session

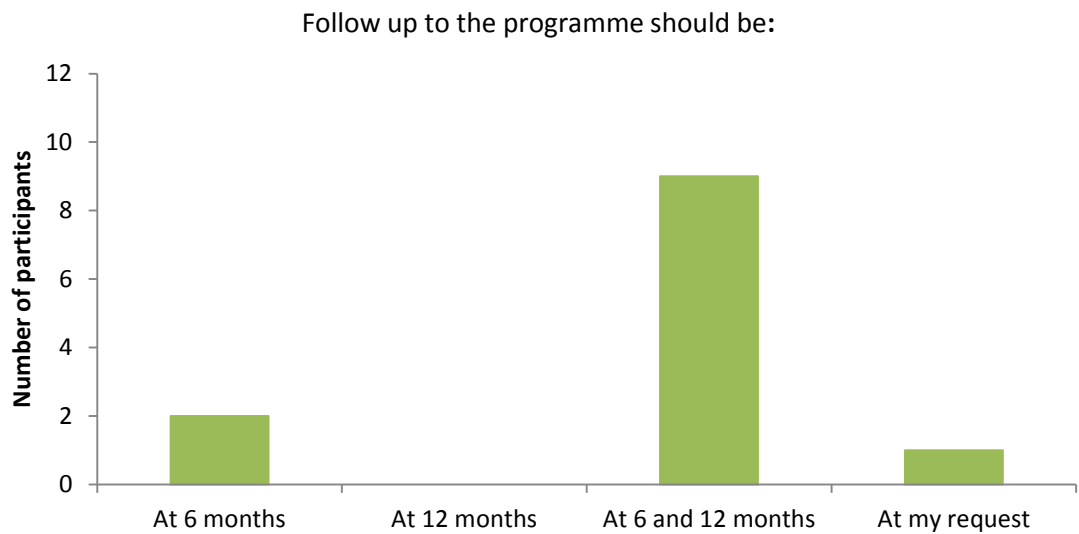


Figure 6.17: Format for follow-up session

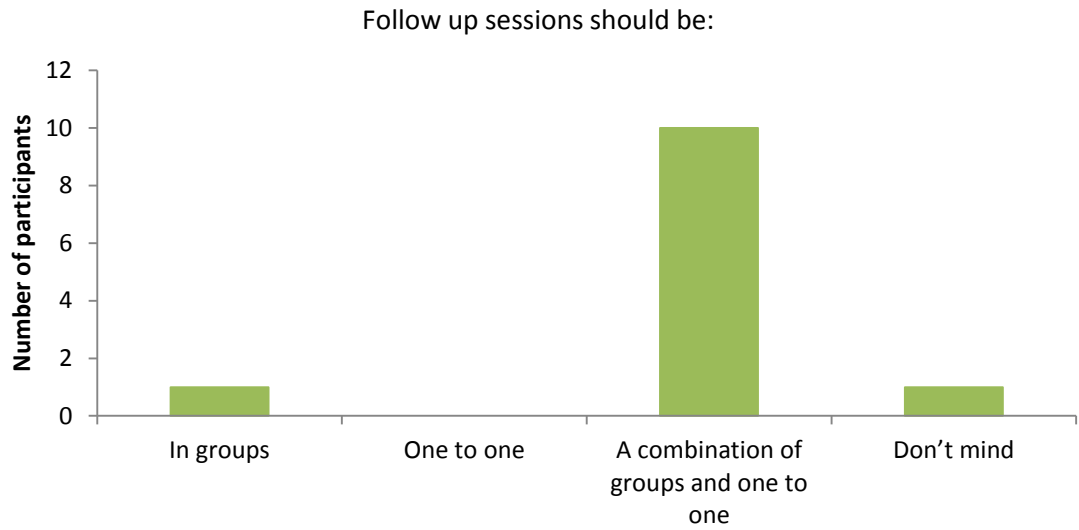


Figure 6.18: Delivery of follow-up session

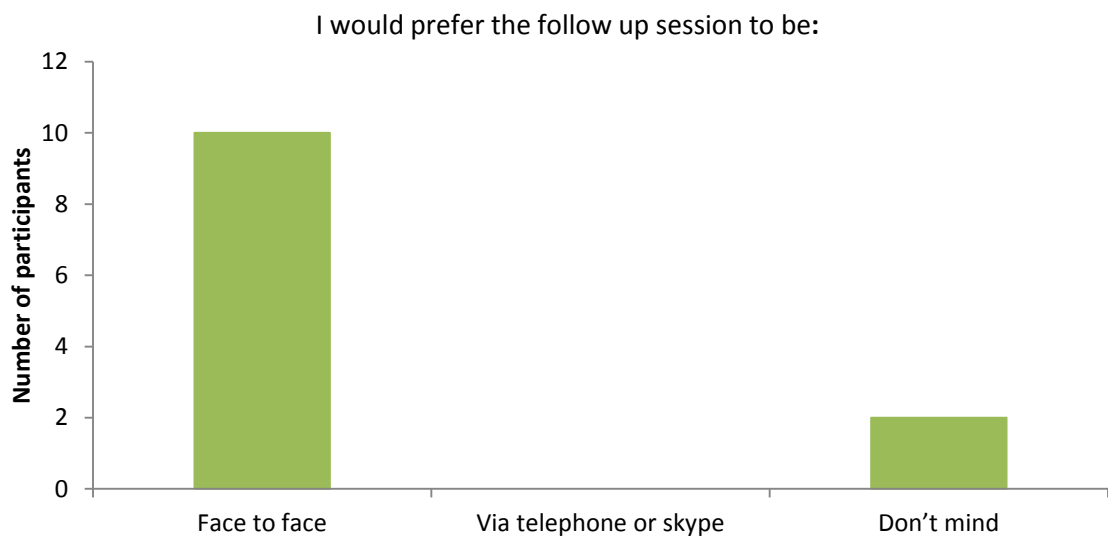


Figure 6.19: Access to professional support

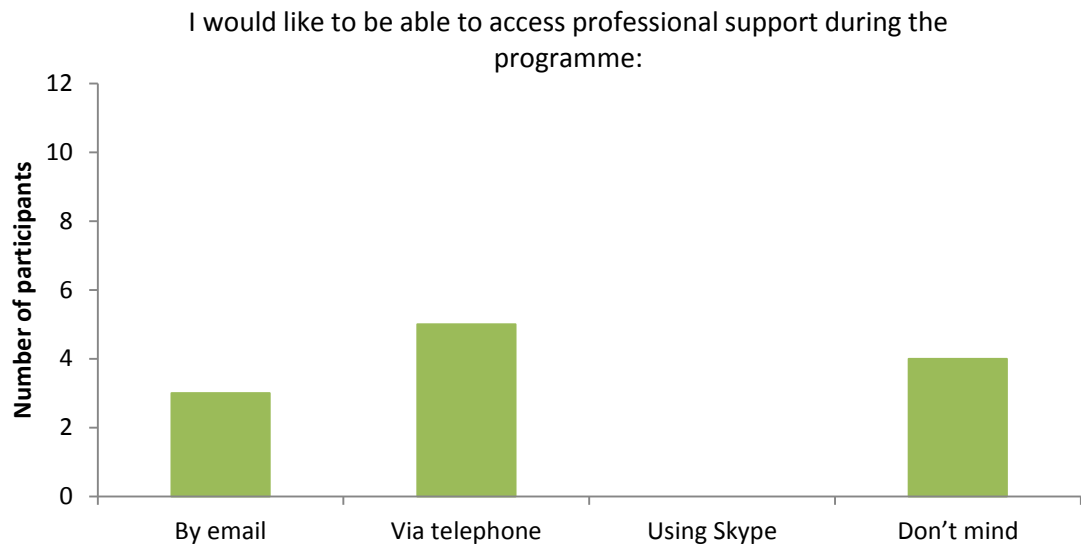


Figure 6.20: Format of support materials

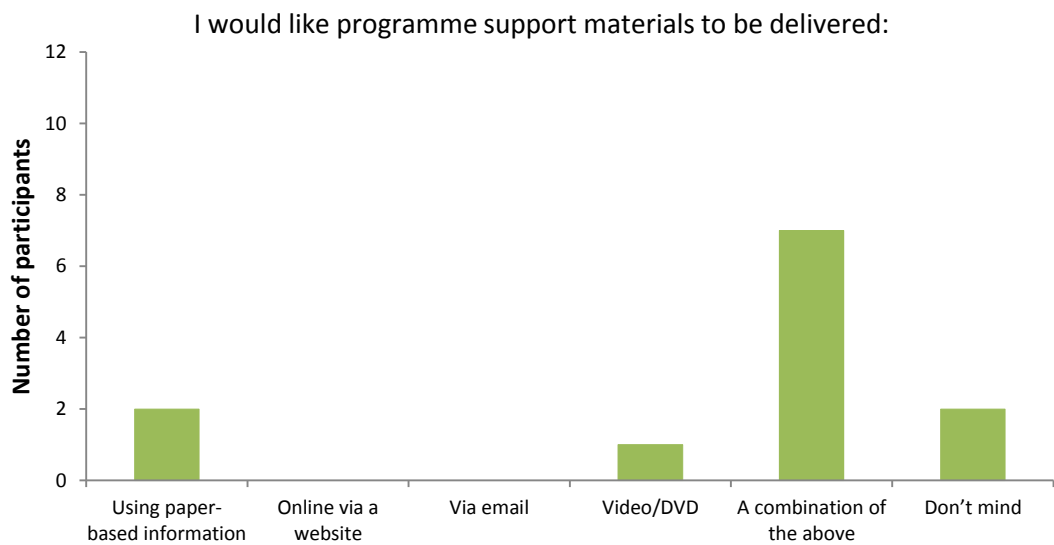
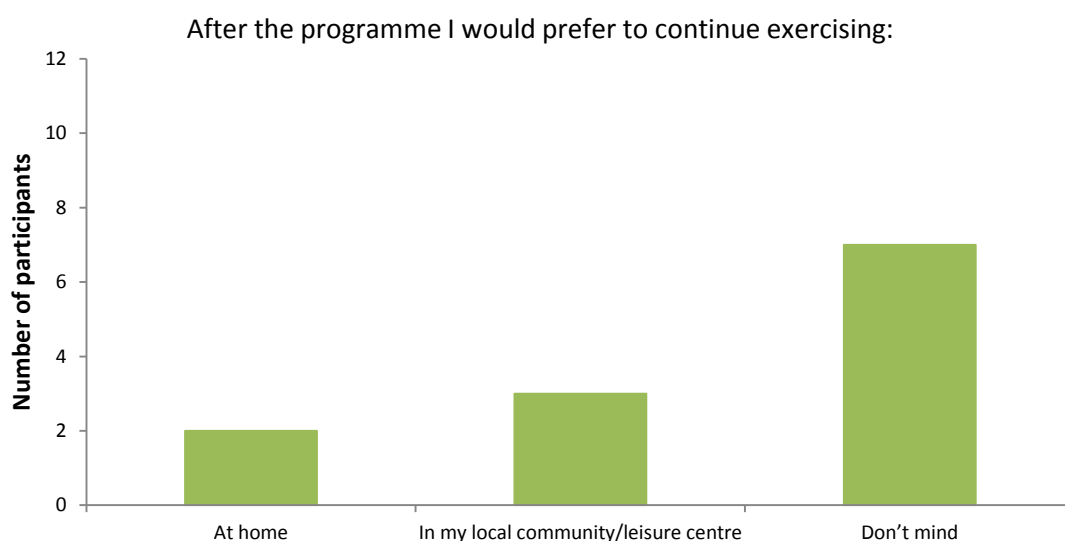


Figure 6.21: Long-term physical activity**Table 6.2: Content of discussion sessions**

The following education topics should be included:	Yes	No	Don't mind
Activity analysis and management	12	0	0
Goal setting (about physical activity)	11	0	1
Managing setbacks and problem solving	12	0	0
Physical activity education	11	0	1
Graded activity or graded exercise therapy	10	1	1
How to maintain physical activity in the long-term	11	1	0
Thoughts and feelings around physical activity and fatigue (CBT based therapy)	10	1	1
Sleep management	11	0	1
Mindfulness	11	0	1
Relaxation (various techniques)	11	0	1
Diet	11	0	1
Occupation and activity	12	0	0
Posture and positioning	11	0	1
Balance and prevention of falls	10	1	1
General education about fatigue and self-management	12	0	0

CBT=Cognitive Behavioural Theory

Table 6.3: Content of practical sessions

Practical sessions should include:	Yes	No	Don't mind
Demonstration of exercises	12	0	0
Practice/rehearsal of exercises	11	1	0
Stretching	11	0	1
Relaxation	11	0	1
Gentle seated exercises	8	1	3
A range of exercises to choose from	12	0	0

Table 6.4: Support materials

Programme support materials should include:	Yes	No	Don't mind
A presentation to support education topics	10	0	2
Programme information booklet/manual	10	0	2
Sheet of exercises performed in the session	11	1	0
Record charts, such as activity diaries, record for exercises	10	1	1
Relaxation materials e.g. CDs	8	2	2
Individual education topic handouts	8	0	4
Information regarding local exercise groups and facilities	9	1	2

6.7.1 Structure - format

Participants indicated a preference for a face-to-face programme either in groups or one-to-one, rather than following written or online materials. There was no consensus on the preferred duration for the programme, although most indicated they would prefer a programme of 5 weeks or more, rather than a one-off session or shorter programme. Whilst half of participants did not mind how long each session was, the other half would choose a longer session of up to 150 minutes. Participants commented that the optimum duration of the programme and programme sessions would depend on the content. There was no clear preference for frequency of sessions.

The majority of participants indicated that they would like an intervention to include education and practical sessions providing an opportunity to try PA.

Participants favoured face-to-face follow-up to the programme.

6.7.2 Structure - content

The majority of participants indicated that they were happy for the programme to include all of the education topics presented in the questions (table 6.2). However, four topics received one 'no' vote each out of 12 responses. These were graded activity/exercise therapy, how to maintain PA in the long-term, thoughts and feelings about PA and fatigue (CBT-based therapy) and balance and prevention of falls. Several participants were not familiar with GET therefore the moderator explained this. There was discussion about restrictions on participation for certain activities, particularly relating to foot pain as a limitation for walking.

Participants felt that most of the practical session elements were appropriate to include (table 6.3). The practice or rehearsal of exercise and the inclusion of gentle seated exercises received one 'no' vote each.

Participants largely agreed with suggestions for support materials. Items receiving a 'no' vote included a handout of exercises performed in the practical session, record charts and details of local exercise facilities. Two participants indicated they were not interested in relaxation materials. All participants indicated that they would like support materials to be available in multiple formats. It was suggested that presentation materials could be put on a DVD or website for patients to access after the programme.

6.7.3 Implementation

Participants indicated that referral to the programme should be from a member of their specialist healthcare team or via self-referral.

Preference for the location of the programme varied between community and hospital settings. For the majority of participants recruited from an inner city hospital available transport options may influence their decision to attend a programme, although they did note that this would depend on where sessions were held.

Two participants abstained from voting for the time of day that sessions should be held because there was no option for evening sessions. Both participants would be unable to attend sessions during working hours.

There was no clear preference between therapist and specialist fitness instructor to deliver a PA programme, although one participant felt that a physiotherapist might push them too hard. Other participants reiterated whoever delivers the programme must be respectful of RA and the impact it has on patients' lives.

6.8 Results: Part 2

6.8.1 Participants

Following initial recruitment via an advertisement on the Chartered Society of Physiotherapy interactive forum, five AHPs expressed an interest in taking part in the Bristol focus group. An additional two AHPs were recruited via snowballing. Two of these potential participants were subsequently unable to attend due to work commitments. Five AHPs agreed to take part.

Eight AHPs expressed an interest in attending the London focus group, but six pulled out the week before it was due to take place. The session was rescheduled to take place in Birmingham, as several AHPs reported that this would be more convenient for them. Of the original eight, only two were able to attend this session, but an additional two participants were recruited via snowballing. Four AHPs attended the session.

Seven physiotherapists and two OTs took part in the focus groups. Background information is shown in table 6.5.

Table 6.5: Part 2 AHP participant information

ID	Profession	Clinical role	Time since qualification (years)	Length of time working in rheumatology (years)
022	OT	OT clinical specialist	15	13
023	PT	Rheumatology clinical specialist, physiotherapy service lead	13	12
024	PT	Clinical specialist physiotherapist in rheumatology	20	15
025	PT	Specialist musculoskeletal physiotherapist	11	6
026	PT	Rheumatology specialist physiotherapist	15	10
027	PT	Physiotherapist in rheumatology	7	5
028	PT	Advanced physiotherapist practitioner in rheumatology	28	15
029	PT	Senior medical educator and rheumatology physiotherapist	28	5
030	OT	OT in outpatients in acute hospital	23	10

ID=participant identification code; OT=occupational therapist; PT=physiotherapist

6.9 Thematic analysis of professional focus groups

Five themes were identified following data analysis. These describe current practice, attitudes and beliefs of patients and HCPs towards RA fatigue, ideas for a new intervention, potential outcome and thoughts about long-term adherence (figure 6.22).

6.9.1 Theme 1: Current practice

6.9.1.1 Fatigue management

Participants reported a variety of ways in which fatigue was managed within their therapy services. For example, fatigue may be discussed soon after diagnosis in an early arthritis clinic or in patient education groups.

However, despite providing information soon after diagnosis it was felt that there was a lack of education in later stages of RA.

028: "... the early arthritis group are being well educated, I think, within this erm ... [early RA] clinic that we do, but it's from about seven months onwards, there's not an awful lot going on..."

Common fatigue management techniques that were used in current practice included activity planning and education about pacing activities. These were frequently supported by activity diaries to aid activity analysis and forward planning.

023: "... we find they quite often use it [activity diary] as a forward planner so they know that there's perhaps an event like a wedding or a choir practice or Christmas or something that they want to do, people are using it a bit more proactively to kind of have periods of relative rest before and after in order to achieve attending whatever event that they want to get to."

Diaries were also helpful for identifying barriers to PA.

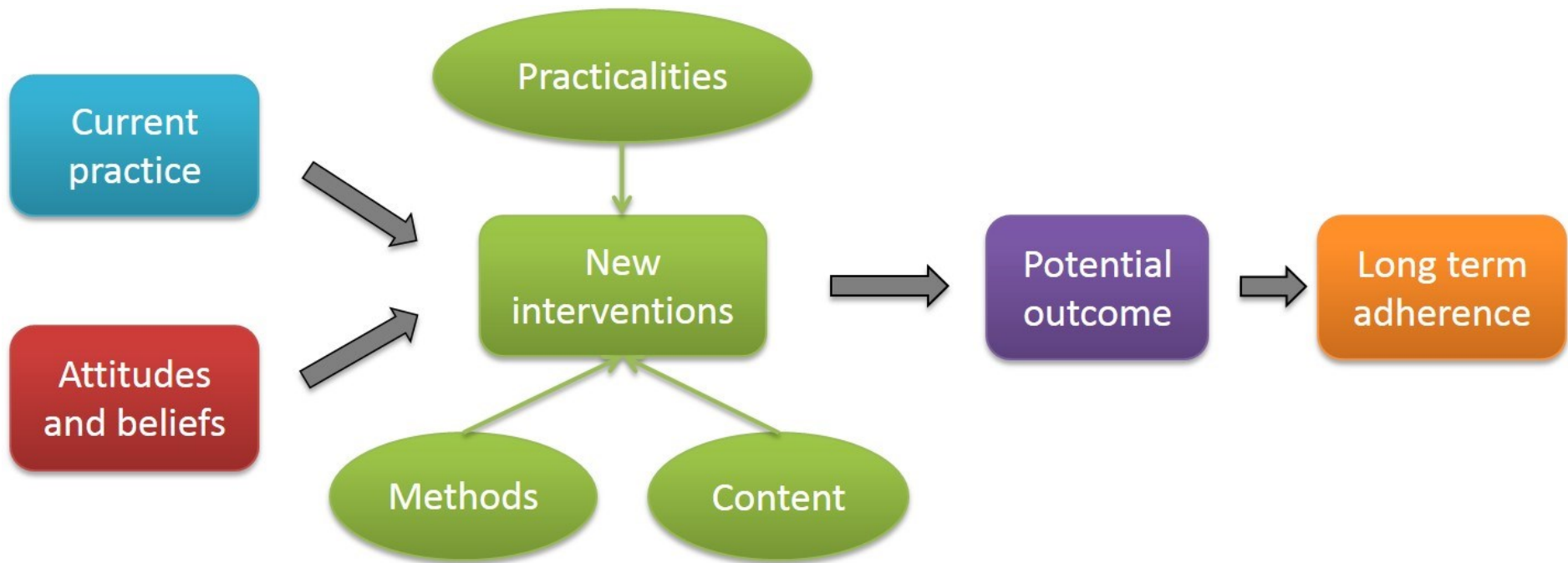
023: "They're really useful for identifying barriers actually because you'll go oh okay so there's lots of red on that, why is that, what can you change and what can't you and it helps unpick that side of things a bit more."

However, it was felt that diaries were only useful if the therapist had time to review them with the patient.

Participants reported that referrals for fatigue management received by the therapy department frequently, though not exclusively, went to OT rather than physiotherapy. Aside from pacing and activity planning, OTs saw patients for advice about other factors that might influence fatigue, such as sleep.

030: "..., we will get er, referrals for fatigue, to do with pacing, sleep hygiene and, you know, everything in that as well..."

Figure 6.22: Influences on and potential outcome of a PA intervention for fatigue management



It was suggested that referrals to physiotherapy were unlikely to be made for fatigue.

025: "I kind of wonder if some of the patients who would get the most out of it [PA intervention for fatigue management], are maybe the patients which are not the ones who are being referred traditionally by a consultant to us..."

Fatigue management was therefore not always seen as a priority by some physiotherapists. Although it may be relevant when considering long-term management of RA it was apparent that physiotherapists did not feel that they had time to tackle this within their therapy session. If physiotherapists were to see patients specifically for fatigue management, referrers would need to be made aware that fatigue is something physiotherapy can help with.

025: "... [fatigue] is something which needs to be tackled but I don't know that we [...] that's not what my treatment's aimed at, at the moment."

026: "... it's the priorities at the time like when you get the referral in, they've got pain in their hand and their wrist or whatever, and you're going to be looking at that, and the fatigue is always a background thing, so it's communicating with the referrers to say we can help fatigue as well, if we had a referral that said fatigue I'm sure we'd all cope with it, ..."

Nonetheless, it was felt that HCPs in general could still be better at managing fatigue.

022: "... as health professionals and this is my personal view is that we have a high tolerance to fatigue and it's accepted a little bit as part of the condition and actually we could do more to manage it"

6.9.1.2 Focus on function

Physiotherapy practice, including PA and exercise advice, usually focused on specific joint or mobility problems and improving physical function and overall fitness rather than fatigue management.

028: "...I give specific exercises and say, [...] our aim is to get you functioning independently and as physically fit as we possibly can..."

Advice aimed to highlight the benefits and safety of PA and exercise in RA.

024: "... [we] talk about the importance of them being active and that it's not going to do them harm and it's actually going to be good..."

For some participants PA advice was directed at restoring pre-diagnosis PA levels as they believed it would be unrealistic to expect more from patients.

025: "...someone who hasn't done the high, you know level of exercise beforehand, getting them back to that, it's not an achievable task"

However, others felt that it was even more important to encourage PA beyond pre-diagnosis levels for those who were previously less active in order to achieve health benefits of PA.

023: "... it's more relevant and more important that they're able to implement and integrate some level of exercise post diagnosis regardless of their level of activity and exercise before..."

Several services offered group exercise sessions for RA patients. The type of exercise included in these groups varied from walking, stretching and Tai Chi to specific progressive resistance training programmes.

030: "[group programme] is a nice introduction to exercise and graded exercise erm, because it looks at both a walking programme, it looks at stretch exercises, strengthening exercises, and Tai Chi."

Some group exercise and education classes made a link between PA and fatigue, but participants felt they could do more to address this.

026: "..., we have sort of a 40 minute circuit based exercise programme anyway and as part of the education component we do talk about physical exercise as being a way of coping with fatigue and depression and anxiety and so it's raised but I'm sure there's a lot more we could be doing for it..."

PA was often raised at the first appointment with a therapist as well as in group classes, but participants again acknowledged that they could do more to make a link between PA and fatigue management.

024: "I don't know how much I talk about them doing the exercise as a way of managing their fatigue, just about building up their stamina..."

6.9.1.3 Measuring outcome

Very few participants measured fatigue in their practice, with some expressing that it was very difficult to quantify.

028: "But it's difficult when it's so subjective, isn't it? [...] How can you quantify fatigue?"

Fatigue measures that were used included a fatigue visual analogue scale and the Bristol Rheumatoid Arthritis Fatigue scales (Nicklin *et al*, 2010b). Some participants discussed the use of timed sit to stand as a measure of endurance and whether this could correlate with a patient's fatigue levels. However, this was more commonly used as an indicator of physical function or lower limb strength.

029: "... I do measure er, sit to stand thirty seconds, sit to stand, which is, you could argue, is it a measure of endurance, fatigue, strength? Whatever it is, it probably encompasses a number of those things, but I'm using it more for measuring lower limb strength ..."

It was generally felt that outcome measurement was an area for improvement. Participants had considered additional measures including quality of life and better measurement of PA, for example, physiological measures such as percentage fat and muscle mass, or using the IPAQ (Craig *et al*, 2003).

022: "I think we could be better at it, and I think it's probably the one thing that we probably don't measure that we should measure is quality of life because I think it feeds directly into that."

029: "... the other thing I'd thought about was trying to get, when patients come for their yearly review, trying to get a measure of their physical activity within that review session [...], whether it should just be something like the IPAQ questionnaire of physical fitness sort of thing."

6.9.2 Theme 2: Attitudes and beliefs towards fatigue management and physical activity

6.9.2.1 Allied health professionals' perceptions of the beliefs and attitudes of patients

It was reported that many patients do not mention fatigue to their HCP.

030: "I also think that patients, that is fairly low on their list of, or they don't even recognise [fatigue] as a symptom so they don't report it so therefore they don't get referred through or they also don't think that there's anybody that can help as well."

It was also believed that patients would not think that physiotherapy could help with fatigue. In fact they may believe that PA or exercise could make their fatigue worse.

026: "... probably the patient as well wouldn't think of coming to a physio because they're tired, I think they would think the opposite ..."

Even where fatigue had been considered and incorporated as part of the physiotherapy treatment plan, participants questioned whether patients would recognise this as part of fatigue management.

024: "... we've formulated their treatment plan with them and with their goals in mind and we're taking fatigue into consideration but whether they would still say I've had treatment for my fatigue or whether they might think that, even though we think that we've incorporated that as much as we can."

Participants acknowledged that for those patients who did report fatigue it can be a major barrier to PA.

024: "... they set their action plan and they identify their barriers how they're going to overcome it but they come back time and time again saying I haven't managed to do it and it's fatigue that's stopped them doing it."

It was queried whether some patients experienced fatigue as a greater barrier than others due to less ability to cope with the same level of fatigue. However, it was argued that fatigue is complicated and that the role of health beliefs and psychosocial factors on the fatigue experience of these patients must be explored.

024: "I wonder whether sometimes the people who have more fatigue is that, [...] is their fatigue higher because they don't, they're not going to push themselves through fatigue at all, whereas actually some of the people who come in and their, they keep themselves at a higher fitness level because they keep going, despite fatigue. Is it that actually their fatigue isn't as high in the first place so they can do that or is it that they're happy to, or that they're able to push themselves despite their fatigue? Does that make any sense?"

023: Um. It's a lot more complicated than that, it's all around their culture, their gender, their health beliefs ..."

Another important barrier to PA was thought to be fear of joint damage.

023: "... a lot of people's fear avoidance is often around the fear of causing damage..."

Nonetheless, health beliefs, engagement and motivation were believed to vary according to previous pre-diagnosis experiences of PA.

030: "... [barriers] it does vary, I think, depending on a person's previous exercise habits."

Although for many patients being previously active might help engagement in PA, participants felt that some RA patients had a tendency to push themselves too hard. This may result in negative PA experiences or a pattern of over- and under-activity that contributed to their fatigue.

028: "Although I do find if they've been physically fit, initially they're really hard, because they ..."

027: They'll push themselves too hard, yes.

028: Yes, they want to go, go, go. Yes, they overdo it and then they get frustrated and then they lose heart."

6.9.2.2 Healthcare professional approaches to PA and fatigue

Definition of PA

Participants reported differentiating between PA and exercise when advising patients. Exercise was defined as an activity that would make you warmer and shorter of breath.

026: "anything that makes you a little bit short of breath or a bit warmer you can count as exercise..."

Many felt that exercise should be more than activities of daily living. As such, they would not count housework as exercise sufficient to contribute to someone's weekly exercise target.

029: "I think there was a study, wasn't there, that looked at housework, and was it enough ... was it counted as exercise, was it enough to strengthen you. But it wasn't [...] I think we should be differentiating between the two. One is just daily activities and isn't going to form part of your exercise ... hours that you need to get in within the week ..."

Using activities of daily living made it harder to control progression of PA or exercise.

027: "It's less easy to control, isn't it, whereas if you've got twenty repetitions of something one week you can make it twenty-two the week after, or whatever."

However, others felt that activities of daily living could be considered as part of a weekly exercise goal, as some might count depending on a patient's current fitness level.

026: "As long as they are feeling, as I say warmer and short of breath then obviously it depends on their fitness levels. Some people Hoovering it might be enough if they are particularly unfit and they're pushing themselves a little bit ..."

Beliefs about fatigue and approaches to fatigue management

Beliefs about RA fatigue and its management varied. One participant expressed beliefs about causes of fatigue that fit with a biomedical model of health. For example, fatigue is related to flare and may be explained by medical issues such as low haemoglobin levels.

029: "...the fatigue they feel with their rheumatoid, if they're in flare, is a different kind of fatigue to erm, the fatigue that comes on after exercise. So I think it's ... it's just interesting to see the difference between those two, and to say erm, yes, maybe when you're in flare you aren't going to feel ... we may not be able to do much about that kind of fatigue, I don't know, with exercise. Whether the medicines and medications need to control that kind of fatigue ..."

029: "... you've got to look into the cause of [fatigue]. [...] we look at their disease [activity] ... you know, their sort of, yes, cells and CRPs and haemoglobin levels, just to make sure that they're appropriate for our strengthening group..."

This initiated a discussion about whether RA needs to be well controlled from a medical perspective before initiating a PA intervention.

028: "... the fatigue levels, very often when their disease modifying drugs kick in, is their fatigue levels do go down, [...] they do tend to feel better in themselves and will then want to start to do a little bit more physical activity."

029: "The ones I tend to see that have poor fatigue are the ones that are still not quite ready for [exercise], because they've not quite got their disease under control ..."

However, others took a more biopsychosocial view and noted that fatigue may be influenced by psychosocial and lifestyle factors as well as disease processes.

027: "... patients, like you say, they can be ... have their disease very well erm, managed, but their fatigue level's really high, and sometimes that can be linked in to their ... how they feel about having this condition and that they're totally fed up ... we won't maybe say depressed or very low, and therefore they're not particularly motivated to do exercise, because they can't maybe exercise to how they did before."

028: "I mean, I've got people that are in full time work, single parents, doing all sorts of things, and their fatigue levels are really high, but then is that through disease or is that because of their ... their actual lifestyle."

030: "... obviously depression and anxiety come with their own fatigue elements as well."

There was a strong feeling that pain and fatigue are inextricably linked in RA and that these symptoms should be addressed simultaneously.

027: "I think the fatigue and the pain together, not necessarily fatigue differently to pain, but the two together ..."

This raised the question as to whether there is a need for a specific PA programme for managing fatigue. Some participants felt that it would be better to incorporate fatigue management into a general PA programme.

024: "...they very rarely present with just fatigue and no pain and so it's about, I think, pulling everything together so..."

MOD: So you think more as a physical activity programme for their RA?

024: Yeah, for the RA rather than just for fatigue, I don't think the two should be separated personally."

026: *"I can't see us doing a specific group just on fatigue. I think we would be bringing it in, highlighting it probably a little bit more in the group that we already run erm and it's hard to know whether there would be the demand for a whole group just to be concentrating on fatigue."*

The absence of evidence for PA for fatigue management was also noted.

029: *"... is there evidence for us to be able to say to patients, if you exercise, your fatigue will improve. I don't think there is, really, is there?"*

6.9.3 Theme 3: Ideas for new interventions for managing fatigue

Participants agreed that in principle PA was a good idea for managing fatigue. Having seen a summary of patient data from part 1 of this study, participants offered their thoughts about the practicalities of implementing an intervention, ideas about what should be included in a programme and suggestions for how these might be delivered.

6.9.3.1 Practicalities

Participants discussed various ideas and issues relating to implementation of a PA intervention in clinical practice. For some services implementing a new programme would be possible if the format was similar to traditional groups, but this would require careful planning that may be challenging.

MOD: *"Would that be feasible in terms of resources, staffing, and organisation?"*

026: *"I think it's diary management, I think that's really difficult for that and just because having, blocking out a chunk of time in the diary..."*

Participants thought that a group PA intervention could be justified from a management perspective, with the potential to save costs. Group sessions also had the advantage of offering peer support for patients,

023: *"It's probably more cost effective to manage this in a group because they're going to have potentially more in common than they are separate..."*

028: *"I think seeing them in a group is ... is so much easier, because there is the peer support ..."*

but participants echoed patient concerns that individualising group exercise can be challenging.

022: *"I think when you're looking at groups everyone is running at a slightly different level and that's always really difficult to manage within a group ..."*

Other challenges to delivery identified by participants included staffing and resource issues. Lack of staffing limited what could be delivered by some services.

028: "... in the Rheumatology department there's me, four days a week, running clinics is my main thing, so I couldn't physically [run classes]. I have no support whatsoever..."

Issues included lack of flexibility amongst staff to deliver evening classes.

027: "... ideally it wants to be later on in the evening, sort of six, seven, eight o'clock when people get home from work, but the staff don't want to wait around, if they're finishing at four they don't want to wait around 'til six, seven, to take a class."

Limited resources and space were identified as further challenges for delivery.

027: "we've got quite a good gym at [place]. We've got some okay equipment, but every evening it's cardiac rehab [...] So it's like, you can't get in the gym, only on a Friday, but who's going to want to come and exercise on a Friday?

028: And you've got to have the premises. [...]

029: ... or at least you've got to have access to somewhere, haven't you, where you can run these things."

Participants suggested putting forward a business case for more resources, but acknowledged that this was difficult.

029: "... you could probably make the case, a business case, [...] But it's an awful lot of effort and time to set these things up and prove the case, I think."

Programme length, session frequency and duration

Many participants expressed concern at the prospect of delivering a fourteen week programme, which was the upper end of the programme length favoured by patients.

They reported that traditionally group programmes would run for six weeks.

MOD: "... is there anything there that really raises alarm bells [...]?"

ALL: 14 weeks [laughing]

[...]

024: ... once a week for six weeks which is a slightly more traditional service delivery for groups ..."

One participant emphasised that an intervention needed to be long enough to see progress in order to encourage adherence.

029: "Ours is ten weeks, or ten sessions, [...] But I think you need enough time for them to see a difference if you want them to adhere to anything."

However, despite initial concerns, participants suggested that it would be feasible to run a programme over a longer period of time if the frequency of the sessions was altered. It was felt that this might also help to encourage self-management and promote independence.

025: "... if they start, so that they did a session with you for week one, two or three, and then you're not seen again until week six and then there's a three-week follow-up and a six-week follow-up to make sure that everyone is again doing the trouble shooting at that point and weaning down and gathering independence I can see you're putting in that same amount of intervention but you're spreading it over a period of time, that could work."

027: "So you may run it for a longer period of time but maybe not see them weekly, see them fortnightly..."

As well as concerns about the programme length, some participants were surprised that patients would want a two hour session.

024: "Two hours is quite a long time isn't it, I'd have thought, particularly if fatigue is a problem..."

However, one participant reported currently running two hour sessions for other patient groups and that these were popular with patients. It was acknowledged that if patients have to travel for sessions then two hours might be appropriate.

022: "... the [fibromyalgia] group that we run is two and a half hours and obviously they have significant fatigue. CFS, chronic fatigue service run 2.5 hours over six weeks, 2 hours over ... it's standard.

024: I must admit a lot of people travel don't they, so actually ...

022: They won't bother for anything less than two hours.

024: And actually the groups that we run that are an hour do feel quite rushed ..."

Programme follow-up

Most services did not offer follow-up to their current group education and exercise classes. One participant reported that they offered a follow-up class for their fibromyalgia groups.

022: "We do a follow-up group for fibromyalgia at three months and that's fairly well attended ..."

Others felt that there was demand for follow-up sessions but that they were difficult to organise.

026: "I think there is a demand for the follow-up I'm I've had quite a few comments saying when can we come back but it's just so hard to organise it all ..."

Time of day

Participants reported that the time of day that sessions were run was important to consider, particular for patients who are working. One participant reported offering morning, afternoon and evening groups for their education and exercise classes.

030: "... we've got a morning, an afternoon and an evening group running. [...] you just have to be able to vary it.

029: Because you want patients to stay at work, obviously ..."

Offering different options for patients required staff to work more flexibly.

027: "[...] we need to work a bit more flexibly and get [staff] to start at 10 o'clock and finish at ...

030: When I run my evening group I'll be working four 'til half nine. [...] It's how you make it work for both people."

6.9.3.2 Suggested content

Education

Education was considered a vital part of managing fatigue, helping patients to accept their condition and understand why PA is important.

023: "... if the person has not got a degree of acceptance of their diagnosis and their condition it's difficult to move forward and to simply add exercise into the equation without a baseline understanding of why it's important, I think is a really, a concept that we have to be clear about getting across."

Equally significant was the timing of education delivery. Participants suggested that patients were not able to process information too soon after diagnosis.

023: "I think a lot of people are too rabbit in the headlights when they first get the diagnosis and all they're concerned about is the medication or something that's going to manage the pain and it's not until much later that the fatigue and the long-term disease management becomes more of an issue and a concept that they can get their heads around so it is you know about the timing of it all, ..."

030: "... our education, we probably don't kick in until about six to seven months, really.

028: Yes, which is ideal though, because that's when they're ready to listen to the next stage."

Having reviewed the data from patient focus groups, there was a comment that general RA education should be included as well as fatigue and PA education.

026: "There is an education about rheumatoid arthritis which might have already happened but perhaps needs to be repeated."

It was felt that education about balance and falls was not important to include as this was not believed to be a major issue.

024: *"I'm quite surprised to see balance and prevention of falls in, in a way. [...]"*

023: *"I mean we don't relate those two quite so readily now, with DMARDs and biologics we see less of the kind of deformity and deterioration so it's not usually such a major issue."*

Conversely, managing setbacks, goal setting and problem solving were all considered essential topics.

025: *"... what to do in a flare, what kind of exercise, kind of what you were saying but that, you know how to manage the exercise levels when you're having a flare, [...]"*

024: *"The goal setting and the problem solving I think is key..."*

One participant also reported that mindfulness was very helpful for pain management.

023: *"... in terms of pain management techniques it [mindfulness] can be really useful if you can get people to engage with it."*

Graded exercise therapy

Most participants reported giving general options for exercise progression in their practice rather than using a strict GET approach.

024: *"...there's a range of progression for each one, so they start off with a baseline [...] and it gives examples of one modification so to make it easier than the baselines and a couple of examples of how they can progress them, ..."*

GET was thought to be useful for managing PA in RA. Those who used this approach felt that patients generally responded well.

027: *"... it's making sure they don't go mad on a good day, [...] they might think, well, today's a really good day so I'll do more, because yesterday wasn't very good and I didn't do anything. So again, it's the education of ... But once they use it and they know how to use it, it works well."*

Participants highlighted that application of GET for fatigue would necessitate starting slowly and building up to the target PA duration gradually to prevent negative experiences of PA due to exacerbation of symptoms.

027: *"... start these guys [fatigued patients] even lower than you would normally start somebody, because at the end of the day, what you want to avoid is that, I've done that and I've suffered from it so I'm not doing it again."*

Participants suggested that being able to see progress gave confidence and was motivating for patients.

024: "... they can see during the six weeks that they've been able to work through at least one progression usually [...] and that gives them quite a boost in terms of motivation for carrying it on after."

029: "I think they like to see the progression, that's what's really motivating..."

028: I think it gives them confidence as well."

There was discussion about how to implement a graded approach during a flare, with one participant questioning whether patients would be able to tolerate the required level of PA.

024: "... people with RA obviously have fluctuating inflammatory symptoms [...] so I don't know that you could be as regimented about it [GET] because then if they have a flare of their RA and you're still saying well you've got to this point and you've got to stick with that same level and that might actually be too much when they're in a flare."

Another participant argued that patients should still be encouraged to do something during a flare even if they dropped back a level with their PA.

023: "... but I think the kind of argument for not doing anything in a flare has changed considerably so I think it's important that they're still aware they're meant to keep as active as they possibly can [...] They may need to modify that baseline but not kind of drop it off altogether ..."

However, despite its advantages it was reported that GET does not work for everyone.

025: "And with all these things it's a person orientated thing, so you know it doesn't work for everyone."

Practical session

Participants discussed ideas about type of PA to address during the programme. One participant expressed that it should always be possible to find something that a patient could do to build confidence and reduce the fear of failing with PA.

026: "...pretty much every patient you can find an exercise however small or gentle for them to do even if it's not exercising that particular area but exercising their ankle instead of their wrist, you can always give someone something to build their confidence up ..."

However, it was felt that a specific fatigue intervention should include aerobic capacity and strength training.

029: *"I mean our group doesn't include aerobic capacity training, and I think that's a drawback. I think there needs to have aerobic and strengthening."*

Some participants considered it a good idea to offer a choice of exercises during the practical session. However, some participants felt that this would be difficult to manage in a group setting. They were concerned that patients would be unsure what to choose and might select something too easy or too hard.

025: *"I think getting them to choose whatever equipment they wanted to use, I think it's going to be difficult to manage."*

026: *"... people going to choose the [exercises] that are the easiest and therefore not going to be as relevant to them, or are they going to choose something that's going to challenge them too much, how do you keep a guide on what patients need to be doing..."*

Although one participant who had experience of offering choice remarked that patients enjoyed trying different options, they also believed that a choice of exercises made it harder to implement a graded exercise approach.

024: *"...they liked the fact that they'd been shown lots of different things and they felt that was more useful to take away with them after but it was harder to give them that graded exercise approach"*

Programme support

It was suggested that programme support should be provided through accompanying materials. Participants agreed that these should be available in a variety of formats. This might include traditional handouts or more interactive online materials and mobile applications ('apps').

023: *"...there are lots of different fancy 'apps' out there and some of them are really quite straight forward to use and ...*

025: *It's just having a reminder."*

Making use of technology may help people engage in behaviour change, for example, by enabling self-monitoring of PA.

023: *"we'll be able to use the Wi-Fi connection and access all the stuff that's out there to bring us into the 21st Century to get people to engage more with different elements of accessing exercise and fatigue management [...]"*

024: *... using people's phones to take pictures of them doing their exercises.*

023: *Exactly and we're going to video them and send it to them so they can use it to self-monitor."*

027: *"Using things like technology, [...] [app] sends you a message to say, you know, where have you been, what are you doing, have you done your exercises today, you know."*

However, some participants highlighted that many people do not have access to this technology, further justifying the need for materials to be available in multiple formats.

028: "...it's amazing the amount of people who are ... don't have a computer, even now, and it wasn't necessarily a certain age bracket, it was all over the place"

The use of multi-media raised concerns about resources within current services. One participant pointed out that they did not have the necessary technology, and another acknowledged that it required investment.

025: "multimedia we don't have that technology to follow it up"

023: "... it takes investment. We're being a bit resourceful at the moment and we're selling our gait trainer [...] but we're going to sell it and get some iPads"

It was highlighted that it would be important to consider data protection and consent issues when using email and other media resources, such as video.

023: "There's something around kind of consent and you know I'm sure there's data protection that it will have to be worked through"

Participants discussed whether there could be a DVD of the programme to provide further support for ongoing PA at the end of the intervention.

027: "It's whether or not you could then put your exercise and education onto your own DVD and give it to patients to do at home, once they've done their six, twelve, fourteen week session."

One participant who had previous experience of making a DVD reported that this was difficult to produce, with a large time commitment and other considerations such as language.

028: "I wanted to do a DVD, [...], but actually sitting down trying to do it is very, very difficult, [...] But then you can't produce something like that if you don't have facilities to change the language and it's how you're presenting and ... [...] I did a fitness DVD for one of the drug companies a couple of years ago, and for teaching them about eight to ten exercises it took three and a half hours to produce, and then three months later it went on the, you know, it's part of the booklet thing, and it's just very, very time consuming."

As well as physical support materials, participants proposed that support from expert patients should be considered.

022: "I certainly think with the support materials there's lots of physical materials in that, but what you're also going to need is your expert patient as well, that link, somebody to talk to"

028: "...the thing that we've found that was most benefit was actually getting some of the expert patients in..."

Additionally, participants pointed out that they often received requests for information or sessions for family members and carers.

022: "it does come up with other groups is that they always want the family sessions, so the family are educated, so that they can then support that person to continue..."

Rather than inviting family to current sessions, which would change the group dynamic, some participants reported that they would like to run a specific family and carer session.

023: "...we do intend putting it into a business plan in the future but again not as part of that patient experience but as a separate education kind of session for families and carers."

Other participants reported that although family members were invited to come to education sessions they rarely attended.

026: "We invite friends and family to our education bit and actually very few ever come, but they are invited, [...], they're welcome to the talk and they don't tend to come.

024: And they're invited to the education programme which we run [...] and occasionally there's a partner but again it's not very often."

6.9.3.3 Methods of delivery

Mode of delivery

Several suggestions were made for delivering an intervention using fewer resources. These included delivering education via a DVD and incorporating education into the exercise session.

027: "...you could look at running the exercise sessions in a group, and then doing your education via a more sort of multi-media kind of way, and then following that up whilst they're exercising."

029: "I mean, the other way you could run it is actually educate while you exercise. [...] so as people are exercising they come in in groups of two or three, and I stagger them through the afternoon, but the messages get delivered during the session ..."

Another idea involved interspersing face-to-face contact with telephone sessions, and using these to address barriers to PA.

022: "... maybe you have a week where you have face-to-face sessional time and then the next week it might be telephone follow-up, [...] so it doesn't always have to be that face-to-face stuff."

However, one participant felt that telephone follow-up might not work in practice.

024: "If it's booked into your diary and then you try phoning the patient and they're not there, and then what happens it gets put into ... on the to do list or do you give them the responsibility to contact you at a certain time. I don't know. I think in theory that works really well but I don't know in practice."

Who should deliver the intervention?

It was felt that someone with knowledge of RA should deliver a PA intervention for fatigue. Some participants suggested that physiotherapists would be best placed to do so as they had knowledge of PA.

026: "I think we [physiotherapists] are the best people to do it because we've got the knowledge of the disease as well the knowledge of the exercise"

Another participant proposed that any member of the MDT could deliver the education sessions with the practical exercise component led by a physiotherapist. An MDT approach may be useful to address complex psychosocial needs that might arise.

024: "The exercise part I think it needs to be physio and obviously for the education as well I think that should be MDTs, I think the nurse specialists, OTs and doctors as well to input into that"

025: "... you do need that MDT approach, you need people with those different skills to enter into it if you want to address those [psychological issues] because you know, hands up, when I can't do it."

Further training or referral to psychology may be necessary for more complex needs, although basic training would be adequate for simple psychological issues.

MOD: "So it might require some extra training?"

025: Extra training or, or someone else to deliver that element of that, of the course."

023: "... in some cases then psychology is appropriate but in others not so much, in others, in the education sessions that we deliver we can address that."

Other training needs identified included GET.

026: "I'd want a bit more training on it before I was to properly do a graded exercise programme."

Addressing motivation

Participants commented that patients' concerns about PA being something extra to fit into their day were normal even for people without a long-term condition. They acknowledged that motivation for PA was especially difficult to maintain with flares and other life events.

022: "... the patients are very keen to be active but find it an extra thing to fit in, that's such a normal response if you look at the general population as well"

030: "There's one motivational factor in getting people started, but there's the other motivational factor of keeping somebody in that habit of doing it, and in that routine and erm, flare ups, you know, come along, or left ... other life events just knock people sideways, and then it's getting them back into that"

It was also noted that motivation could be related to the priority given to PA.

022: "I'm wanting to know how keen are they, you know what is the priority they actually give to exercise?"

Participants emphasised that patients need to be active in the management of their RA and their fatigue right from the start of any therapy input to ensure a positive outcome.

026: "You need to get the patient to be an active participant and take responsibility from the beginning"

Various methods were proposed for helping to address motivation, including goal setting and building confidence, recommending the use of training buddies for motivational support and offering incentives to encourage PA.

024: "...finding out what their goals are and working towards them, and building their confidence with that."

025: "... to have a training buddy that's always a really positive thing to ensure kind of longer term people keeping up with exercise you know someone else to motivate you when you're not feeling it"

Reframing of negative thoughts into positive achievements was also suggested as a means of reducing patients' fear of failing with PA.

025: "... if they're pleased when they do the exercise as opposed to beating themselves with a stick when they don't manage to do it, that you kind of look at the times when you've done it, that kind of changes their perspective on whether they've actually felt they're achieving what they're doing, ..."

In order to maintain motivation it was important to recognise and address potential barriers. It was reported that motivational interviewing techniques could be useful in this regard.

022: "...for hand exercises and we used motivational interviewing where they had to keep an exercise diary and then we came in really hard on the barriers and actually that did, they did carry things through for up to 12 months afterwards [...]

023: Absolutely, it's troubleshooting the barriers before they happen.

022: Yeah, the barriers, because you think you've got a really good patient that seems very motivated and then when you unpick it all there are loads of barriers that are popping up that they didn't even realise."

Participants suggested that it would be particularly difficult to motivate patients with fatigue to undertake PA. It was reported that any change in fatigue was unlikely to be immediate and in fact PA may make fatigue and pain worse initially. This would make it difficult to sell PA for fatigue management.

025: "...telling someone that by doing more, and them actually feeling quite tired at the end of it, is going to have an effect, well it doesn't have an immediate effect..."

028: "...it's very difficult to motivate somebody, because they're not going to do it just because you want them to do it. They've got to believe in it, haven't they, and it's ... it's selling that, and when you're feeling tired and you're in pain"

As a result, a PA intervention designed specifically for fatigue management would require more education and reassurance than a general PA programme. Patients need to be persuaded that PA will make them feel better.

027: "So there is more education and reassurance. Slowly, slowly, and then start to build up."

028: "...they very often put down that they're too tired to exercise, and you then try and talk to them and explain that actually, when I'm really tired and I get home from work, the last thing I want to do is take the dog for a walk, but actually, once you have, you initiate things, you feel a lot better ..."

Participants discussed that PA can have an immediate effect on sleep, which might improve fatigue. Engagement and motivation was likely to be higher for these patients.

025: "And the best are the people who sleep really well afterwards [all 'um' in general agreement] and suddenly there's at least something in the cycle of fatigue that broken by an immediate..."

023: That's a positive yeah.

025: ... so there's an immediate effect and then they're kind of sold about..."

023: Investing more in it..."

025: Yeah, investing more in it and I think they're the ones which I feel that adopt it and will see it through a bit more..."

Some participants felt that the key to a successful intervention was in the delivery. While it was easy to promote a certain approach, it could be hard to ensure that patients received the intended message.

030: "..., it's all in the literature, is it's not so much the content, it's how you deliver the content that makes it effective or not. [...] even with a sort of CBT approach and erm, and lots of sort of motivational interview techniques and things, [...] some of [name]'s patients are coming back and they've got completely the wrong idea, and you just think [frustrated noise] er, because that wasn't the message they were given."

6.9.4 Theme 4: Potential outcomes from physical activity interventions for fatigue management

Overall, participants believed that PA could make a positive difference to fatigue.

029: "... you get a good fatigue with exercise, and ... and a healthy fatigue and tiredness with exercise."

Several potential benefits of PA were identified beyond improved fatigue, such as increased social participation, improved psychosocial wellbeing, and better sleep. Participants also noted that PA could improve self-efficacy and a sense of control.

022: "I think certainly as well with physical activity it is linked in with the social participation, so both as a person, so maybe the working mum or the mum that's at home, if you're more physically active you're able to participate in the tasks that your family are doing, that your children are doing, maybe working as well, ..."

024: "I would think reduced anxiety and depression and improved mood and feeling of control and self-efficacy."

026: "I hope they would have a better quality sleep after doing some exercise so if someone's struggling to sleep then it might help with that ..."

It was suggested that whilst managing fatigue with PA may not reduce the severity it might increase the amount someone can do at the same level of fatigue, hence reducing the overall impact.

024: "So they still think well we've got the fatigue but actually they're able to do more with that same level of fatigue but the fatigue doesn't necessarily get better."

Although participants generally supported the use of PA for fatigue management, HCPs should be aware of other forms of fatigue, for example cognitive fatigue that might respond to different management approaches.

030: *"I wouldn't necessarily use erm ... er, a physical activity intervention to manage a cognitive fatigue element. Erm, I'd be looking at more cognitive strategies really. Erm, er, you know, managing the environment, developing concentration, those sorts of things erm, to build stamina cognitively."*

6.9.5 Theme 5: Long term adherence

Participants noted that adherence to PA was difficult for most people, not just for those with a health condition. It was acknowledged that patients often found it difficult to continue exercise after a group exercise programme had ended.

029: *"I mean, it's hard enough to get [patients] to adhere even when they rave about how much better they feel, you know, we're all human, aren't we? It's that keeping them going with it afterwards."*

A PA intervention for fatigue management must emphasise the importance of long-term maintenance through education, with initial therapy input supplemented by encouragement for practice at home.

024: *"I think how to maintain physical activity in the long-term I think that's one of the key things"*

026: *"... they need the support in the beginning but they also need to be doing it at home as well and having a follow-up and support in the hospital."*

The importance of implementing strategies to facilitate ongoing PA was discussed. Participants reported various ways in which long-term maintenance of PA was supported. These included attending private classes and access to community based groups and PA initiatives.

024: *"...we do give them erm all the information about [community exercise scheme] which is run by [local council] and give them a booklet about all the things that are available"*

028: *"We've got Healthy Lifestyles, that's hospital based, that will do different things. So you could get a personal trainer"*

030: *"They do the [group programme] then they can get referred to the six week Tai Chi, and then they can pay."*

Payment for classes was also highlighted as a means of income generation for the trust.

029: *"It's income generation now, I think it's ... it's good as well from that side of things."*

It was reported that links with community PA and leisure services were often poor, with large variability in the standard of exercise professionals and regular changes to timetabling making it difficult to know what to recommend to patients.

028: "I don't know the standard of people, I don't have the time to go out and check everything. [...] The Asian community are doing really, really well, because they've got erm ... they've brought in people that are within their own little community that do exercises with them, [...] That is fantastic, but then the others, there isn't very much out there at all. [...] I'm trying to fit other people in to classes and ... I have had a look, and it's really difficult, [...]. As fast as something's available it changes the next month ..."

As a result, participants felt that improved links with these other services would be needed to ensure long-term continuation of PA.

It was queried whether the responsibility for delivering PA interventions for managing fatigue should be a multi-sector approach. This would similarly require improved links and better communication between the NHS and these potential partnership organisations.

023: "...is it our remit to be delivering all of it? Is it our remit to start this process off and then integrate that pathway back into working in partnership with community and leisure services? [...] it would be more of a clearly defined self-management partnership kind of working programme where it isn't entirely the responsibility or the financial bill of health to carry that from beginning to end ..."

Participants felt that it would be possible to train community exercise professionals to deliver long-term PA programmes for RA to follow on from therapist-led hospital programmes. In fact, one service reported that they were exploring this as a strategy to improve long-term adherence.

029: "... so what we're doing now as well as that is looking to make links with the local council to see if there would be ways in which we can educate fitness instructors out there in the community to provide a similar kind of service to what we do."

6.10 Discussion

This study explored the views and ideas of people with RA regarding fatigue and PA in RA and identified preferences for potential components of a PA intervention for managing RA fatigue (part 1). The perspectives of rheumatology AHPs were investigated and practical considerations for implementation of such interventions were discussed (part 2). Figure 6.1 presented a conceptual model of patient perceptions of the internal and

external factors associated with living with and managing RA, fatigue and PA, and their influence on motivation for PA. AHP views of using PA for fatigue management in RA were illustrated in figure 6.22. Both parts of this study are now discussed together to aid comparison between findings.

This study confirmed previous findings that the experience of RA fatigue is unpredictable and patients report receiving minimal professional advice (Hewlett *et al*, 2005). AHP participants acknowledged that fatigue management could be improved. While they believed that physiotherapists were capable of managing fatigue they felt this would require education of referrers to change referral practices, as fatigue advice was usually provided by OTs. Some additional training for AHPs in fatigue management, GET and basic psychosocial skills might also be needed, depending on experience and knowledge. Lack of confidence of HCPs with providing PA advice has previously been reported in the RA literature (Hurkmans *et al*, 2011) and has been identified as a training need (Lillie, Ryan and Adams, 2013). Previous research also reported that RA patients perceive a lack of PA knowledge amongst HCPs (Law *et al*, 2010, Law *et al*, 2013) or receive conflicting advice (Wang *et al*, 2014). Therefore it is important that persons delivering PA interventions are competent to do so.

This study confirmed that despite an awareness of potential benefits of PA, patient participants were unsure what exercises they should do, with fear of pain and damage to joints presenting a barrier to engagement with PA (Law *et al* 2010, 2013). These patient beliefs were recognised by AHP participants, and considered critical to engagement in PA. Whilst AHPs felt able to address these concerns with fatigued patients, it should be noted that they all had an interest in fatigue management, therefore may have had a better knowledge of fatigue than other rheumatology AHPs.

Patients' past experiences and beliefs affected their ability to live with and manage RA fatigue and influenced their motivation for PA. They struggled to establish a daily routine and therefore implementing regular PA was difficult. Nonetheless, those who had an opportunity to analyse and interpret their activity patterns with HCP support found this extremely useful. AHPs also reported this as a useful technique. Findings demonstrate overall agreement that enabling patients to identify and problem-solve barriers and explore potential solutions that are relevant to them would be important to include in a PA intervention.

Patients in this study confirmed that fatigue can affect PA experiences, with external demands contributing to role overload, as previously reported (Kaptein *et al*, 2013). Acknowledgement by two RA patients that PA could potentially improve fatigue adds support for a PA self-management intervention for managing this symptom. However, it was apparent that PA advice from HCPs was rarely linked to fatigue. Both patients and

AHPs reported that physiotherapy tends to focus on PA for improving fitness and function rather than for fatigue management. This may be partly explained by lack of evidence for the effectiveness of PA for this purpose, but also by limited knowledge of fatigue by some HCPs.

Findings from AHP discussions indicated that they generally supported the use of PA for managing fatigue, although they perceived potential barriers to patient engagement. These included the lack of an immediate positive response to PA, possible initial worsening of fatigue, and pain. They believed that highlighting potential positive outcomes, such as better sleep, and exploring patients' expectations at the outset was important to promote engagement.

Despite acknowledging potential benefits of PA for fatigue management, not all AHPs were convinced there would be sufficient demand for a specific intervention, particularly as it was not clear whether all patients were able to differentiate fatigue from other symptoms, such as pain. This may reflect the synchronous relationship between symptoms, meaning that they are often experienced simultaneously (van Dartel *et al*, 2013). Instead, they felt that boosting fatigue advice in education programmes may be sufficient. This belief could reflect a lack of awareness of the prevalence of RA fatigue. This might be due to lack of reporting of fatigue by RA patients, or because patients with fatigue may not attend physiotherapy if they believe it will worsen their symptoms. Of course, it is possible that a generic PA programme would be appropriate, particularly given competing demands on time and resources for both patients and AHPs. However, patients who experience fatigue as a significant problem might become rapidly disengaged if they are participating in an intervention with others who do not experience fatigue.

Patient participants and some AHPs expressed confusion around definition of PA versus exercise. This requires clarification to ensure that patients who are afraid of harm or who fear that they will fail with PA have more confidence. For example, given that participants reported that stiffness was affected by static postures, and that moving or changing position might reduce fatigue, strategies to reduce sedentary behaviour may be an appropriate starting point to reframe and introduce PA.

Pain is another recognised barrier to PA (Wilcox *et al*, 2006). Current findings suggested that this was influenced by previous experiences where PA has exacerbated joint pain. Consequently, patients reported reducing PA to avoid repeating this negative experience (fear avoidance). Fear of joint pain or damage to joints as a result of PA has previously been highlighted as a concern for RA patients (Law *et al*, 2010). The fear of failure described by patients in this study may be associated with this fear avoidance cycle. For some patients fear of failure was linked to difficulty accepting the life-changing

consequences of living with RA. Despite these beliefs, meta-analyses have shown that dynamic exercise programmes are safe and effective in RA, and can increase aerobic capacity and muscle strength, with a small improvement in pain and physical function (Hurkmans *et al*, 2009, Baillet *et al*, 2010, Baillet *et al*, 2012). Behaviour change interventions are required to address these PA-related cognitions, including negative beliefs and lack of motivation, that have been shown as determinants of PA behaviour (Larkin and Kennedy, 2014).

Patients would like help and support with managing psychosocial issues, such as low mood, anxiety and depression. This should be included in future fatigue management interventions. Whilst several AHPs also recognised the influence of psychosocial factors on fatigue, some appeared to take a biomedical view of causality, believing that RA disease processes, such as inflammation and muscle weakness, and other medical causes such as low haemoglobin, cause fatigue. This view does not encompass the complexity of fatigue and its potential aetiology (Hewlett *et al*, 2011b), which may result in the causal roles of personal, cognitive and behaviour factors being overlooked. This biomedical view also led to assumptions that RA fatigue is only experienced during flare or in uncontrolled disease, and therefore might only be managed using pharmacological approaches. However, previous research has indicated that fatigue can occur at any time, not only during a flare (Hewlett *et al*, 2005, Hewlett, Nicklin and Treharne, 2008). It is important that these beliefs are addressed so that psychosocial issues are not neglected by HCPs. A bio-psychosocial approach to fatigue management is required in future interventions (Hewlett, Nicklin and Treharne, 2008).

Although patients were aware of the need to self-manage, there was an apparent lack of knowledge of how to achieve this. Both AHPs and patients mentioned pacing, but patients indicated that they did not find this technique easy to apply. This may be due to lack of skills or insufficient understanding about how to implement pacing effectively. Patient participants indicated that they are often just given a leaflet or told to pace with little understanding of how to apply this in the context of their daily lives. Further education and clarification for patients would be helpful. HCPs also need to feel confident with training patients in pacing skills. Nonetheless, patients who had received more detailed one-to-one advice from an HCP and had a good understanding of the principles still found pacing difficult to implement.

Patient participants who used PA as a coping strategy reported feeling more in control of RA and fatigue. This might imply that enhanced self-efficacy for PA relates to improved fatigue management skills, supporting the use of PA as a fatigue management strategy. Whilst self-efficacy for PA has been associated with achievement of PA goals (Knittle *et al*, 2011) and higher self-efficacy for coping with RA correlates with less fatigue

(Riemsma *et al*, 1998), the relationship between self-efficacy for PA and coping with fatigue has not been examined. Further research is needed to determine whether there is a significant relationship between these factors.

Beyond self-management, patients in this study looked to others for support with managing their daily lives. Peer support was particularly valuable. Consequently, the majority of patients would prefer a group programme for delivery of a fatigue management intervention, providing an opportunity for shared experiences and vicarious learning. Peer support might also improve motivation for PA. The effects of social support and social networks on health status are widely recognised, with several social network theories seeking to explain the relationship between social systems and structures and the behaviour of network members (Berkman *et al*, 2000). Berkman *et al* (2000) proposed that the structure and function of social networks can influence social and interpersonal behaviour in several ways: through provision of social support; social influence; social engagement and attachment; and access to resources. They suggested that these behavioural processes can in turn influence health status, including psychological factors, such as self-esteem and self-efficacy, and health-promoting behaviours, such as PA or exercise. A study of 542 people with early RA noted a cross-sectional link between greater specific social support or stronger support network and less functional limitations and psychological distress (Demange *et al*, 2004). The concept of shared experiences, including peer modelling and vicarious learning is also a key tenet of SCT (Bandura, 1977, Bandura, 1998). These findings support the consideration of SCT as the theoretical basis for a PA self-management intervention for RA fatigue.

AHPs agreed that group programmes are useful for peer support and may be easier to implement in clinical practice. They believed that groups might be more cost effective than individual treatment. This supports the beliefs of some HCPs reported in chapter 5. However, lack of staff and limited resources reported by some AHPs may prohibit group sessions in some services.

Most patients supported the inclusion of a practical component within a PA intervention. Patients would like a choice of exercises, with options to accommodate different levels of ability to ensure that PA can be adjusted to suit individual needs. Some AHPs were unsure about offering choice as they believed this might be difficult to manage in a group setting, but others felt that choice was important for patients. HCPs delivering PA interventions for fatigue in other conditions considered patient choice and decision-making crucial for a successful outcome (chapter 5).

Addressing motivation was thought to be vital for managing PA. This suggests that an awareness of patient preferences for PA, such as type of PA, being outdoors or being creative, is important when helping patients select appropriate PA. This mirrors findings

presented in chapter 5. Similarly, highlighting physical and social opportunities, such as community exercise classes or identifying a training 'buddy', might encourage participation in PA, particularly in the longer term.

As well as valuing peer support, patients indicated that they would like expert advice during programme sessions for reassurance with PA and fatigue management. This would enhance confidence with PA. Therefore, someone with good knowledge of RA, fatigue and PA should lead the intervention. Patients indicated that this could be a HCP or a trained exercise professional. As in chapter 5, physiotherapists believed that they were best placed to deliver a PA intervention, with support from the MDT. Issues regarding professional boundaries discussed in chapter 5 were also evident. However, some AHPs felt that long-term PA could be managed by community leisure services. This would necessitate a multi-sector approach, requiring improved communication and collaboration between health and leisure services.

Some AHPs suggested using expert patients for delivering or supporting a programme. Evidence from the arthritis self-management programme suggests that lay-led programmes can be as effective as those delivered by HCPs (Lorig *et al*, 1986). A UK study of this programme delivered by lay tutors showed improvements in outcomes such as greater participation in relaxation and PA at four months, with similar improvements at 12 months, including less pain and fewer general practitioner visits (Barlow, Turner and Wright, 2000). However, this study did not follow up the control arm beyond four months therefore only within-group comparisons were reported at 12 months. Whilst lay tutors have the potential to be clinically- and cost-effective the feasibility of utilising this model requires careful consideration.

For some patients managing external demands, such as caring roles and responsibilities or employment issues, made it difficult to prioritise their own self-management and coping strategies. This has previously been identified as an issue in RA (Kaptein *et al*, 2013) and may be an ongoing barrier to engagement in PA and self-management programmes. Previous findings have also reported that RA patients of working age highly valued their work, prioritising this over other activities, including physical exercise (Feldthusen *et al*, 2013). The external demands of patients in this study led to some adopting stoicism as a coping strategy. Feldthusen and colleagues (2013) also noted that patients tried not to show fatigue at work and felt it important to keep up appearances.

It is evident from the findings of this study that employment issues have an important impact upon patients. Understanding and support from employers appeared to be highly variable. For those who did not have good support, juggling work and managing RA was particularly challenging, and taking time off to attend appointments during working

hours was often not possible. This was recognised by AHPs. Patients would want flexible delivery times for a PA fatigue management intervention, for example, evenings or weekends. However, delivering classes out of standard working hours would require flexible staffing. Whilst this may be difficult for many therapy services to offer, some do manage to provide evening group education classes. This is important to consider for future implementation of interventions, and may suggest a role for community-based services.

Time of day was important to all RA patients, regardless of their employment status. Generally patients indicated a preference for afternoon sessions, as it can take considerable time and effort to get going in the mornings. This is in agreement with findings from chapter 5, and is likely to reflect RA symptoms being worse in the morning (Sierakowski and Cutolo, 2011).

Time since diagnosis was an important factor for timing of intervention delivery. Whilst early preventative advice was considered useful and desirable, the need for ongoing advice and support for those with established disease was identified as lacking by patients and AHPs. Ongoing self-management support needs in patients with chronic disease have been highlighted in previous research (van Houtum *et al*, 2013). This cross-sectional study of 1,300 Dutch patients found that self-management needs were not related to disease duration. This has important implications for implementing self-management interventions in clinical practice to ensure that all patients are able to access support when they most need it.

Patients did not have a strong preference for programme length, session frequency or duration. However, input for between five and 14 weeks was preferred by more than half of the participants. AHPs initially had concerns about delivering a programme of more than six weeks duration. However, they were able to problem-solve this scenario and concluded that longer programmes could be delivered by adjusting the frequency of sessions. They suggested that this could also promote independence with PA, which may improve long-term adherence. Indeed, a previous review of maintenance of behaviour change following PA and dietary interventions in adults (including both primary prevention and chronic disease self-management interventions) noted that maintenance was more likely to be achieved if interventions were longer, although these authors suggested programmes of more than 24 weeks (Fjeldsoe *et al*, 2011). However, it has been suggested elsewhere that adherence to lifestyle- and behaviour-change interventions in musculoskeletal conditions is more likely to be associated with improvement in self-regulation skills and enhanced motivation for behaviour change regardless of session frequency or programme duration (Knittle, De Gucht and Maes, 2012).

Findings indicated that education was believed to be vital for fatigue management. Patients suggested that programme content should include a variety of education topics some of which have already been discussed. Other key topics included weight management, pain, managing fatigue in the workplace, goal setting, problem solving and managing setbacks. The AHP group discussion recognised that the way in which information and education are delivered can influence intervention outcomes. This is supported by the literature recommending that patient education should be based on psycho-behavioural approaches (see chapter 1). Although CBT was mentioned in this study, specific techniques were not described.

GET, as recommended by HCPs in the interview study (chapter 5), was also discussed by AHPs. They agreed that starting at a low level of PA and slowly building on this baseline was important for introducing PA to patients who experience fatigue. Patients in this study would also prefer a graded approach.

Patients and AHPs thought materials to support programme content would be useful. Patients would like a variety of formats to suit different preferences and learning styles. Suggestions included DVD, online and paper-based materials. Information for family, friends and employers was also identified as desirable. AHPs emphasised that producing multi-media materials required considerable investment, both in terms of time and resources. This must be accounted for when developing new materials for future interventions. However, mobile technology including mobile applications were recognised by AHPs as potential tools to aid behaviour change, acting as prompts and enabling self-monitoring of behaviour. A recent review identified modest effects for mobile technology for promoting PA, but suggested that the emergence of a wide range of novel and engaging interventions shows potential (Bort-Roig *et al*, 2014).

Other considerations highlighted for implementing a PA fatigue management intervention included choosing appropriate outcome measures. AHPs did not routinely measure fatigue and many were not aware of a suitable measure. This reiterates findings from the interview study (chapter 5) that HCPs find outcome measurement challenging. Where possible, future intervention design needs to identify appropriate, easy-to-use outcome measures.

6.10.1 Strengths and limitations

The small number of participants included in this study might be criticised as not representative of the broader patient and AHP populations. However, this was not the aim of recruitment. Instead patients were sampled to include a range of age and disease duration, and AHPs to include those with more than two years rheumatology experience. This enabled access to a variety of patient and AHP experiences and beliefs about living

with and managing fatigue and PA. It was intended to sample for gender but 50% of patients recruited were male which is more than would be expected in an RA population (30%: Crowson *et al*, (2011)). This may in fact be a strength of the study given the tendency for under-representation of men in PA trials in RA (Vervloesem *et al*, 2012, Nordgren *et al*, 2014). It is important that men's views are taken into account when developing new interventions as they may have differing support needs and coping styles (Flurey *et al*, 2015).

Patients were not stratified according to self-reported fatigue therefore it is not known whether a broad range of fatigue experience was included or not. All patients participating in the study reported that they had experienced fatigue since their diagnosis but the level was not measured.

Recruitment for one patient focus group was from a rheumatology clinic linked to a research-intensive department with a focus on fatigue. This is likely to impact on the overall patient experience as they have greater exposure to information and research relating to RA fatigue. On the other hand, the second patient focus group was recruited from a clinic that had relatively little involvement in research. It is hoped that the views of these participants might represent a more naïve perspective of fatigue and its management in clinical practice. Similarly, two AHPs worked within the research-intensive clinic and other AHPs who participated in this study are likely to have had a specific interest in PA and/or fatigue in RA. Their views may suggest a greater awareness of current issues in this field than other rheumatology AHPs. As discussed in chapter 5, recruitment relies on voluntary participation. Time and work-load constraints can present a major barrier for HCPs to prioritise attendance at a half day event during the working week, particularly if the topic is not their specific area of interest.

The study involved focus groups, enabling participants to share experiences and debate particular questions while reflecting on their own experiences (Kitzinger, 1995). This allowed new ideas to be generated that may not have come up in a one-to-one interview and is a strength of this study design. Furthermore, the workshop format in part one enabled presentation of a large amount of data, which could be discussed whilst gathering interactive feedback in real time. This allowed patients to discuss and debate questions or answers and prompted additional thoughts and feelings about potential format, structure and content of a future PA intervention for fatigue management. These issues may not have arisen during the focus group discussions.

It is often recommended that researchers should aim for homogeneity within a focus group to maximise discussion of the shared experience (Kitzinger, 1995, McLafferty, 2004). For the patient groups this was achieved through a shared experience of RA and fatigue. The AHP group was homogeneous in that all participants worked in

rheumatology. It could be argued that the inclusion of different professional groups (physiotherapists and OTs) caused heterogeneity. However, the range of professions allowed the group to explore different perspectives (Kitzinger, 1995).

In part one of the study the candidate and focus group note-taker introduced themselves as researchers, rather than physiotherapists, so that they were not associated with the clinical team. It was felt that this allowed patients to talk openly about their experiences without fear of offending or expectations of clinical knowledge or advice. However, for the AHP focus groups, although the candidate and note-taker did not explicitly disclose their professional background, some participants already knew that they were physiotherapists.

Transcripts were independently analysed by members of the supervision team. One patient focus group transcript was analysed by a PRP (Maria Morris) and a supervisor (Nicola Walsh), and one AHP transcript by another supervisor (Fiona Cramp). Findings were discussed with the supervision team to enhance rigour and improve the quality of the research through minimising the chance for researcher bias (Meyrick, 2006).

6.11 Conclusions

Overall, participants in this study supported the use of PA for managing RA fatigue. A range of issues were discussed and preferences for the structure and content were identified. Patients and AHPs agreed that delivery of PA interventions should be face-to-face in groups providing peer support. A practical PA component must be tailored to suit individual needs. Key education topics were identified, including GET, weight management, pain, sleep, motivation and managing fatigue in the workplace. Practicalities relating to implementation and delivery raised concerns relating to timing, duration and frequency of sessions, but on the whole participants believed that these could be overcome.

Patient and AHP perspectives regarding barriers and motivators for PA and concerns regarding implementation and delivery were taken into consideration during programme development. This is presented in Chapter 7.

Chapter 7: Developing a physical activity intervention for managing fatigue in rheumatoid arthritis

Previous chapters have identified the need to develop evidence-based interventions for managing RA fatigue. Chapter 6 presented primary data relating to RA patients' and rheumatology AHPs' views of the acceptability and practicalities of using and implementing such interventions in RA, including preferences for format and content. Findings confirmed that fatigue management practices need to be improved. Overall, there was support for the development of a novel intervention to improve self-management of RA fatigue. This chapter details the process of designing and developing an intervention to manage RA fatigue using PA, based upon existing evidence. The rationale for the choice of theoretical framework and selection of intervention components is also discussed, and a draft intervention outline presented.

7.1 Background

7.1.1 Developing complex interventions to improve health

Interventions to improve health through a change in health-related behaviour, such as PA, are made up of several interacting components (MRC, 2000, MRC, 2008, Michie *et al*, 2009b). These behaviour change interventions have been defined as “co-ordinated sets of activities designed to change specified behaviour patterns” (p. 1, Michie, van Stralen and West, 2011). Such complex interventions often have several dimensions, including the number of and interactions between elements of the intervention; the number and difficulty of behaviours required by recipients and those delivering the intervention; the number and range of potential outcomes; and the permissible degree of flexibility or tailoring of the intervention (MRC, 2008). Development of effective interventions needs to follow a rational, systematic approach to identify and select appropriate components to bring about the desired behaviour change (MRC, 2000, Michie, van Stralen and West, 2011).

MRC guidance for developing complex interventions advises that intervention development should include three stages: 1) identify an existing evidence base; 2) identify or develop appropriate theory; and 3) model processes and outcomes (MRC 2008). It suggests key considerations, including the desired outcome; how change will be achieved; a coherent theoretical basis to the intervention; and the systematic use of

theory (MRC 2008). As well as considering the interacting components, designers need to take into account potential outcomes and effectiveness in clinical practice. The variability amongst recipients, providers, between clinical sites and over time must also be understood (MRC 2008).

7.1.2 Selecting a theory to facilitate behaviour change

A recent review of the use of theory in interventions designed to change PA and dietary behaviour in healthy adults noted large inconsistencies between application of theory and the effects of interventions (Prestwich *et al*, 2014). Of 109 studies included in the review, 56.3% were explicitly based on theory. However, it was noted that theory was rarely used to develop or evaluate the intervention, with less than 10% of these linking specific BCTs with theoretical constructs. The authors concluded that links between type of theory, mediating pathways and intervention outcomes must be more explicit. This reinforces the need to use a systematic method for designing theory-informed behaviour change interventions. Recent research in rheumatology has also recognised the need for an explicit theoretical basis for behaviour change interventions (Iversen, Hammond and Betteridge, 2010). Systematic review of the literature (chapter 4) indicated that theory is often lacking in reports of interventions to improve PA in RA. This finding supports other reviews in this field (Cramp *et al*, 2013a, Larkin, Kennedy and Gallagher, 2015).

A brief description of some common behaviour change models used in health interventions was presented in chapter 4. These include social cognition models (for example, SCT (Bandura, 1998) and the TPB (Ajzen, 1991)), stage-based theories (for example, the transtheoretical model (Prochaska and DiClemente, 1984)) and theories of motivation (for example, SDT (Ryan and Deci, 2000)). SCT has been recommended as a suitable theoretical basis for self-management and education interventions in rheumatic diseases (Iversen, Hammond and Betteridge, 2010, Zangi *et al*, 2015). Despite these recommendations, a review by Prestwich and colleagues (2014) in healthy adults noted that application of SCT may not increase intervention effectiveness for changing PA behaviour. Unfortunately SCT is often not applied appropriately, with studies of interventions that claim to be SCT-based only assessing one or two components of the model, such as self-efficacy and outcome expectancies (Abraham *et al*, 2008). This may explain the apparent insufficiency of SCT-based interventions for effecting medium to long-term behaviour change (Prestwich *et al*, 2014). Prestwich and colleagues (2014) recommended that links between theory, potential mediating pathways and intervention outcomes need to be made more explicit. As reported in chapter 1, an SCT-based intervention to improve self-management and exercise for adults with chronic knee pain has demonstrated significant improvements in exercise health beliefs and self-efficacy

that were sustained for 18 months following the intervention (Hurley *et al*, 2012). Long-term improvements in physical function were also noted, suggesting that appropriate application may in fact lead to maintained changes. However, although successful in changing PA-related cognitions, PA levels were not measured therefore associated changes in actual PA behaviour are not known.

A more recent review of behaviour change theories suggested that TPB-based interventions might be more appropriate than SCT for increasing PA in people with RA, (Larkin, Kennedy and Gallagher, 2015). TPB proposes that behaviour is determined by intentions to perform a behaviour, in turn informed by attitudes, beliefs and social norms and perceived control over that behaviour (Abraham *et al*, 2008). However, while social cognition models such as SCT and TPB may be useful to explain beliefs and intentions, they may not be sufficient to explain how to change these cognitions and hence to change behaviour (Abraham *et al*, 2008). This criticism applies to all social cognition models and has been referred to as the intention-behaviour gap (Abraham *et al*, 2008, Ogden, 2012). Problems with addressing this intention-behaviour gap may explain the limited evidence for the effectiveness of any of the social cognition models for eliciting long-term maintenance of PA, although this may also reflect limited availability of long-term follow-up data (Fjeldsoe *et al*, 2011).

Formulating plans to aid implementation of behavioural intentions, such as goal setting and action planning, has been suggested as a means of closing this intention-behaviour gap (Ogden, 2012). However, potential limitations to this approach must be considered. Firstly, it is possible that behaviour is predicted by past behaviour or habit rather than cognitions. In other words, it is possible that a person does not have volitional control over their behaviour. Therefore, habit formation and breaking habits might need to be addressed in order to attain the desired change in behaviour. Secondly, the extent to which a person feels a sense of choice regarding their decision to make a plan may be important. If a person has chosen to make a plan they may be more motivated to carry it out than if they are told to do so (Ogden, 2012). This concept is described within SDT (Ryan and Deci, 2000), whereby autonomous motivation relates to a person's sense of choice and personal importance when deciding to undertake a behaviour such as PA, rather than taking part because someone has told them to (controlled motivation). Therefore motivational strategies might also be required to bring about actual behaviour change.

Larkin and colleagues (2015) reported that practical application of TPB involves motivational and volitional strategies (implementation intentions). However, these are not integral to TPB (Abraham *et al*, 2008). While TPB-based interventions may change PA-

related cognitions it might not initiate change in actual behaviour. This change in cognitions but not in PA behaviour was noted in a recent TPB-based intervention in RA (John *et al*, 2013). Neither does TPB incorporate motivational strategies. Motivational interviewing grew from practice-based evidence and was initially linked with the stage-based Transtheoretical Model (Rollnick, Mason and Butler, 1999). However, it has since been linked to SDT (Markland *et al*, 2005). Therefore, an intervention based on a social cognition model such as SCT or TPB combined with implementation intentions and motivational strategies informed by SDT might be most appropriate for promoting PA in RA. Exploring theories of motivation in addition to SCT in the development of future PA or exercise interventions has been suggested previously (Knittle, De Gucht and Maes, 2012). A recent intervention to increase PA in RA incorporated motivational interviewing to address autonomous motivation for PA (Knittle *et al*, 2013). An RCT showed a significant effect on the number of patients meeting PA recommendations at 6 months following a 5-week intervention compared with participants in the control arm (Knittle *et al*, 2013) (see chapter 4 for an in-depth critique of this study). However, long-term follow-up data are not yet available making it difficult to fully appreciate the effect on continued engagement with PA.

This analysis suggests inadequacies in some common behaviour change theories. Therefore a more comprehensive model of behaviour change is required to recognise active components of behaviour change, identify strategies that are effective for eliciting change and match these to specific behaviours in the target population (Ogden, 2012). Use of a theoretical framework to aid the intervention development process offers a potential solution.

7.1.3 A framework for intervention development

Guidelines for improving reporting of non-randomised evaluations of behavioural and public health interventions state that theories involved in intervention development need to be explicitly described (TREND statement) (Des Jarlais *et al*, 2004, Boutron *et al*, 2008). While the MRC guidelines strongly advocate a theoretical basis and provide an outline approach to intervention development, they do not provide detailed guidance on how to choose or apply appropriate theory (French *et al*, 2012, Michie, van Stralen and West, 2011).

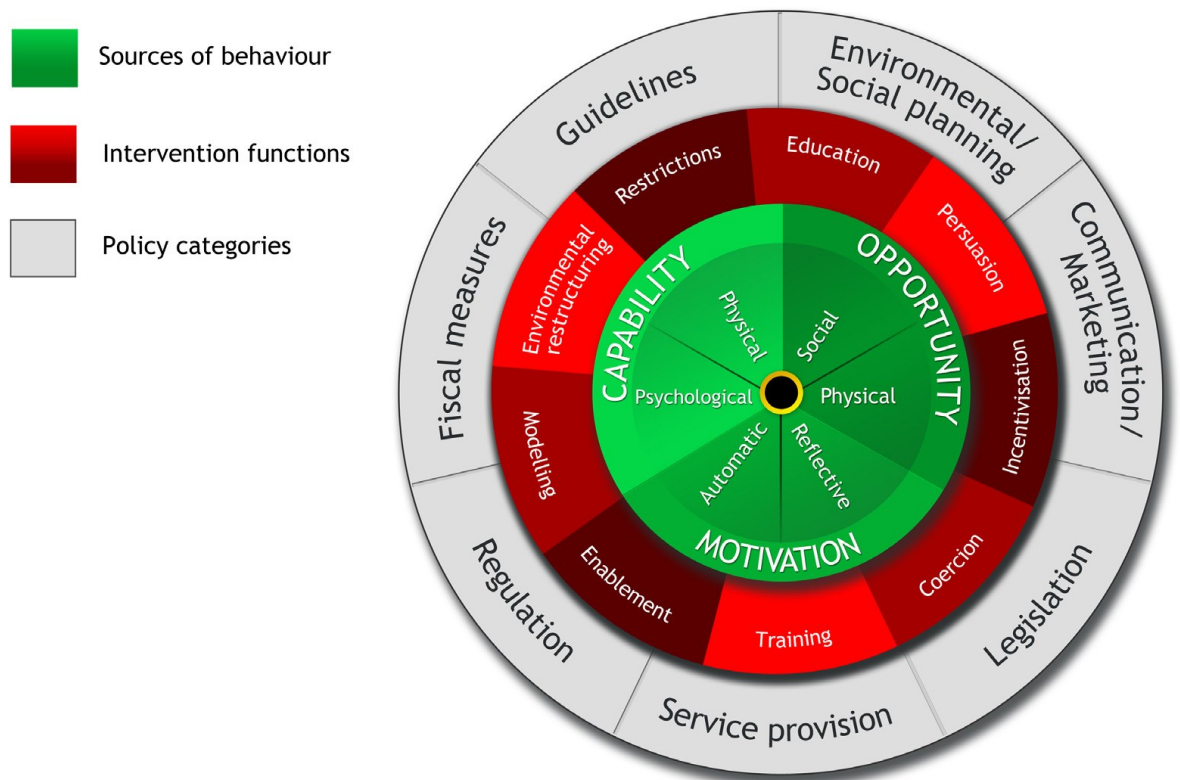
In recognition of the need for a comprehensive framework, Michie and colleagues (Michie, van Stralen and West, 2011) set out to review existing frameworks and to assess their usefulness according to their comprehensiveness, coherence and link to an overarching model of behaviour. Their review included 19 frameworks and identified nine intervention functions and seven policy categories. However, none of the existing

frameworks incorporated all functions or categories; therefore the authors concluded that they did not meet the criterion of comprehensiveness. Only seven were linked to an overarching behaviour change model and three met the criterion of coherence (Michie, van Stralen and West, 2011). For example, the Intervention Mapping approach described by Bartholomew *et al* (2011) provides some guidance for selecting theory-informed intervention methods and practical strategies. However, Michie, van Stralen and West (2011) noted that this framework did not meet the criteria for comprehensiveness or coherence.

Following this review a new framework was developed based on a synthesis of the 19 existing frameworks (Michie, van Stralen and West, 2011). The resulting framework is a three-layered model, referred to as the Behaviour Change Wheel (BCW) (figure 7.1). This links policy to behaviour via intervention functions and is based on an overarching behaviour system. The wheel aims to assist intervention developers in identifying important potential concepts required for behaviour change, as well as aiding designers in analysing target behaviours and characterising interventions and their active components (Michie, van Stralen and West, 2011). The BCW builds on approaches such as Intervention Mapping (Bartholomew *et al*, 2011) through provision of explicit methods for linking theory to recognised BCTs. This is an advantage of the BCW over existing frameworks included in the review by Michie, van Stralen and West (2011). Other advantages include provision of a comprehensive model of behaviour without the need for extensive knowledge of formal behaviour change theories, a wider range of intervention features and distinction between what the intervention is designed to influence (intervention functions) and how this might be achieved (policy) (Michie, Atkins and West, 2014).

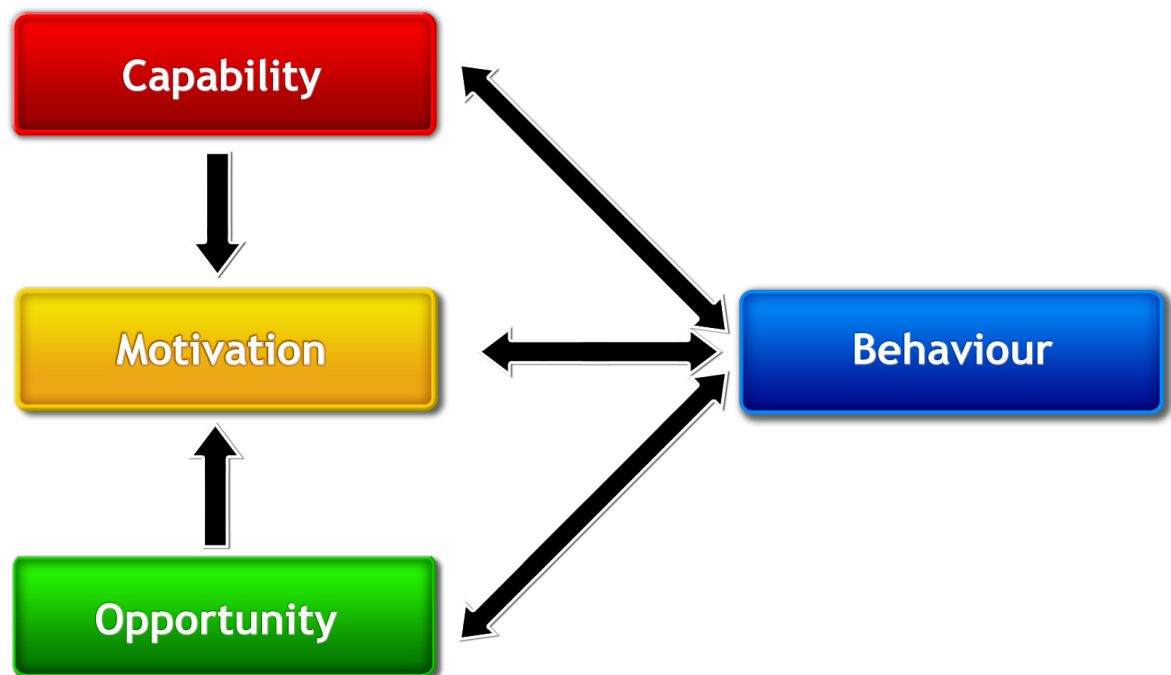
At the time of development of the current intervention the BCW presented the most comprehensive framework available to support intervention design. This choice of framework was supported by its clear links to other theory-based resources developed by international behaviour change experts, such as the Theoretical Domains Framework (Michie *et al*, 2005) and the BCT taxonomy (Michie *et al*, 2013), and its recommended use in UK national policy guidance for individual-level behaviour change interventions (NICE, 2014b). Details of the BCW components will now be described.

Figure 7.1: The Behaviour Change Wheel (from Michie, van Stralen and West, 2011, open access)



The sources of behaviour at the centre of the wheel describe the essential conditions that need to be met for behaviour change to occur. The central behaviour system employed in the BCW is the theoretically-based Capability, Opportunity, Motivation – Behaviour (COM-B) model (figure 7.2). This model suggests that a change in behaviour at a given time will require a change in at least one of the following components: the capability of a person to carry out that behaviour; the opportunity for the behaviour to occur; and motivation to perform the behaviour at that moment in time (Michie, van Stralen and West, 2011).

Figure 7.2: The COM-B model (Michie, van Stralen and West, 2011, open access)



Arrows indicate interactions between components of the COM-B model, and illustrate that an intervention that changes one component might result in changes elsewhere in the system

Michie and colleagues (2011) propose that each component of COM-B is made up of two aspects. Capability is composed of the physical and psychological ability required to carry out the behaviour. The opportunity to engage in the behaviour is afforded by the physical and social environment, including contextual factors such as time, resources, physical barriers, and social and cultural expectations. Motivation involves use of reflective processing for planning and evaluating the behaviour, and automatic processes triggered by emotion, impulse and reflex reactions (Michie, Atkins and West, 2014).

The COM-B model provides a simple starting point for understanding and explaining behaviour. This understanding can be further developed using the Theoretical Domains Framework. The framework contains 14 domains based on theoretical constructs identified from 33 behaviour change theories, and was developed by international experts in behaviour change (Michie *et al*, 2005, Cane, O'Connor and Michie, 2012). It was developed to assist intervention designers in selecting and applying appropriate theory from the large number of available theories, many of which have overlapping constructs (Michie *et al*, 2005, French *et al*, 2012). SCT, TPB and SDT were included in the development of the Theoretical Domains Framework (Michie *et al*, 2005). The framework has been linked to relevant COM-B components and can help deepen understanding of the target behaviour (Michie, Atkins and West, 2014). The Theoretical Domains Framework includes: knowledge; skills; memory, attention and decision processes;

behavioural regulation; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; intentions; goals; reinforcement; emotion; environmental context and resources; and social influences. Development of the Theoretical Domains Framework, with domain definitions and the theoretical constructs that they represent is described in Michie, *et al* (2005). The COM-B system and Theoretical Domains Framework combined provide a comprehensive theoretical model with which to understand behaviour change. Parallels with common behaviour change models are evident and it was felt that this intuitive system at the centre of the BCW would provide a thorough explanation of active components and mechanisms required to change PA. This was therefore used as the theoretical basis for intervention development described in this chapter.

The BCW proposes that in order to change behavioural components an intervention must perform certain functions. This is represented by the middle layer of the wheel (figure 7.1). These theoretically-based functions were identified via an extensive coding process of existing frameworks of behaviour change interventions (Michie, van Stralen and West, 2011). The outer layer of the wheel represents potential policy changes that might be utilised to put interventions into practice. Definitions of intervention functions and policies are presented in table 7.1.

Table 7.1: Definitions of intervention functions and policy categories

Intervention functions	Definition^a
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to increase the target behaviour by reducing opportunity to engage in competing behaviours
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)
Policies	
Communication/marketing	Using print, electronic, telephonic or broadcast media
Guidelines	Creating documents that recommend or mandate practice. Includes changes to service provision
Fiscal	Using the tax system to reduce or increase the financial cost
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental/social planning	Designing/controlling the physical or social environment
Service provision	Delivering a service

^aas defined by Michie et al (2011), p. 7

The BCW, centred on the COM-B and Theoretical Domains Framework, offers a comprehensive, systematic approach to intervention development based on established behaviour change theory (Michie, van Stralen and West, 2011). The authors identify limitations to this model including possible missing frameworks, the involvement of personal judgement and potential difficulties with its use, such as linking the framework to BCTs. An attempt has been made to minimise this last concern through the production of a step-by-step guide to using the BCW for designing and evaluating behaviour change interventions (Michie, Atkins and West, 2014). The method for intervention design employed in this study has been based on this guide.

7.2 Aims

To develop a theory-informed PA fatigue management programme for people with RA based on published evidence, HCPs' experiences of delivering similar programmes in other long-term conditions, and RA patient and AHP preferences and priorities for implementation and delivery.

7.2.1 Objectives

1. To develop theory-based programme content to support a change in PA behaviour with the main purpose of reducing fatigue impact in RA
2. To design programme sessions and develop resources required for delivery
3. To develop support materials to supplement programme content

7.3 Methods

In accordance with MRC guidelines, this intervention was developed using a systematic framework to understand the likely process of change in PA behaviour for adults with RA who experience fatigue (MRC, 2000, Craig *et al*, 2008, MRC, 2008). Theory was supplemented by evidence and data gathered in earlier phases of the research, presented in chapters 2 to 6. Programme manuals for existing PA fatigue management interventions provided by HCPs in the interview study (chapter 5) and for current research trials for a PA self-management intervention for chronic pain (Walsh *et al*, 2013) and a CBT-based RA fatigue self-management intervention (RAFT trial, www.isrctn.com/ISRCTN52709998) were also used to inform intervention development.

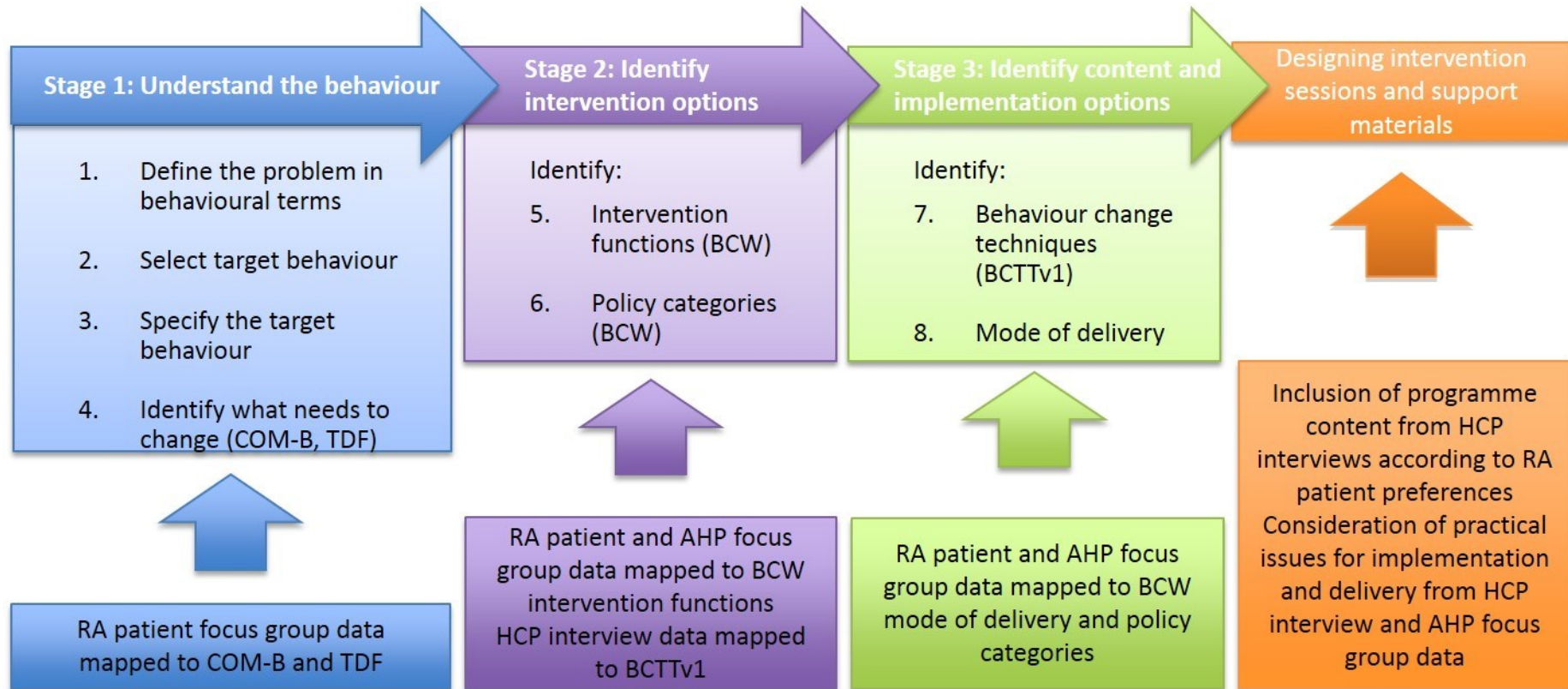
Intervention development consisted of the following stages:

1. Understanding the behaviour
2. Identifying intervention components
3. Identifying delivery options
4. Developing session plans and support materials

Stages 1-3 were based on the BCW. Each stage was divided into smaller steps comprising eight steps in total. A detailed description of this process can be found in the BCW users' guide (Michie, Atkins and West, 2014). This method used the BCW in conjunction with the other theory-based tools that are described within the relevant stages below. The resultant intervention design process is summarised in figure 7.3.

Figure 7.3: Behaviour change intervention design process, modified and reproduced from 'A guide to using the behaviour change wheel' with permission from the authors (Michie, Atkins and West, 2014)

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AHP=allied health professional; BCTTv1=Behaviour Change Technique Taxonomy version 1; BCW=Behaviour Change Wheel; COM-B=Capability, Opportunity, Motivation, Behaviour model; HCP=healthcare professional; RA=rheumatoid arthritis; TDF=Theoretical Domains Framework

7.3.1 Stage 1. Understanding the behaviour

The target behaviour was specified, defined and analysed using the chosen BCW theoretical framework (Michie, Atkins and West, 2014). This involved:

1. defining the behaviour problem in behavioural terms
2. selecting the target behaviour
3. describing the target behaviour
4. understanding what needs to change to achieve the target behaviour.

Qualitative data from interviews and focus groups presented in chapters 5 and 6 were mapped onto different domains of the COM-B model and Theoretical Domains Framework. This developed a comprehensive theoretical understanding of what might need to change in order for RA patients to modify their PA as a means of managing their fatigue.

7.3.2 Stage 2. Identifying intervention components

Having developed a thorough understanding of the behaviour in stage one, behavioural components were linked to selected intervention components. This process involved:

1. identifying intervention functions
2. identifying potential BCTs

Intervention functions have been described as broad categories that indicate ways in which an intervention can change behaviour (Michie, Atkins and West, 2014). The nine intervention functions classified during development of the BCW were education, persuasion, incentivisation, coercion, training, restrictions, environmental restructuring, modelling and enablement (Michie, van Stralen and West, 2011). A full description of these functions is provided by Michie and colleagues (2014). A consensus exercise with behaviour change experts has identified links between functions, COM-B components and Theoretical Domains Framework and these are also presented in the guide (Michie, Atkins and West, 2014).

Using the BCW guide, intervention functions that might effectively elicit a change in behaviour were selected. Each potential function was judged according to the following criteria:

- Evidence of effectiveness of the function for the given situation and population
- Relevance to the target behaviour, setting and population
- Feasibility of delivery of the function
- Acceptability to patients and professionals
- Affordability of implementation

Following selection of functions, possible BCTs that might be used to deliver these were identified. Michie and colleagues (2014) have mapped BCTs defined in the taxonomy (Michie *et al*, 2013) to intervention functions. BCTs have also been linked to the Theoretical Domains Framework (Cane *et al*, 2015) and techniques that might be effective for changing PA have been identified (Michie *et al*, 2009a). Potential BCTs for use in the current intervention were selected using these guides. The same criteria of effectiveness, relevance, feasibility, acceptability and affordability used to select functions were applied when choosing BCTs.

7.3.3 Stage 3. Identifying options for delivery and implementation

This step involved making decisions about how the intervention might be delivered and implemented in clinical practice, through selecting an appropriate mode of delivery and considering policy options to support this. The policies included in the BCW are communication/marketing, guidelines, fiscal measures, regulation, legislation, environmental/social planning, and service provision (figure 7.1). These are defined in table 7.1.

The mode of delivery was selected following consideration of the evidence, practical issues identified following review of existing literature and analysis of qualitative interviews and focus groups (chapters 2 to 6). Mode of delivery is a key element of the intervention and a fundamental part of intervention design (Michie, Atkins and West, 2014). As in 7.3.2, this was selected following consideration of effectiveness, relevance, feasibility and acceptability. The style of delivery was also considered during this stage, as didactic information giving has been shown to be less effective than psycho-behavioural approaches for improving outcomes such as functional disability in RA (Riemsma *et al*, 2004).

7.3.4 Stage 4. Developing session plans and support materials

Following completion of the BCW intervention development process, the theory-informed content and delivery options were combined with patient and AHP preferences and practical issues to produce a draft intervention. Individual session plans were written along with patient education materials. Further decisions about who should deliver the intervention, intervention format and setting, session frequency and duration, and fidelity were considered. A description of these intervention components is recommended for inclusion in research reports (Davidson *et al*, 2003).

The supervision team reviewed each individual session plan and accompanying support materials. In-depth discussions were held with PRPs to check the order of session topics and to help ensure that content and materials were readable, comprehensive and

useful. Comments provided by all team members were used to amend and refine the intervention.

7.4 Results

7.4.1 Stage 1: Understanding the behaviour

7.4.1.1 Defining the problem in behavioural terms

The chosen target group for this intervention were adults with RA who experience fatigue. The behavioural problem was variable PA levels in daily life that may impact on the experience of fatigue.

7.4.1.2 Selecting the target behaviour

The BCW guide encourages intervention developers to generate possible target behaviours that might bring about the desired outcome. For this intervention it was decided that individual recipients should choose the type of activity they would like to target, as it was felt important that they select an activity that is relevant to them. This decision was based on evidence from interviews and focus groups (chapters 5 and 6) suggesting that patient choice was important to facilitate engagement in PA. Providing choice should enhance autonomy, which is considered essential for intrinsic motivation in SDT (Ryan and Deci, 2000). A list of example target PA behaviours that patients might choose to modify is presented in box 7.1.

Box 7.1: Example target behaviours to modify PA in RA patients who experience fatigue

At home:

- Include activities of daily living as part of regular PA
- Reduce sedentary behaviour, e.g. advise on regular movement/change in position, avoid prolonged sitting/lying
- Encourage choice of enjoyable PA

Travel:

- Encourage active travel, for example, walk to the shops

Social support:

- Recognise the influence of behaviour of others
- Identify community support for PA, including access to local community facilities and resources
- Link with active RA patients and encourage a buddy system

At work:

- Identify possibilities for being active at work
- Reduce sedentary behaviour

7.4.1.3 Describing the target behaviour

As future intervention recipients should be encouraged to choose their own PA target, a specific target behaviour was not defined. Instead, PA in the context of daily living should be encouraged. Target behaviours should be described according to who needs to do what, when, where, how often and with whom (table 7.2) (Michie, Atkins and West, 2014) and future course leaders should support participants to specify their chosen behaviour in these terms.

Table 7.2: Description of target behaviours

Specification criteria	Example target behaviour	
	Reducing sitting time	Encourage active travel
Who	Adults with RA who experience fatigue	
What	Get up from sitting and engage in simple PA before sitting again	Walk or cycle for all or part of a given journey
When	At regular intervals during the day	Identify a convenient time, e.g. on the way to the shops, when going to/from work
Where	In any location or situation where prolonged sitting occurs	Any location where it is safe to use active travel
How often	At regular intervals throughout the day, e.g. every hour	When undertaking a journey and safe to use active travel
With whom	N/A	N/A

N/A=not applicable; PA=physical activity; RA=rheumatoid arthritis

7.4.1.4 Understanding what needs to change to achieve the target behaviour

Information collected through workshops with RA patients who had experience of fatigue, and focus groups with rheumatology staff who might deliver the intervention was mapped onto the COM-B model and Theoretical Domains Framework. This enabled identification of what might need to change in order for RA patients to engage in PA to manage their fatigue, and what would need to happen for this change to occur. This analysis and example data are presented in table 7.3.

Table 7.3: Combined COM-B and theoretical domains analysis

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur?	Example of evidence of need for change or support for inclusion
Physical capability	Physical skills	Know how to carry out desired PA	<i>017: "I can't walk very far."</i>
		Have physical strength and stamina to carry out desired PA	<i>019: "I actually used to go to the gym two or three times a week, but since [RA], nothing."</i>
Psychological capability	Knowledge	Develop an understanding of the principles of PA, including why it might help fatigue	<i>010: "...when I filled the questionnaire in a fortnight ago I didn't know what [fatigue] was."</i>
		Have an awareness of the benefits of PA for RA and potential benefits for fatigue	<i>024: "... [we] talk about the importance of them being active and that it's not going to do them harm and it's actually going to be good..."</i> <i>029: "... you get a good fatigue with exercise, and ... and a healthy fatigue and tiredness with exercise."</i>
	Cognitive and interpersonal skills	Have the mental stamina to plan and engage in PA	<i>011: "I didn't think there was any way of forward planning [PA] like that."</i> <i>014: "I don't know what pacing is, what is pacing?"</i>
		Develop self-management skills Develop skills to analyse, plan and implement PA	Encourage RA self-management through participation in education programmes (Luqmani <i>et al</i> , 2009, NICE, 2009)
	Memory, attention and decision processes	Improve ability to make informed decisions about PA, and help prioritise PA in daily life	<i>011: "... you want to get out there and you want to do stuff but then you become so tired and absolutely just can't do anything."</i>
		Notice and remember to undertake PA and reduce sedentary behaviour	UK PA guidelines: the amount of time spent sitting (sedentary) should be reduced (Department of Health, 2011)

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur?	Example of evidence of need for change or support for inclusion
	Behavioural regulation	Identify and develop systems for self-monitoring PA/inactivity and sedentary behaviour	<p><i>012: "... it was the one-to-one that I really got a better understanding of it because I was actually given a sheet, um, to chart, I think it was every hour, high energy, low energy, rest and that actually was quite an eye-opener, and it was having that to take away and do that actually made me more aware of how to manage it"</i></p> <p><i>002: "I gave them all a sort of diary sheet so they could take it away and they could use it through the week to plan when they were going to do things"</i></p> <p><i>006: "we've also got pedometers, erm, which we can give out"</i></p>
Physical opportunity	Environmental context and resources	<p>Explore what physical or resource factors might facilitate or hinder PA</p> <p>Be able to allocate sufficient time to undertake desired PA</p> <p>Have access to appropriate environment in which to perform chosen PA, e.g. identify community groups/local leisure facilities</p> <p>Have access to appropriate equipment to undertake desired PA (e.g. walking shoes/trainers)</p>	<p><i>018: "It would be useful if there were some, some more concessionary benefits or the GP could sort of ... I know sometimes they can prescribe things..."</i></p> <p><i>029: "... so what we're doing now as well as that is looking to make links with the local council to see if there would be ways in which we can educate fitness instructors out there in the community to provide a similar kind of service to what we do."</i></p> <p>Potential barriers to change:</p> <p>Work commitments – <i>015: "I'm on school holiday so that's why I'm here, I can't do any other ... obviously I can't come to meetings, [work] won't allow me to come to meetings and things like that, appointments yes, but if this was on a regular basis they wouldn't allow that."</i></p> <p><i>021: "... exercise is the last thing on your mind when you get in from work."</i></p>
Social opportunity	Social influences	<p>Identify someone to undertake PA with, or seek support from others, e.g. Friends/family to encourage PA</p> <p>Meet with other RA patients for peer support with RA</p> <p>Identify other RA patients who are engaged in PA as potential role models</p>	<p><i>011: "... sat there listening to other people, this is one of the main reasons I come today, just to listen to others cos you learn so much more from other people ..."</i></p> <p><i>018: "I think this is the first time I've spoken to other people with RA."</i></p> <p><i>025: "... to have a training buddy that's always a really positive thing to ensure kind of longer term people keeping up with exercise you know someone else to motivate you when you're not feeling it"</i></p>

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur?	Example of evidence of need for change or support for inclusion
Reflective motivation	Professional/social role and identity	Encourage being active as part of identity	<p>011: <i>“it’s a long ongoing battle where you’ve had to forget your old life, what you used to do, I’ve given up work and stayed home.”</i></p> <p>015: <i>“... [RA] it’s changed my life, I get depression. I have changed, I am not the same person I was three years ago. I can’t talk for anybody else, but I’ve changed, I know I have.”</i></p>
	Beliefs about capabilities	Explore acceptance of having RA and its effect on ability	014: <i>“You can’t work to a regime of fitness because you never know what you’re allowed to do the next day.”</i>
		Address confidence with PA Identify PA that feel capable of doing, that is achievable	016: <i>“Mine’s quite bad in my joints. I’ve got chronic in my shoulders, in my neck, my feet, my hands, that’s it. I’ve got bare movement so I can’t do nothing.”</i>
	Optimism	Explore confidence with achieving PA goals	<p>011: <i>“The minute you mentally make yourself kitted up ready to do it and then you fail at the first hurdle.”</i></p> <p>013: <i>“And it’s horrible failing.”</i></p>
	Beliefs about consequences	Address beliefs about the effects of PA on fatigue and general consequences of PA	011: <i>“I think physical activity does increase your fatigue, but also, on the other foot, decrease it as well.”</i>
Encourage belief that managing PA will have positive benefits for managing fatigue Address negative beliefs		021: <i>“... I tried swimming and it caused flares in my shoulders. So I went to see the doctor about it and they said try an exercise bike for a minute a day, and that used to set off in my knees.”</i>	
Intentions	Explore plans/intentions to be more active or to manage PA	011: <i>“Just like getting up and thinking, “Right, am I going to be able to do this today,” to try and do that and get myself to the swimming pool. Then the minute you get out of bed you collapse because you can’t put your foot to the floor”</i>	
	Encourage formulation of plans to carry out PA and implementation of specific PA goals	007: <i>“if a patient comes in and they’ve had a sudden setback [...] we would look at where they are in that setback, look at setback planning and how to think about and learn from that setback.”</i>	
	Address setbacks and potential barriers to PA		

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur?	Example of evidence of need for change or support for inclusion
Reflective motivation continued	Goals	Explore expectations and desired achievements Set specific goals for PA	<i>024: "...finding out what their goals are and working towards them, and building their confidence with that."</i>
Automatic motivation	Reinforcement	Establish a routine with PA that is regular and realistic to encourage habit formation Consider increasing the likelihood of carrying out PA by arranging a dependent relationship between response and stimulus Reinforce routines and habits	<i>030: "There's one motivational factor in getting people started, but there's the other motivational factor of keeping somebody in that habit of doing it, and in that routine"</i> <i>005: "I'm really taking them through the process of introducing exercise into their life going for regularity. It doesn't really matter too much what they do, but getting something as a, as part of a regular routine."</i>
	Emotion	Address fears about PA, e.g. fear of failing, fear of damage, fear of pain Identify positive emotions, e.g. improved mood	<i>010: "It's the fear of the pain for me [as a barrier to PA]."</i> <i>011: "... when you're having a bad period, where you can't do things, you don't accomplish stuff, and when you're failing at stuff that puts you in a blue mood anyway."</i> <i>018: "I mean also, [PA] makes you mentally more alert and I think that tends to sort of, um, stave off fatigue a little bit and there's the sort of feeling of achievement as well, if you've done it, you know."</i> <i>020: "... it is rewarding, yeah, you can see actually that you've done things, it is good."</i>

GP=general practitioner; PA=physical activity; RA=rheumatoid arthritis

Red text=quotations from RA patients in focus groups (chapter 6)

Green text=quotations from allied health professionals in focus groups (chapter 6)

Blue text=quotations from healthcare professionals in interviews (chapter 5)

The resultant behavioural diagnosis indicated that there is a potential need for change in all components of the COM-B model in order for RA patients to change their PA behaviour within the context of their fatigue. The amount of change required for each element of the COM-B or Theoretical Domains Framework is likely to vary between individuals. For example, one participant might already possess the necessary psychological capability in terms of cognitive skills for planning and implementing PA, but their fear of exacerbating fatigue, pain or joint damage may prevent them from changing their PA behaviour. In this instance there will be a need for change in automatic motivation, and more specifically emotion relating to PA, in order to achieve the desired change in PA. Another participant may not be afraid of PA and have adequate motivation but instead they may lack the necessary psychological capability to plan and implement the desired behaviour.

7.4.2 Stage 2: Identifying intervention components

7.4.2.1 Identifying intervention functions

The behavioural analysis in stage one suggested that a change in any aspect of the COM-B behavioural system could initiate change in PA in the target patient group, depending on the needs of the individual recipient. This implies that any of the intervention functions might bring about a change in PA. Intervention functions were selected according to the criteria of effectiveness, relevance, feasibility and acceptability, as recommended by Michie and colleagues (2014). When possible these criteria were supported by evidence from data collected from interviews, focus groups and workshops. Where these data were not available selection was made on the judgement of the candidate and reviewed by the supervision team and PRPs.

Definitions of the nine intervention functions included in the BCW have been presented in table 7.1. Of these, five have been linked to effective BCTs for increasing PA (Michie, van Stralen and West, 2011). These are:

- Education
- Persuasion
- Incentivisation
- Training
- Enablement

Therefore these were considered for this intervention. Modelling was also included as an additional intervention function. However, coercion, environmental restructuring and restrictions were not included. These functions are linked to external sources and are more likely to act as extrinsic motivators rather than stimulating the desired autonomous

behaviour resulting from intrinsic motivation (Ryan and Deci, 2000). It has been suggested that they are less relevant for interventions to change PA where self-regulation and personal agency seem to be key for success (Michie *et al*, 2009a, Michie, van Stralen and West, 2011).

Education

Education as a function is defined as increasing knowledge or understanding (Michie, Atkins and West, 2014). As well as its obvious role in changing knowledge, and therefore influencing psychological capability as a COM-B component, education can influence reflective motivation. For example, whilst qualitative data in earlier phases of this research and published data indicate that patients are aware of potential benefits of PA in RA, beliefs about consequences of PA, such as potential joint damage, often present a barrier to engagement (Law *et al*, 2013). Addressing these beliefs through education could improve reflective motivation and encourage a change in PA behaviour. Education may also affect other components of reflective motivation, such as behavioural regulation, social role and identity, intentions and goals (Michie, Atkins and West, 2014). This function was judged as meeting the necessary criteria for inclusion as a function of the intervention.

Persuasion

Persuasion has been defined as “the use of communication to induce positive or negative feelings or stimulate action” (pp.7, Michie, van Stralen and West, 2011) and can affect both reflective and automatic motivation. Mapping of data from focus groups with AHPs onto the BCW implied that this function may be employed to convince fatigued patients that PA will be beneficial at a time when they may be tired or in pain, or may be reluctant to try it if they have had a negative experience in the past. Persuasion could influence patients’ PA behaviour through boosting confidence and providing reassurance.

Incentivisation

Evidence suggests that effective BCTs for increasing PA serve this function (Michie, van Stralen and West, 2011). Although material rewards, such as prizes or financial reward, might not be appropriate, creating incentives through forming intentions and goals to change PA might have a positive influence on reflective motivation. Similarly, outcome expectancies of improved symptom management, such as reduction in fatigue may provide sufficient incentive to change behaviour through stimulating an emotional, automatic motivation for PA. Improvements in sleep, as suggested by AHPs (chapter 6), might be an incentive for some. BCTs that serve this function were coded during

deductive analysis of HCP interviews (chapter 5), suggesting its use in existing PA interventions for managing fatigue.

Training

Data mapping revealed that AHPs would utilise training to enhance physical capability (for example, strength training) and psychological capability (for example, to improve cognitive skills for planning, implementing and self-monitoring PA and rest).

Modelling

Modelling is defined as “providing an example for people to aspire to or imitate” (p. 7, Michie, van Stralen and West, 2011). According to theoretical mapping, modelling has the potential to address psychological capability, reflective and automatic motivation and social opportunity (Michie, Atkins and West, 2014). Modelling by the person delivering the intervention and other participants in a group programme was felt to be practicable. Modelling may be considered an external influence on motivation rather than placing emphasis on personal agency (Michie et al 2011b) but its inclusion was considered appropriate as HCPs using PA fatigue management interventions in other long-term conditions have noted the importance of vicarious learning (chapter 5). Similarly, RA patients expressed a preference for group programmes for peer support and this was supported by AHPs (chapter 6). These findings are supported by the literature, with participants in an SCT/CBT-based group self-management intervention for RA fatigue reporting benefits from a group environment (Dures *et al*, 2012). As discussed previously, social learning and modelling are central to SCT (Bandura, 1998). Similarly, strong social support and social networks have been associated with less psychological distress in early RA patients (Demange *et al*, 2004) and are recognised to have an important effect on health status and behaviour in the wider population (Berkman *et al*, 2000). Additionally, modelling by HCPs in the form of demonstration of PA was felt to be useful by interview participants (chapter 5) and was considered necessary for safety reasons to demonstrate safe use of gym equipment during practical sessions.

Access to expert patients was suggested as a useful means of improving social opportunity and reflective motivation in terms of enhancing social identity as someone with RA who is physically active. This form of modelling may not be feasible for this intervention but should be considered for future development.

Enablement

Enablement has been defined as “increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)” (p.7, Michie, van Stralen and West, 2011). AHP data (chapter 6) suggested

that enablement might enhance psychological capability through exploration of memory, attention and decision process in relation to PA. Patients felt that further support with psychosocial aspects of RA and fatigue would help them engage with PA. Enablement could address emotional responses to PA and fatigue as an element of automatic motivation, as well as influencing the theoretical domains of beliefs about capabilities and consequences, and optimism as part of reflective motivation (Michie, Atkins and West, 2014).

7.4.2.2 Identifying behaviour change techniques

Frequently used BCTs that might deliver the selected intervention functions are presented in table 7.4. BCTs identified during deductive coding of qualitative data from interviews with HCPs (chapter 5) are highlighted in bold, including those reported as less frequently used to deliver the intervention function according to the BCW users' guide (Michie, Atkins and West, 2014).

As mentioned previously, meta-analyses of PA interventions in healthy adults suggest that effective interventions should include self-monitoring and self-regulatory BCTs (Michie *et al*, 2009a, Bird *et al*, 2013). Self-regulation includes intention formation (action planning), goal setting, problem-solving and review of behavioural goals.

Table 7.4: Possible BCTs for selected intervention functions

Intervention function	Frequently used BCTs (Michie, Atkins and West, 2014)	Less frequent BCTs coded in PA programmes for fatigue in long-term conditions
Education	Information about social and environmental consequences Information about health consequences Feedback on behaviour Feedback on outcome(s) of behaviour Prompts/cues Self-monitoring of behaviour	Biofeedback Self-monitoring of outcome of behaviour Re-attribution
Persuasion	Credible source Information about social and environmental consequences Information about health consequences Feedback on behaviour Feedback on outcome(s) of behaviour	Biofeedback Re-attribution Verbal persuasion about capability
Incentivisation	Feedback on behaviour Feedback on outcome(s) of behaviour Monitoring of behaviour by others without evidence of feedback Monitoring outcome of behaviour by others without evidence of feedback Self-monitoring of behaviour	Biofeedback Self-monitoring of outcome of behaviour Discrepancy between current behaviour and goal
Training	Instruction on how to perform a behaviour Feedback on behaviour Feedback on outcome(s) of behaviour Self-monitoring of behaviour Behavioural practice/rehearsal	Biofeedback Self-monitoring of outcome of behaviour Graded tasks
Modelling	Demonstration of the behaviour	
Enablement	Social support (unspecified) Social support (practical) Goal setting (behaviour) Goal setting (outcome) Adding objects to the environment Problem solving Action planning Self-monitoring of behaviour Restructuring the physical environment Review behaviour goal(s) Review outcome goal(s)	Social support (emotional) Reduce negative emotions Self-monitoring of outcome of behaviour Generalisation of target behaviour Graded tasks Body changes Verbal persuasion about capability Discrepancy between current behaviour and goal Pros and cons

BCT=behaviour change technique; PA=physical activity

Emboldened text = BCTs coded in deductive thematic analysis of interviews (chapter 5)

7.4.3 Stage 3: Identifying delivery options

7.4.3.1 Selecting mode and style of delivery

Face-to-face group delivery was selected for this intervention. This decision was based on RA patient preferences. Distance delivery at population level, such as leaflets, or individual level, such as email, was not acceptable to patients (chapter 6).

It was decided that a person-centred delivery approach should be utilised. An interactive delivery style based on principles of motivational interviewing and CBT should use open-ended questioning to encourage and facilitate patient-generated ideas. Links between cognitions and behaviour should be identified and problem-solved using a collaborative approach to behaviour change (Rollnick, Mason and Butler, 1999, Sage *et al*, 2008). As mentioned in section 7.1.2, SDT has been proposed as a theoretical framework underpinning motivational interviewing techniques, thus supporting their use to enhance intrinsic motivation in this intervention (Markland *et al*, 2005). Authors of a review of lifestyle- and behaviour-change interventions in musculoskeletal conditions advocated the use of person-centred rather than prescriptive approaches (Knittle, De Gucht and Maes, 2012). This was also recommended by HCPs delivering current PA programmes for fatigue management in long-term conditions (chapter 5).

7.4.3.2 Selecting policy categories

At this early stage of intervention development, service provision was considered the most appropriate policy category for intervention delivery. If following further testing and evaluation this is proven to be an effective intervention for managing RA fatigue it might be incorporated into future fatigue management guidelines.

For now, considerations for service provision must take into account issues raised by both HCPs and patients (chapters 5 and 6) relating to intervention implementation. Key patient issues related to location and timing of intervention delivery, with those who work indicating concerns regarding access to services out of working hours (chapter 6). Other concerns raised by HCPs, particularly rheumatology AHPs (chapter 6), regarding practicalities for implementation included resource issues, such as staffing, administrative support and access to suitable premises, and consideration of economics of face-to-face group delivery. Other issues related to addressing staff training needs and potentially altering current referral patterns for fatigue management. Many of these issues are likely to differ according to local circumstances and must be addressed prior to implementation.

7.4.4 Stage 4: Intervention strategy and programme outline

7.4.4.1 Intervention structure and content

The theoretically-derived intervention components (sections 7.4.1 to 7.4.3) were combined with qualitative data from current PA interventions (chapter 5) and patient and AHP preferences and practical issues (chapter 6) to develop a 12-week, seven session PA intervention to support adults with RA to manage symptoms of fatigue. The frequency and duration of sessions were designed to allow for gradual withdrawal of therapist support within a structured environment. This withdrawal aimed to optimise self-efficacy and autonomy for PA behaviour change to encourage self-management, so that patients would be able to cope effectively without assistance, as recommended by Bandura (1977).

The intervention was designed to be delivered as a face-to-face, group programme by a physiotherapist with knowledge of RA fatigue, PA and behaviour change. Optimal group size was set between 6 and 10 patients. This was felt to be large enough to minimise a diminished group-learning effect if attrition occurred, yet small enough to enable sufficient individual attention and support, and to ensure patient safety, particularly in the practical sessions.

An outline of intervention is presented in table 7.5. A list of key BCTs selected to deliver intervention content for each session is presented in table 7.6. BCT taxonomy codes were used and definitions for these techniques can be found in Michie *et al* (2013). BCTs were selected from those recommended for inclusion in PA programmes (Michie *et al*, 2009a, Bird *et al*, 2013), as well as additional BCTs that were identified for inclusion from interview data (chapter 5) (table 7.4).

Table 7.5: Outline of session content

Week number	Session number	Group discussion topics (45-55 mins) followed by coffee break (10-15 mins)	Practical session (30-45 mins)	Support materials and homework tasks
1	1	<ul style="list-style-type: none"> • Introduction to the course – aims and expectations, Ground rules and housekeeping • Discussion topic: Share and discuss current feelings and experiences relating to fatigue and PA • Discuss benefits of PA in RA • Introduction to activity diaries 	<ul style="list-style-type: none"> • Demonstration of exercises and gym equipment • Patient choice of exercises with supervision as time allows • Example exercises: static bicycle, walking on a treadmill, step-ups, wall squats. For full details see appendix N1 	<ul style="list-style-type: none"> • Handouts – Arthritis Research UK fatigue booklet, Causes of fatigue, PA in RA, List of exercises included in the practical session • Task – Activity diary to complete for next session
2	2	<ul style="list-style-type: none"> • Review and discuss activity diaries • Activity analysis, pacing and energy management • Introduce principles of graded exercise therapy (GET) and progression of PA • Introduction to goal setting 	<ul style="list-style-type: none"> • Individual goal setting (PA goal) • Discuss potential barriers to PA and possible solutions • Introduce Borg scale for monitoring exertion • Patient choice of exercises with supervision 	<ul style="list-style-type: none"> • Handouts – Pacing, GET, Goal setting, Borg scale • Task – Goal setting activity and graded PA plan, establish a baseline for chosen PA, continue activity diary
3	3	<ul style="list-style-type: none"> • Review and discuss pacing and activity analysis • Discuss impact of sleep and rest on PA and fatigue • Effects of stress and techniques for relaxation 	<ul style="list-style-type: none"> • Review individual goals • Patient choice of exercises with supervision • Progression of exercises as appropriate • End with relaxation 	<ul style="list-style-type: none"> • Handouts – sleep, stress and relaxation, relaxation CD • Task – try out relaxation CD, continue with PA goal and activity diary
4	4	<ul style="list-style-type: none"> • Review general progress. Discuss barriers and potential solutions • Discuss ideas for self-monitoring PA • Discuss diet and weight management in relation to PA 	<ul style="list-style-type: none"> • Review individual goals • Patient choice of exercises with supervision • Progression of exercises as appropriate 	<ul style="list-style-type: none"> • Handouts – self monitoring, pedometers, healthy diet • Task – try out tools for self-monitoring and prompting PA, continue with PA goal and activity diary

Week number	Session number	Group discussion topics (45-55 mins) followed by coffee break (10-15 mins)	Practical session (30-45 mins)	Support materials and homework tasks
6	5	<ul style="list-style-type: none"> Review general progress How to manage setbacks Discuss managing PA alongside occupation 	<ul style="list-style-type: none"> Review individual goals Patient choice of exercises with supervision Progression of exercises as appropriate 	<ul style="list-style-type: none"> Handouts –Managing external demands, managing setbacks Tasks – think about and formulate a setback plan, continue with PA goal and activity diary
8	6	<ul style="list-style-type: none"> Review general progress Review and discuss setback plan Discuss how to continue and maintain PA in the longer term 	<ul style="list-style-type: none"> Review individual goals Patient choice of exercises with supervision Progression of exercises as appropriate 	<ul style="list-style-type: none"> Handouts – Template for planning long-term PA Task – continue with PA goal and activity diary, complete long-term PA plan
12	7	<ul style="list-style-type: none"> Review general progress, setback plan, options for long-term maintenance and continued progression of PA 	<ul style="list-style-type: none"> Review individual goals Patient choice of exercises with supervision Progression of exercises as appropriate 	<ul style="list-style-type: none"> Handouts – List of resources for long-term PA

GET=graded exercise therapy; PA=physical activity; RA=rheumatoid arthritis

Table 7.6: Core behaviour change techniques used in each session

BCT (taxonomy code, Michie et al, 2013)	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7
Behavioural practice/rehearsal (8.1)	✓	✓	✓	✓	✓	✓	✓
Credible source (9.1)	✓	✓	✓	✓	✓	✓	✓
Demonstration of the behaviour (6.1)	✓						
Framing/re-framing (13.2)	✓						
Information about health consequences (5.1)	✓	✓	✓				
Instruction on how to perform the behaviour (4.1)	✓	✓					
Re-attribution (4.3)	✓						
Self-monitoring of behaviour (2.3)	✓	✓	✓	✓	✓	✓	✓
Social support (unspecified) (3.1)	✓	✓	✓	✓	✓	✓	✓
Action planning (1.4)		✓	✓	✓	✓	✓	✓
Body changes (12.6)		✓	✓	✓	✓	✓	✓
Feedback on behaviour (2.2)		✓	✓	✓	✓	✓	✓
Generalisation of target behaviour (8.6)		✓	✓	✓	✓	✓	✓
Goal setting (behaviour) (1.1)		✓	✓	✓	✓	✓	✓
Graded tasks (8.7)		✓	✓	✓	✓	✓	✓
Problem solving (1.2)		✓	✓	✓	✓	✓	✓
Self-monitoring of outcome of behaviour (2.4)		✓					
Information about emotional consequences (5.6)			✓				
Reduce negative emotions (11.2)			✓				
Review behaviour goal(s) (1.5)			✓	✓	✓	✓	✓
Social support (emotional) (3.3)			✓				
Biofeedback (2.6)				✓			
Prompts/cues (7.1)				✓			

BCT=behaviour change technique






Session content was guided by data generated from interviews (chapter 5) and chosen based on preferences of RA patients and rheumatology AHPs, as indicated in focus group and workshops (chapter 6). Content was also informed by existing literature (chapters 2 to 4) and guided by programme manuals for a GET programme for fatigue management in CFS (White *et al*, 2011), an exercise and self-management intervention for people with chronic knee, hip or back pain (Walsh *et al*, 2013) and a CBT-based self-management intervention for RA fatigue (RAFT trial, www.isrctn.com/ISRCTN52709998).


A session guide was developed for each individual session to ensure intervention fidelity (appendix N1 to N7). The objectives for each session informed the discussion session. Further information with suggested questions and prompts was detailed for each of the main objectives for that session. Patient handouts were developed using ideas from existing literature and support materials (White *et al*, 2011, Walsh *et al*, 2013, RAFT trial manual, www.isrctn.com/ISRCTN52709998). A list of equipment required to run the session was also generated. Exercises included in the practical session were derived from a PA self-management intervention for chronic pain (Walsh *et al*, 2013, with permission), with some additional upper limb exercises adapted from the EXTRA programme handbook (with permission, Manning *et al*, 2014).

All session plans and support materials were reviewed in detail by the supervision team and PRPs. Some of the materials were tested by members of the team, for example the activity diary. This was adapted from the RAFT trial with permission (www.isrctn.com/ISRCTN52709998). Feedback gathered from the supervision team and PRPs was used to modify the diaries to make sure they were fit for purpose and understood by participants. The diary instructions and template are presented in figures 7.4a and b. The diary provides an example of the patient-centred approach and illustrates how BCTs are applied in the intervention. This is shown in table 7.7.

Figure 7.4a: Activity diary instructions for use

Instructions for Use:

-  High Energy Physical Activity (PA) - Colour Red
-  Low Energy PA - Colour Yellow
-  Sedentary Activity - Colour Black
-  Rest/Chill out Time - Colour Green
-  Sleep - Colour Blue

 Crash - Mark with a cross

<u>Examples of high energy PA may be:</u>	<u>Examples of low energy PA may be:</u>
<u>Examples of sedentary activity may be:</u>	<u>Examples of rest or chill out time may be:</u>

However, whether they are low or high really depends on you and how involved you get with these activities

Figure 7.4b: Activity diary template

Week 1	Morning - am											Afternoon/evening - pm												
__/__/__	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11
Day 1																								
Day 2																								
Day 3																								
Day 4																								
Day 5																								
Day 6																								
Day 7																								

Week 2	Morning - am											Afternoon/evening - pm												
__/__/__	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11
Day 1																								
Day 2																								
Day 3																								
Day 4																								
Day 5																								
Day 6																								
Day 7																								

Key

High Energy PA <input type="checkbox"/>	Low Energy PA <input type="checkbox"/>	Sedentary time <input type="checkbox"/>	Rest or Chill Out Time <input type="checkbox"/>	Sleep <input type="checkbox"/>	Crash
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Table 7.7: Activity diary as an example of the relationship between patient-centred delivery, COM-B model, BCW and BCTs

Session number	Mode of delivery	COM-B component	Intervention functions	BCTs (defined in Michie <i>et al</i> , 2013)
Session 1	Course leaders provide guidance on how to use the diary.	Psychological capability (Theoretical domains – Cognitive and interpersonal skills, memory, attention and decision processes, behavioural regulation)	Training Education	Provide a tool to support self-monitoring of PA (BCT 2.3 – Self-monitoring of behaviour)
Introduce activity diary	Participants define their own activities that they experience as high or low energy PA. This ensures that they are personal and relevant to them. Activities can be re-categorised by the patient at any time. The diaries are voluntary and are completed by the patient.			Enable patients to self-monitor the outcome of PA (BCT 2.4 – Self-monitoring of outcome(s) of behaviour)
Session 2-7	Patients are encouraged to complete the diary every week. This is reviewed with the group and/or course leader in the following session.	Psychological capability (Theoretical domains – Cognitive and interpersonal skills, memory, attention and decision processes, behavioural regulation) Reflective motivation (Theoretical domains – Beliefs about capabilities, beliefs about consequences, intentions, goals)	Training Education Modelling Enablement Persuasion	Provide a tool to support self-monitoring of PA (BCT 2.3 – Self-monitoring of behaviour)
Ongoing diary review	Participants are asked to describe what they see in their own diary. They are encouraged to interpret this themselves. Diaries may be discussed amongst the group if patients wish to do so. Participants continue to use diaries as they wish, for example, to monitor progress, review goals, make action plans Participants can monitor changes in other outcomes as a result of changing PA, such as improved sleep patterns or changes in the duration and/or frequency of fatigue ‘crashes’ where they cannot do anything as a result of their fatigue. This is marked with an X on the diary.			Facilitate problem-solving issues that might have arisen (BCT 1.2 – Problem solving) Group discussion providing peer support (BCT 3.1 – Social support) Help set and review PA goals (BCT 1.1 – Goal setting, BCT 1.5 – Review behaviour goals) Provide visual feedback on PA performance (BCT 2.2 – Feedback on behaviour) Support action planning (BCT 1.4 – Action planning) Enable patients to self-monitor the outcome of PA (BCT 2.4 – Self-monitoring of outcome(s) of behaviour)

In addition to paper-based support materials, pedometers were offered to participants in session 4 if they wished to use them to aid self-monitoring of PA behaviour. Pedometers were suggested as a useful tool by an interview participant (chapter 5) and have been demonstrated to be useful for improving step-counts in adults with low levels of PA (Baker *et al*, 2008, Fitzsimons *et al*, 2012). A relaxation CD was offered to complement relaxation strategies discussed in session 3.

7.4.4.2 Requirements for implementation

Access to suitable premises is required for implementation of the intervention. These must allow for a group of 6 to 10 patients to be seated comfortably for the discussion session, followed by access to an appropriate space, such as a therapy department gym, where the practical session can take place.

Sessions are recommended to be delivered in the afternoon. Patients have indicated that they are likely to find it difficult to attend a session first thing in the morning, as fatigue and other RA symptoms are often worse at this time of day.

Delivery during working hours on a weekday also restricts access for those patients who work. Flexible staffing may provide opportunities for delivering out-of-hours sessions in the evening or at weekends, but patients may be too tired or too busy to attend after work (chapter 6).

7.5 Discussion

This chapter has described the design and development of a PA self-management intervention to support adults with RA with managing fatigue. Intervention development was based on preferences expressed by RA patients and professionals, and informed by a theoretical framework for HBC.

7.5.1 Strengths

The main strength of the intervention development process is that it used a rigorous, systematic method that drew together theory, preferences and practical considerations. These were based on an examination of existing literature and primary research with HCPs working in fatigue management for long-term conditions, RA patients and rheumatology AHPs. Development was supported by a supervision team with experience of developing theory-based self-management interventions for rheumatic diseases with input from two PRPs. The development process can clearly be linked to MRC guidelines for developing complex interventions to improve health (MRC, 2000, MRC, 2008).

The intervention also meets the majority of recommendations of Iversen and colleagues (2010) for self-management programmes for rheumatic diseases. These suggested that interventions should be based on theory, delivered in groups by an HCP, have a protocol for delivering the sessions and be more than six weeks duration. Iversen and colleagues (2010) also recommended that interventions are based on SCT or CBT. Another intervention to increase PA in RA implied that SDT in addition to SCT might be used as the theoretical framework, although this was not explicitly stated (Knittle *et al*, 2013). While this intervention was not specifically based on SCT, CBT or SDT, it was felt that use of the COM-B model, Theoretical Domains Framework and BCW combined with the BCT taxonomy provided a comprehensive theoretical basis. The BCW offered a theoretical framework derived from consensus work that identified overlapping theoretical constructs and domains from several theories, rather than using one 'named' theory (Michie, van Stralen and West, 2011). As discussed previously, the COM-B model has parallels with constructs in social cognition models, and Theoretical Domains Framework incorporates constructs from SCT, TPB and SDT. It is hoped that using the COM-B and Theoretical Domains Framework in conjunction with the BCW will have assisted in overcoming some of the limitations of these other behaviour change theories. Use of a broad theoretical framework instead of a single theory has previously been proposed as a more thorough means of analysing potential barriers and facilitators of behaviour change (French *et al*, 2012).

7.5.2 Limitations

Although the intervention has been developed using a systematic method, there still remains a large element of subjectivity in the choice of intervention content and delivery options (French *et al*, 2012). For example, a wide range of BCTs exist and although the choice of techniques for inclusion was based on the best available evidence, decisions still had to be made that relied primarily on the judgement of the candidate and the supervision team. Michie, van Stralen and West (2011) noted that there are still infinite possibilities for classifying behaviour change interventions and that as the field progresses the BCW may become rapidly out of date. Nonetheless, this appeared to be the most comprehensive, well-researched framework for developing such interventions at the time of writing.

The candidate's background as a clinical physiotherapist should also be noted. Although this experience provided an insight into clinical practice and delivery of similar interventions, potential biases regarding professional identity and cultural influences should not be overlooked. Also, decisions regarding RA patient preferences for intervention content and delivery were based on two small qualitative studies. Therefore this cannot be claimed to be representative of the general RA population. Further exploratory work, such as a quantitative survey might have confirmed or refuted these findings. However this research was conducted using the resources available and further quantitative work, whilst potentially useful, would have delayed intervention development. Furthermore, the expertise of the supervision team and collaboration with PRPs will have considerably strengthened the intervention design. Pilot testing and refinement of the intervention with novel groups of RA patients in further development work will also continue to strengthen the intervention in this regard.

7.6 Summary

This chapter has presented a systematic process for developing a PA behaviour change intervention for managing RA fatigue, using a theoretical framework combined with existing evidence and exploratory data. This constitutes the first phase of developing complex interventions to improve health, in line with MRC guidelines (MRC, 2000, MRC, 2008). The next phase of development required modelling of intervention processes and outcomes, including preliminary exploration of the acceptability of the intervention to RA patients who experience fatigue. This was conducted in a proof-of-concept study, which included identification of potential outcome measures and trial delivery of intervention content and support materials. This is presented in chapter 8.

Chapter 8: Exploring the acceptability of a physical activity self-management intervention designed for fatigue management in rheumatoid arthritis

The previous chapter described the development of a PA self-management intervention (chapter 7). This chapter presents a proof-of-concept study that was carried out to explore the acceptability of the intervention and its associated support materials. The results of the study are presented and implications for future development are discussed.

8.1 Background

As outlined in chapter 1, MRC guidance recommends three phases during the early development of complex interventions to improve health: 1. identifying an existing evidence base; 2. identifying appropriate theory; and 3. modelling process and outcomes prior to an exploratory trial and larger scale evaluation (MRC, 2008).

Earlier phases of this research explored existing evidence for the use of PA to manage RA fatigue (chapter 2). This identified that although there appears to be a moderate effect of PA for reducing the impact of fatigue for patients with RA, none of the interventions were designed for fatigue management (Cramp *et al*, 2013b). Further exploration of evidence for the use of PA to manage fatigue in other long-term conditions was presented in Chapter 3. Meta-analyses demonstrated that PA is effective for managing CRF (Cramp and Byron-Daniel, 2012) and CFS (Edmonds, McGuire and Price, 2004). Reports in which interventions were shown to be effective were also examined for the presence of appropriate theory that might inform a new intervention. However, the theoretical basis for most interventions was not explicitly mentioned. Interviews with HCPs delivering PA interventions for fatigue management in clinical practice confirmed that, although some BCTs were described, a theoretical model for behaviour change was lacking (chapter 5). Given these programmes aimed to address PA behaviour it was decided that behaviour change theory would be a useful basis for a PA intervention.

Identification of existing evidence (chapters 2 and 3) and appropriate theory (chapters 4 and 7) was supplemented by primary research to explore ideas and aspirations of the target population (chapter 6). Interviews with HCPs delivering existing PA interventions for fatigue management in long-term conditions generated ideas

regarding intervention format and content (chapter 5). Subsequent focus groups and workshops with RA patients discussed these ideas for use in RA and raised issues regarding implementation, for example, concerns regarding accessibility for people who work (chapter 6). Similarly, focus groups with rheumatology AHPs who were likely to be involved in delivering PA interventions also discussed practical considerations for implementation (chapter 6). Both patients and professionals expressed support for further intervention development.

As a result of this detailed preliminary work, a PA self-management intervention was designed based on the preferences of patients and AHPs, informed by a theoretical framework for HBC (Michie, van Stralen and West, 2011, Michie, Atkins and West, 2014) (chapter 7). Having developed this new intervention, it was necessary to model the intervention processes and explore acceptability in a proof-of-concept study to identify any weaknesses and undertake refinements.

8.2 Aims

To model processes and explore acceptability of a PA self-management intervention for managing RA fatigue.

8.2.1 Objectives

1. To explore acceptability of the mode of delivery, format and content of the intervention to study participants
2. To test the intervention education and support materials with respect to comprehensiveness, utility and acceptability to participants
3. To explore acceptability of completing potential outcome measures for use in future research

8.3 Methods

8.3.1 Research design

A proof-of-concept study was conducted to assess whether the intervention had the potential to be applied in a clinical practice setting. A mixed methods approach was used, whereby both qualitative and quantitative data were collected and analysed (Cresswell and Clark, 2011). The study did not aim to look at the feasibility of the research processes nor was it designed to pilot research methods, such as recruitment and randomisation methods prior to full scale testing of the intervention. Rather, it was designed to model processes and refine the intervention format, content and delivery in advance of a feasibility or pilot of an RCT.

8.3.2 Identification and sampling

Ethics approval was granted for this study by the Wales REC5 Committee (Reference 14/WA/1073).

Patients were recruited from the Royal National Hospital for Rheumatic Diseases NHS Trust. Selection criteria included adults (over 18 years old) with a diagnosis of RA as confirmed by a rheumatologist according to ACR criteria (Arnett *et al*, 1988). The main inclusion criteria was a score of greater than or equal to 6/10 (moderate) on the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scale (BRAFF-NRS) (severity) (Nicklin *et al*, 2010b). Patients were only excluded if they did not meet the criteria for fatigue severity, they had insufficient English to participate in group discussions or they lacked capacity for informed consent.

Multiple recruitment methods were used for this study. Firstly, a research and development officer at the NHS Trust sent letters of invitation to 50 RA patients (appendix O). Patients were selected from a database of RA patients who had previously agreed to be contacted about research studies taking place in the Trust. Letters included a participant information sheet, a reply slip and a pre-paid return envelope (appendix P). A member of the healthcare team also invited RA patients to take a recruitment pack when they attended the rheumatology therapy department. HCPs checked eligibility and recorded participant contact details for those who were interested on a recruitment record form (appendix Q). Lastly, posters advertising the study were displayed in the rheumatology clinic so that interested patients could request further information (appendix R).

All potential participants were provided with an information sheet explaining the purpose of the study. This emphasised that the study would explore implementation, delivery and acceptability of an intervention that had not previously been used for fatigue management in RA. Interested patients were given the contact details of the research team so that they could ask further questions if they wished. They were also provided with information regarding session dates, location, time and duration. Those patients who returned the reply slip were contacted by the candidate who checked eligibility and answered any further questions about the study. Patients who met the inclusion criteria were invited to participate in the intervention. All interested patients who wanted to and were able to take part and gave their informed consent received the intervention. Participants travel expenses were paid.

Recruitment closed once ten eligible patients had confirmed that they were able to attend the intervention on the specified dates. Any patients that contacted the candidate after recruitment had closed would be provided with contact details for an OT at the Trust

who had a special interest in fatigue management. Alternatively they were invited to attend an RA self-management programme being held at the Trust at the same time as the intervention.

In order to determine acceptability of this intervention it was important to understand reasons for declining participation. Therefore patients who declined were invited to indicate on the reply slip the main reason why they did not wish to take part.

8.3.3 Intervention

An outline of the intervention and session topics is presented in chapter 7 and appendices N1 to N7. All participants received a group intervention designed to help them manage RA fatigue using PA. They were invited to attend seven sessions over a 12 week period, each up to two hours in duration. Participants were contacted prior to the start of the intervention to confirm the time and location. Sessions commenced mid-morning (11.15am) according to patient preferences and HCP experiences expressed in the earlier phases of intervention development (see chapters 5 and 6). According to these preferences, ideally the intervention would have been delivered in the afternoon. However, access to an appropriate room and gym was only available at this time.

Participants were given information about what to wear and what they might expect from each session. They were advised to wear comfortable clothing to the sessions if they were willing to take part in the practical session. The candidate delivered all the sessions. An assistant helped with sessions 2 to 7. The candidate and assistant will be referred to as the course leaders.

All sessions followed the same general outline. The first hour involved discussion around a given topic relating to RA, PA and fatigue. This was introduced by the course leader who then asked open questions to encourage participants to explore their thoughts and experiences relating to the topic in question. At the end of each discussion session there was a suggested homework task to complete for the next session. Participants were given the opportunity to take breaks during the sessions and were reminded that they could move around if they needed to during both the discussion and practical components. After the guided discussion participants had a refreshment break for approximately 15 minutes while the course leaders prepared the gym. This allowed participants time to debrief on what they had discussed in the absence of the course leaders and allowed the leaders time to reflect on the session.

During the second part of each session participants had the opportunity to undertake PA in a gym setting. The gym was set up with laminated cards to illustrate suggested exercises. Each card had instructions on what to do and how to progress the exercise, accompanied by a photograph to demonstrate how to do it. Participants also had

access to gym equipment such as the static bicycle, treadmill and stepper. However, this specialist equipment is not a requirement for intervention delivery. In the first session all the exercises were demonstrated by the course leader. During subsequent sessions participants could choose the exercises they wanted to try, with guidance and support from the leaders as required. The number of available exercises (n=16) exceeded the number of participants so there were no concerns about participants waiting to try out the next exercise.

Participants had access to the gym for up to 45 minutes, but they could choose how much to do and could leave when they had finished their PA. Between each session participants were encouraged to complete an activity diary to monitor their day to day PA and check their progress. This has been described in chapter 7.

8.3.3.1 Development of session plans and support materials

A detailed session plan and support materials were developed for each session to aid delivery and facilitate learning (appendix N1 to 7). These have been described in more detail in chapter 7.

8.3.4 Data collection

Written consent was requested and obtained immediately prior to the first session. Participants were encouraged to ask questions and the candidate clarified any issues prior to taking consent.

8.3.4.1 Demographic information

Those who gave consent were asked to provide demographic information, such as age, gender, RA disease duration, medication, employment status and comorbidities on a case report form (appendix S) at the time of the initial assessment.

8.3.4.2 Programme evaluation

The primary outcome of interest for this study was acceptability of the intervention to RA patients with experience of fatigue, including acceptability of the education and support materials and delivery methods. Participants were asked to complete an anonymised patient experience questionnaire (appendix T) to rate the intervention components and provide feedback regarding their experiences. Although this was not a validated questionnaire it was designed specifically for this study by the research team and PRPs. The questionnaire was completed at the end of the final session, facilitated by a researcher not involved in intervention delivery (Fiona Cramp) in the absence of the course leaders. Participants were given a summary outline of each session along with the questionnaire to remind them of session content.

It was important to hear the views and experiences of any participants who withdrew from the intervention early. Therefore it was agreed that anyone who left the study before the end of the intervention would be invited to complete this questionnaire. Attendance was recorded as an additional measure of the acceptability of the programme. Reasons for declining to take part in the study were also considered for this purpose.

Course leaders delivering the intervention recorded personal reflections at the end of each session, making note of their performance, what went well, what could be better and ideas for improving the session for next time (appendix U). As the intervention progressed session plans were modified based upon these reflections.

8.3.4.3 Outcome measures

The study explored possible outcome measures that might be used in future evaluation of this intervention. Prior to the first session, and at the end of the final session, participants were asked to complete outcome questionnaires. Included outcome measures are presented in table 8.1.

Table 8.1: Description of outcome measures used in the study

Name	Description	Score interpretation	Reliability and validity
Fatigue			
BRAF NRS (Nicklin <i>et al</i> , 2010a, Nicklin <i>et al</i> , 2010b)	Self-administered 3 single-items for fatigue severity, effect on life and coping ability Developed specifically for RA to provide a standardised NRS for measuring fatigue domains	Score range: 0–10 Higher scores reflect greater severity and effect Lower scores reflect worse coping	RA: Strong for severity and effect, moderate for coping (Hewlett, Dures and Almeida, 2011, Dures <i>et al</i> , 2013)
BRAF MDQ (Nicklin <i>et al</i> , 2010a, Nicklin <i>et al</i> , 2010b)	Self-administered 20-item scale assessing overall RA fatigue experience and impact, including 4 fatigue domains: physical fatigue, living with fatigue, cognitive fatigue, emotional fatigue Developed specifically for RA	Score range: total fatigue 0-70, physical fatigue 0-22, living with fatigue 0-21, cognitive fatigue 0-15, emotional fatigue 0-12 Higher scores reflect greater severity Provisional testing suggests MCID of >7.43 might indicate improvement or >2.58 worsening on total BRAF score (Dures <i>et al</i> , 2013)	RA: Strong (Hewlett, Dures and Almeida, 2011, Dures <i>et al</i> , 2013)
RA disease activity			
PDAS2 (Choy <i>et al</i> , 2008)	Patient-assessed measure of RA disease activity 4-item scale including patient-assessed 28-item SJC, PtGA, MHAQ, EMS	Score range: 0-8 Higher scores reflect greater disease activity <3.8 = remission; 3.8-4.5 = low disease activity; 4.6-5.0 = moderate disease activity; >5.0 = high disease activity (Leung <i>et al</i> , 2012)	RA: Acceptable (Choy <i>et al</i> , 2008, Anderson <i>et al</i> , 2011)

Name	Description	Score interpretation	Reliability and validity
Functional status and quality of life			
MHAQ (Pincus <i>et al</i> , 1983)	Self- or clinician-administered assessment of functional status 8-item scale regarding daily activity, including dressing & grooming, arising, eating, walking, hygiene, reaching, gripping, errands & chores	Total score range: 0.0 –3.0 Higher scores reflect worse function and greater disability normal function = MHAQ <0.3; mild functional loss = MHAQ <1.3, moderate = 1.3<MHAQ<1.8, severe = MHAQ>1.8 (Maska, Anderson and Michaud, 2011)	RA: Good (Maska, Anderson and Michaud, 2011)
HAQ Pain VAS (Fries <i>et al</i> , 1980)	Self-administered measure of pain intensity	Score range: 0-100mm Higher scores indicate greater pain intensity	RA: Good (Hawker <i>et al</i> , 2011)
HAQ PtGA VAS (Fries <i>et al</i> , 1980)	Self-administered measure of the overall way RA affects the patient at a point in time	Score range: 0-100mm Higher scores indicate greater disease activity	RA: Good reliability, acceptable validity (Anderson <i>et al</i> , 2011)
HADS (Zigmond and Snaith, 1983)	Self-administered 7-item scale to measure cases (possible and probable) of anxiety and depression	0-7 = normal range; 8-11 = borderline presence of anxiety/depression; >11 = probable presence of anxiety/depression (Snaith, 2003)	Good validity in the psychiatric and primary care patients and in the general population (Bjelland <i>et al</i> , 2002)

Name	Description	Score interpretation	Reliability and validity
Physical activity			
IPAQ-SF (Craig <i>et al</i> , 2003)	Self-administered measure of PA Designed for large population surveys or PA surveillance	1 to 3: Higher category indicates greater PA level 1. Low PA (do not meet criteria for 2 or 3); 2. Moderate PA (3 or more days vigorous-intensity activity of at least 20 minute per day OR 5 or more days of moderate-intensity activity +/- walking of at least 30 minutes per day OR 5 or more days of any combination of walking, moderate or vigorous-intensity activities achieving energy expenditure of at least 600 MET-minutes/week; 3. High level PA (vigorous-intensity activity at least 3 days and accumulating at least 1500 MET-minutes/week OR 7 or more days of any combination of walking, moderate or vigorous activities accumulating at least 3000 MET-minutes/week)	Validated for use in population surveys (Craig <i>et al</i> , 2003) Criterion validity testing in RA suggests limitations for estimating energy expenditure (Tierney, Fraser and Kennedy, 2014)
Self-efficacy and outcome expectations for exercise			
SEHBQ (Gecht <i>et al</i> , 1996)	Self-administered 17-item Likert scale measuring exercise beliefs in people with arthritis (strongly agree to strongly disagree) Includes four domains assessing beliefs about self-efficacy, barriers to exercise, benefits of exercise and impact of exercise on arthritis	Score range: Self-efficacy 4-20 Barriers to exercise 3-15 Benefits of exercise 3-15 Impact of exercise on arthritis 7-35 Higher scores represent stronger beliefs	Good face and content validity in arthritis (RA and OA) (Gecht <i>et al</i> , 1996)

Name	Description	Score interpretation	Reliability and validity
MOEES (Wojcicki, White and McAuley, 2009)	Self-administered 15-item measure of outcome expectations for exercise Includes three domains assessing physical, social and self-evaluative outcome expectations	Score range: Physical outcome expectations: 6-30 Social outcome expectations: 4-20 Self-evaluative outcome expectations: 5-25 Higher scores represent better outcome expectations	Valid and reliable in middle and older aged adults (Wojcicki, White and McAuley, 2009) including those with physical and functional comorbidities (Hall <i>et al</i> , 2012)

BRAF MDQ=Bristol Rheumatoid Arthritis Fatigue Multi-dimensional Questionnaire; BRAF NRS=Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scale; EMS=early morning stiffness; HADS=Hospital Anxiety and Depression Scale; HAQ=Health Assessment Questionnaire; IPAQ-SF=International Physical Activity Questionnaire short form; MCID=minimal clinically important difference; MET=metabolic equivalent; MHAQ=modified Health Assessment Questionnaire; MOEES=Multi-dimensional Outcome Expectations for Exercise Scale; OA=Osteoarthritis; PA=physical activity; PDAS2=Patient-based Disease Activity Score 2; PtGA=patient global assessment of disease activity; RA=rheumatoid arthritis; SEHBQ=Self-Efficacy and Health Beliefs Questionnaire; SJC=swollen joint count; VAS=visual analogue scale

8.4 Analysis

8.4.1 Demographic and outcome measure data

Quantitative data were entered onto a spreadsheet in Microsoft Excel (2013) and analysed using descriptive statistics to summarise demographic characteristics, changes in outcomes and quantitative questionnaire data. As this was a proof-of-concept study it was not powered to identify statistical changes in outcomes and there was no comparison arm. Therefore it would not be appropriate to make statistical comparisons. As a result inferential statistics were not performed on these data.

8.4.2 Patient experience questionnaire

Likert scores were recorded for each question and summarised using descriptive statistics. Free text response data from questionnaires were analysed using qualitative content analysis (Joffe and Yardley, 2004).

Although there is no firmly accepted definition of content analysis, it has been described as *“the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns”* (p. 1278, Hsieh and Shannon, 2005). Whilst this may seem similar to thematic analysis, this systematic approach also has a quantitative element, as it involves identification of categories and counting their occurrence within textual data (Kondracki, Wellman and Amundson, 2002, Joffe and Yardley, 2004). Data may be presented as quantified content, highlighting emphasis on certain topics, a qualitative description or both (Kondracki, Wellman and Amundson, 2002). Therefore content analysis may be used to obtain a condensed description of the data (Elo and Kyngas, 2008). This method was chosen because it is well suited to the analysis of open-ended survey questions (Kondracki, Wellman and Amundson, 2002).

Despite the lack of agreement regarding definition, there is consistency regarding the need for a reliable and transparent approach to content analysis (Kondracki, Wellman and Amundson, 2002, Graneheim and Lundman, 2004, Hsieh and Shannon, 2005, Elo and Kyngas, 2008). Graneheim and Lundman (2004) and Hsieh and Shannon (2005) have described content analysis processes, and these were used to inform the current analysis.

The first step of the analysis used a qualitative approach. This focused on ‘manifest content’, that is, that which is visible and obvious, as opposed to ‘latent content’, where the meaning may be more implicit (Graneheim and Lundman, 2004). This was felt to be the most appropriate level of analysis, given the brief, sometimes single word comments recorded in response to questions. Inductive coding (see chapter 5, section 5.3.4.2) was

performed to capture content generated by the participants and codes were then grouped into categories for each question. A quantitative analysis followed, allowing the candidate to check the frequency of occurrence of each response category to indicate participants' thoughts regarding the intervention (Joffe and Yardley, 2004). This process of manifest content analysis has also been referred to as summative content analysis, whereby the text is analysed for the appearance and frequency of specific content (Hsieh and Shannon, 2005).

A second round of analysis looked at the questionnaires as a whole, rather than by question. Data were analysed using a hybrid analysis, as described in chapter 5. This analysis looked for latent themes within the questionnaire data (Graneheim and Lundman, 2004). Deductive analysis was conducted by mapping the free-text data against the COM-B model (Michie, van Stralen and West, 2011) used as the theoretical framework during intervention development (chapter 7). This was to identify whether the evaluation provided any evidence that the intervention had influenced behaviour change in accordance with the theoretical model on which it was based. The data were also analysed using the BCT taxonomy (Michie *et al*, 2013) to look for evidence that selected BCTs had been used within the intervention. Following the deductive process, inductive analysis sought to highlight additional themes within the data. The two analyses were combined and presented together as a hybrid analysis. Example quotations presented in the results do not include participant identification numbers as the questionnaires were anonymous.

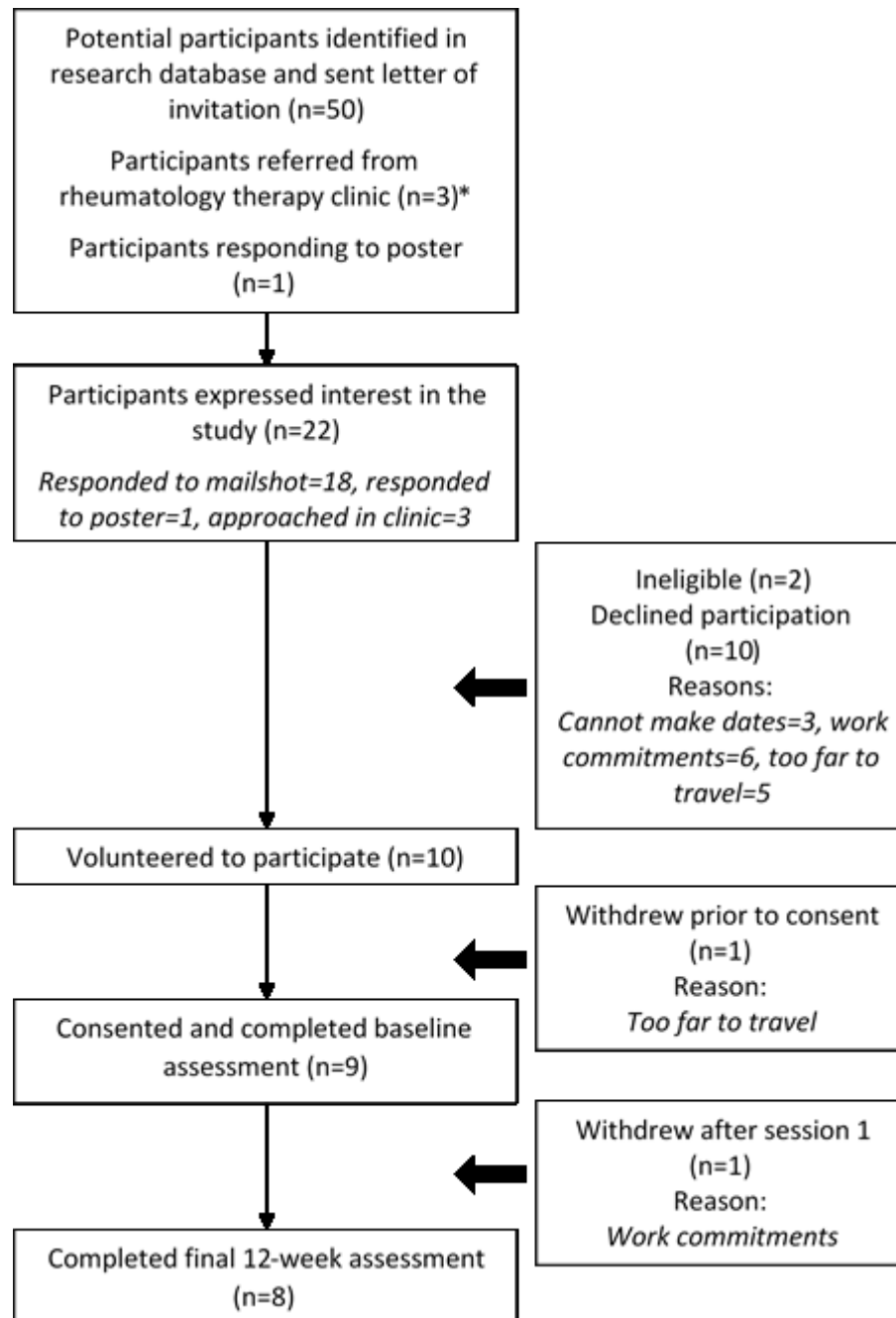
8.5 Results

8.5.1 Participants

A total of 22 patients (15 female) expressed an interest in the study. Of these, 18 (82%) had responded to the mailshot, giving a response rate of 36% (18/50). The other four interested patients had been approached when attending an outpatient therapy clinic (n=3) or had responded to a poster (n=1). Two respondents were ineligible to take part due to the absence of fatigue or insufficient severity of fatigue to meet the inclusion criteria. Ten participants declined participation. Of these, three participants were interested but unable to take part on the given dates. The remaining seven respondents were unable to take part due to work or other time commitments (n=6) and/or had too far to travel (n=5). Some participants gave more than one reason for declining. The ten remaining respondents indicated that they were able to attend on the given dates and volunteered to participate. However, one withdrew before the first session having decided it was too far to travel. Nine patients (8 female) consented to take part in the study. A

flowchart illustrating participant progression through the study is presented in figure 8.1. Participant demographic information is presented in table 8.2.

Figure 8.1: Participant progression through the study



Participants provided more than one reason for declining participation

**It is not known how many participants were approached by therapy staff on behalf of the candidate*

Table 8.2: Participant information

ID	Gender	Age (years)	Disease duration (years)	Fatigue severity (BRAAF NRS)	Work status	Medication	Other health problems
031	M	65	4	7	Retired	DMARD	High BP, Mild asthma
032	F	45	5	7	Unemployed, receiving incapacity benefits	DMARDs, folic acid, analgesia	*
033	F	64	7	6	Retired	DMARDs, NSAID	N/A
034	F	55	4	7	Paid work	DMARD, NSAID, folic acid, omeprazole	Euticaria
035	F	67	3	8	Retired	DMARDs, analgesia, biologics	Hypothyroidism, high BP, depression
036	F	38	4.5	7	Receiving ESA	NSAID, medical marijuana	Bulging disc L4/5 with osteoarthritis, Coeliac
037	F	53	4	6	Paid work	DMARDs, analgesia, gabapentin	Fibromyalgia, Plantar fasciitis
038	F	63	4 months	9	Retired	DMARD	High BP
039	F	75	12	8	Retired	DMARDs, folic acid	Lactose intolerance

*BP=*blood pressure; *BRAAF NRS=*Bristol Rheumatoid Arthritis Fatigue Numeric Rating Scale (range 0-10; high = worse fatigue); *DMARD=*disease modifying anti-rheumatic drug; *ESA=*Employment and Support Allowance; *F=*female; *ID=*participant identification code; *M=*male; *N/A=*not applicable; *NSAID=*non-steroidal anti-inflammatory drug

* = no data

8.5.2 Attendance and attrition

Of the nine patients who started the course, eight completed the intervention. One participant withdrew after the first session reporting that they were no longer able to attend due to work commitments. They were sent an evaluation questionnaire to complete, along with a pre-paid return envelope. However, the questionnaire was not returned.

Attendance for the remaining eight participants was high, with a mean of 6.5 sessions (93%) attended. Over half of the participants (n=5) attended all 7 sessions, two were unable to attend one session due to other commitments and one participant was unable to attend two sessions due to other commitments and illness.

8.6 Patient experience questionnaire

8.6.1 Likert rating scores

Overall feedback from participants was positive. Rating scores (0-10, higher scores represent greater acceptability) recorded for questions 1 to 8 suggested that the intervention was acceptable to participants completing the programme, with mean scores ranging from 8.9 to 10.0 (table 8.3).

Table 8.3: Rating scores for the intervention evaluation questionnaire (n=8)

Question	Lowest score	Highest score	Mean (SD)
1 How useful was the discussion session?	7	10	9.3 (1.1)
2 How useful was the practical session?	8	10	9.5 (0.9)
3 How helpful were the handouts?	8	10	9.4 (0.7)
4 Were the course leaders encouraging?	9	10	9.8 (0.4)
5 Was the programme well run?	10	10	10.0 (0.0)
6 How easy was it to complete the questionnaires?	7	10	8.9 (1.0)
7 How satisfied were you overall?	10	10	10.0 (0.0)
8 Would you recommend this programme?	10	10	10.0 (0.0)

8.6.2 Response categories by individual question

Content analysis of free-text identified response categories for each question. These categories and the frequency of each response are presented in tables 8.4.1 to 8.4.10. These will be discussed in further detail within the qualitative analysis in section 8.6.3.

Table 8.4.1: Discussion sessions

Free-text prompt: Was any topic particularly helpful or less helpful?	
Coded response categories	Coding frequency
All were helpful	4
Pacing useful	3
Goal setting useful	2
Activity diaries helpful	2
Managing setbacks useful	2
Sharing experiences of RA and fatigue helpful	2
Helpful strategies for improving fitness and motivation	1

Table 8.4.2: Practical sessions

Free-text prompt: Were any exercises too hard or too easy?	
Coded response categories	Coding frequency
Choice of exercises and ability to select own level was helpful	3
Appropriate level of exercise	2
Improved mood	2
Good range of materials/aids, e.g. Theraband	2
Gave ideas for exercise/PA at home	2
Improved confidence with PA	1
Would have liked longer to exercise	1

Table 8.4.3: Support materials

Free-text prompt: Were any particularly helpful? Were they clear?	
Coded response categories	Coding frequency
Activity diary/exercise charts very helpful	3
Pedometer useful	2
Handouts were very clear	2
Relaxation CD useful	1
Pacing handout useful	1
Good for future reference	1

Table 8.4.4: Course leader performance

Free-text prompt: Were course leaders encouraging? Was anything particularly good/bad?	
Coded response categories	Coding frequency
Good explanations	2
Good pace	1
Professional, encouraging and motivating	1

Table 8.4.5: Programme organisation and delivery

Free-text prompt: Was the programme well run? Was anything particularly liked/disliked?	
Coded response categories	Coding frequency
Group format is invaluable	3
Practical session was good	2
Good delivery	2

Table 8.4.6: Questionnaire and outcome measure completion

Free-text prompt: How easy or difficult was it to complete questionnaires?	
Coded response categories	Coding frequency
Hurts to write	2
Scales (1-10) are easier to complete	1

Table 8.4.7: Overall satisfaction

Free-text prompt: What made you satisfied/dissatisfied with the programme?	
Coded response categories	Coding frequency
Improved motivation	2
Helpful meeting others with RA	2
Well-structured discussion and practical sessions	2
Good support from tutors	1
Well explained and informative	1
Well planned and delivered	1
Relaxed atmosphere but focussed	1

Table 8.4.8: Recommendation to others

Free-text prompt: Why would you or would you not recommend the programme?	
Coded response categories	Coding frequency
Improve understanding of RA and lifestyle management	3
Improved coping and self-management skills	3
Benefit from group support	2
Enjoyable	1

Table 8.4.9: Suggested changes to improve the programme

Coded response categories	Coding frequency
Ongoing course for continued peer support	2
Increased course availability	2
Recording activity was challenging	1
Would like more classes	1

Table 8.4.10: Any further comments

Coded response categories	Coding frequency
Grateful for opportunity	2
Pedometer boosted motivation	1
6 months follow-up	1
Enjoyable, made me feel better, have increased physical activity	1
Talking to others improves coping	1

8.6.3 Qualitative content analysis

Themes derived following hybrid analysis of the questionnaires related to components of the COM-B behavioural model and acceptability of the intervention process. As discussed in chapter 7, the COM-B model proposes that behaviour is influenced by capability, motivation and opportunity (Michie, van Stralen and West, 2011). The analysis revealed that participants made reference to aspects of the intervention that might address each component. It is important to note that it is not suggested that the intervention had influenced or altered these behavioural elements; rather that the comments implied that it could potentially do so. Codes and coding frequencies for each component can be found in appendices V1-3. Each component will be discussed as a separate theme.

8.6.3.1 Factors affecting capability

The first component of the COM-B model is capability. As indicated in chapter 7, this can be divided into physical and psychological capability (Michie, van Stralen and West, 2011). Questionnaire responses provided some evidence that the intervention could potentially influence the capability of participants (appendix V1). For example, physical capability may be enhanced by carrying out practical exercise.

“Practical help in improving fitness and providing motivation to do it”

The practical sessions were well received by participants (table 8.4.2), although one participant reported that they would like to have spent longer exercising during the session.

“Would have liked longer to exercise.”

Acknowledgment of undertaking practical PA demonstrates the application of BCT 8.1- behavioural practice/rehearsal (Michie *et al*, 2013).

Responses to individual questions indicated that participants particularly liked selecting their own exercises and choosing the level to suit their own ability. This enabled them to tailor the exercises to their individual needs. The range of exercises available also facilitated this choice.

“...you could choose what exercises to do oneself and stop when you wanted to.”

It is possible that these comments indicated that participants took a graded approach to PA, as encouraged by the course leaders (BCT 8.7 – graded tasks (Michie *et al*, 2013)).

Influences on psychological capability were inferred by several references to intervention content that had been selected to address this component of behaviour. For example, recognition that the activity diary helped, the pacing strategy was useful and the intervention enhanced understanding of RA all relate to psychological capability. These responses suggest that the intervention facilitated acquisition of self-management skills to improve PA behaviour, for example using the activity diaries helped participants to monitor their PA.

“The chart for showing your day that you colour in is really good as you can see where you do and don't do movements and what activity you do”

This was evidenced by responses to individual questions, where all discussion topics were considered useful. Self-management strategies such as pacing, goal setting and activity diaries were specified most frequently (Table 8.4.1).

“All were very helpful, especially the activity diary”

Activity diaries were also most frequently mentioned as helpful support materials (table 8.4.3).

References to setting goals, managing setbacks, activity diaries, pedometers and the relaxation CD provided some evidence that key BCTs were used in the intervention

(Michie *et al*, (2013): 1.1 - goal setting (behaviour), 1.2 - problem solving, 1.4 - action planning, 2.3 - self-monitoring of behaviour, 2.6 - biofeedback, 12.6 - body changes).

Although activity diaries were generally useful, one participant reported that they found keeping activity diaries challenging and did not manage to keep this up for the duration of the programme.

“I found small scale recording a problem, but many others found this very useful. The activity diaries were a good review, but I failed to keep them up to date over the course”

8.6.3.2 Factors affecting opportunity

The second component of the model related to physical and social opportunity (Michie *et al*, 2011). Responses to the questionnaire demonstrated that participants appreciated the opportunity to take part in the intervention (appendix V2).

“So pleased that I was able to take part”

The intervention provided appropriate and useful resources that enabled participants to take part in PA.

“Good range of materials/aids etc.”

Whilst the intervention itself offered a physical opportunity for PA, there is less evidence that participants were inspired to seek out and identify their own opportunities. However, it was reported that the practical session provided ideas for home exercise.

“The exercises gave some good ideas about what can be done at home.”

Similarly, one participant suggested that they would continue PA after the intervention.

“It made me want to carry on doing gym work”

Despite this, the majority of suggested improvements for the programme related to participants' desire for the programme to continue. They wanted further provision of this opportunity, through ongoing classes and more availability.

“Maybe run the course a bit longer”

“I would like it to be ongoing”

“More of them [classes], for more people”

Other suggestions included having a follow-up session to the programme.

“It would be helpful to meet up in 6 months' time to see what progress has been made by group [sic].”

As well as providing a physical opportunity for PA, the intervention provided a social opportunity that was highly valued by participants. The group format was powerful, with group support being the most frequently coded category across all questionnaires (11 references). Reasons for this social opportunity being so highly valued were that the group provided general peer support, reassurance from hearing experiences of other patients, and learning from others to enhance their own self-management. During the programme some participants commented that they had never met other people with RA before.

"It was nice to be with people with understanding of the illness."

"Liked meeting fellow RA sufferers and any tips they had with handling RA"

It was acknowledged that the support offered by the group would be missed after the intervention ended. The implication was that patients do not regularly have access to these groups and that they highly valued the peer support. The evidence for social opportunity provided by the intervention demonstrates BCT group 3: social support (Michie *et al*, 2013).

8.6.3.3 Factors affecting motivation

There is some evidence that the intervention might address reflective motivation for PA, for example through changing beliefs in capabilities and improving confidence. Codes relating to this component are presented in appendix R3.

"Given confidence to do more [sic]"

Automatic motivation relating to emotional response to PA was evidenced through references to feeling better and improved mood.

"I really enjoyed it and it has made me feel better"

"Making one see that it is not a downward spiral and that things can be done to stabilize or reverse the emotional and some physical issues"

Other comments suggested that the intervention improved motivation, but further detail cannot be determined from the responses. Motivation to achieve PA both during the intervention and to continue after the programme was reported.

"I didn't feel any pressure yet wanted to achieve some exercise each session"

"It made me want to carry on doing gym work as it mentally stimulated me"

8.6.3.4 Influences on physical activity behaviour

One participant noted that they had increased their PA behaviour as a result of taking part in the intervention.

"I have increased my exercise considerably."

There were no other specific references to a change in PA.

8.6.3.5 Intervention processes are acceptable

Generally, comments were positive and suggested that participants found the intervention processes acceptable. Participants indicated that they enjoyed taking part.

"It was something I really looked forward to attending"

"For me, it was very rewarding."

Responses to questions relating to the programme organisation demonstrated that the intervention was well structured and delivered (table 8.4.5). These aspects of the programme contributed to participants' overall satisfaction (table 8.4.7).

"I thought it was really well planned and would be invaluable to anyone diagnosed with RA."

"A good structure to have 1 hr of learning and then 1 hr of physical exercise [sic]."

The group format was highly valued, as reported previously.

"Again the forming of the group was imp [sic]. RA can make one feel isolated. V [sic] reassuring to hear people talk of how RA has affected them"

Sessions were judged to be informative and well explained. It was suggested that they were delivered at an appropriate pace in a supportive and inclusive environment (tables 8.4.4, 8.4.7).

"Everything was explained well. Very informative"

"Excellent. Supportive. Kept things on track. Made everybody feel included"

The course leaders were found to be professional and encouraging, providing good support and motivating participants. This contributed to overall satisfaction with the programme.

"The support of the people running the group was wonderful"

"I thought that they were very professional and motivation and encouraged the group very well"

Participant comments indicated that the sessions did not feel threatening or pressurised.

“...not threatening - not over intense but helped me to focus on what I need to do to help myself”

Course support materials were considered clear and useful for future reference (table 8.3.3).

“Good reference points for the future”

In general participants reported that they would recommend the intervention to others to gain a greater understanding of RA and to improve coping and self-management skills (table 8.4.8). It was not clear whether these comments related to RA in general, to RA fatigue or to both.

“It helps you to cope with your illness”

Top rating scores for programme organisation, overall satisfaction and recommendation to others, and high scores for course leader performance also reflect acceptability of the intervention processes (table 8.3).

8.7 Outcome measures

Outcome scores at baseline, post-intervention and changes in scores for all outcome measures are shown in tables 8.5 and 8.6. These include data for eight participants who completed the intervention. Data for the participant who withdrew were removed prior to the analysis. As the study was not designed to evaluate changes in outcome measures only descriptive statistics are presented. Completion rates for all measures were 100%. However, data for IPAQ-SF calculations were removed for two participants following the application of data processing rules that specify exclusion of ‘don’t know’ responses (IPAQ, 2005).

Table 8.5: Outcome scores at baseline and post-intervention and change in scores for fatigue, disease activity and quality of life, and self-efficacy and outcome expectations for exercise (n=8)

Outcome measure	Baseline	Post 12 week intervention	Change in scores
Fatigue			
BRAf NRS			
<i>Effect</i>	6.50 (3 to 10)	4.25 (2 to 8)	-2.25 (-6 to 0)*
<i>Severity</i>	7.00 (5 to 10)	4.63 (2 to 8)	-2.38 (-6 to 0)*
<i>Coping</i>	4.50 (1 to 8)	6.25 (2 to 8)	1.75 (-6 to 5)*
BRAf MDQ			
<i>Physical</i>	14.50 (10 to 22)	10.38 (6 to 20)	-4.13 (-8 to -1)*
<i>Living</i>	9.50 (3 to 21)	6.13 (1 to 17)	-3.38 (-7 to 1)*
<i>Cognition</i>	7.75 (2 to 15)	5.88 (0 to 15)	-1.88 (-7 to 0)*
<i>Emotion</i>	6.63 (1 to 12)	4.75 (1 to 10)	-1.88 (-6 to 0)*
<i>Total</i>	38.38 (19 to 70)	27.13 (9 to 62)	-11.25 (-25 to -4)*
RA disease activity and quality of life			
Pain VAS (mm)	58.50 (19 to 91)	45.88 (5 to 73)	-12.63 (-52 to 29)*
Patient Global VAS (mm)	46.88 (18 to 73)	38.13 (0 to 81)	-8.75 (-34 to 17)*
MHAQ	1.34 (0 to 2.25)	1.11 (0 to 2.38)	-0.23 (-0.63 to 0.13)*
PDAS2	4.55 (2.98 to 5.71)	4.28 (2.91 to 6.92)	-0.27 (-1.72 to 0.92)*
HADS			
<i>Anxiety</i>	9.88 (6 to 13)	8.88 (5 to 15)	-1.00 (-6 to 2)*
<i>Depression</i>	9.75 (6 to 16)	7.63 (3 to 12)	-2.13 (-5 to 1)*
Self-efficacy and outcome expectations			
SEHBQ			
<i>Self-efficacy</i>	11.75 (5 to 17)	15.75 (13 to 19)	4.00 (0 to 9)*
<i>Barriers to exercise</i>	11.88 (10 to 15)	12.25 (11 to 14)	0.38 (-1 to 1)*
<i>Benefits of exercise</i>	12.00 (10 to 15)	12.75 (11 to 14)	0.75 (-1 to 2)*
<i>Impact on arthritis</i>	26.63 (21 to 33)	29.38 (20 to 35)	2.75 (-1 to 9)*
MOEES			
<i>Physical outcomes</i>	24.88 (21 to 30)	25.75 (23 to 30)	0.88 (0 to 3)*
<i>Social outcomes</i>	13.75 (12 to 16)	14.88 (12 to 17)	1.13 (-1 to 4)*
<i>Self-evaluative outcomes</i>	21.13 (17 to 25)	21.50 (19 to 25)	0.38 (-2 to 4)*

All scores are mean (range); *=change in direction of improvement

BRAf MDQ=Bristol Rheumatoid Arthritis Fatigue Scale Multi-Dimensional Questionnaire; BRAf NRS=Bristol Rheumatoid Arthritis Fatigue Scale Numeric Rating Scale; HADS=Hospital Anxiety and Depression Scale; MHAQ=Modified Health Assessment Questionnaire; MOEES=Multidimensional Outcome Expectations for Exercise Scale; PDAS=Patient-based Disease Activity Score; RA=rheumatoid arthritis; SEHBQ=Self-efficacy and Exercise Health Beliefs Questionnaire; VAS=Visual Analogue Scale

Table 8.6: Individual physical activity questionnaire scores at baseline and post-intervention (n=8)

Study ID	PA on at least 5 days		PA on at least 7 days		Daily sitting time (minutes)		IPAQ category	
	Baseline	Post intervention	Baseline	Post intervention	Baseline	Post intervention	Baseline	Post intervention
031	Y	Y	Y	Y	480	480	3	3
032	N	N	N	N	Unknown	360	1	1
033	*	*	*	*	480	240**	*	*
034	Y	Y	N	Y**	300	540	2	3**
035	Y	Y	Y	Y	360	240**	3	3
036	*	*	*	*	Unknown	Unknown	*	*
038	Y	Y	Y	Y	240	180**	2	3**
039	Y	Y	N	Y**	240	180**	1	3**

ID=participant identification code; IPAQ-SF=International Physical Activity Questionnaire Short Form; N=No; PA=physical activity; Y=yes

**=data excluded; **=change in direction of improvement*

IPAQ-SF categories:

1. Low PA (do not meet criteria for 2 or 3)

2. Moderate PA (3 or more days vigorous-intensity activity of at least 20 minute per day OR 5 or more days of moderate-intensity activity +/- walking of at least 30 minutes per day OR 5 or more days of any combination of walking, moderate or vigorous-intensity activities achieving energy expenditure of at least 600 MET-minutes/week)

3. High level PA (vigorous-intensity activity at least 3 days and accumulating at least 1500 MET-minutes/week OR 7 or more days of any combination of walking, moderate or vigorous activities accumulating at least 3000 MET-minutes/week)

Mean change scores for all outcomes changed in the direction of improvement, although ranges highlight that this was not the case for all individual scores (table 8.5). No adverse events were reported during the study.

The lowest scoring component of the patient experience questionnaire related to ease of completing outcome measurement questionnaires (mean Likert rating: 8.9). Whilst few participants commented on this, those that did noted that writing was painful (table 8.4.6). Responses suggested that selecting metrics that use rating scales is preferable to open questions.

“My hands hurt holding the pens so maybe too much writing”

“It’s easier when [questionnaires] have a scale of 1-10”

8.8 Reflective practice

Course leaders recorded written reflections after each session to refine the intervention and modify future sessions where necessary. Comments for each session and suggested improvements are summarised in table 8.7.

Table 8.7: Session reflections

Session number	Comments	Ideas for improvements
1	<p>Good group dynamic</p> <p>Covered all content although felt quite hurried with a lot to get through. Discussion session felt rushed as a result.</p> <p>This was partly due to overrunning with completing outcome questionnaires before the session began.</p> <p>Setting up the gym between sessions was challenging with only one person.</p>	<p>For next session:</p> <p>Arrange for an assistant to help with room set up and facilitation of small group work</p> <p>For future delivery:</p> <p>Allow more time to complete outcome measures before the session</p> <p>Ensure full 60 minutes for discussion session</p>
2	<p>Another good session, good engagement from participants</p> <p>Assistant present for this session which was much better, particularly for reviewing activity diaries in smaller groups and for setting up the gym. Also useful when facilitating individual goal setting during practical session</p> <p>Ensure delivery remains interactive and not didactic</p>	<p>For next session:</p> <p>Have all handouts in one pack and hand out at the end of the session rather than handing out individual ones for each topic.</p> <p>Make better use of flipchart/board for recording participants comments and ideas</p> <p>For future delivery:</p> <p>Ask patients to recap previous session to check understanding, and discuss as necessary</p>
3	<p>Discussion flowed well and group responded to prompts</p> <p>Stress/anxiety discussions and relaxation CD well received by participants</p> <p>Grounding exercise in the practical went well</p> <p>Participants are engaging really well with exercises in the practical session and report that they enjoy this, particularly having a choice of exercise and intensity</p>	<p>For future delivery:</p> <p>Sleep discussion could include more information on phases of sleep</p> <p>Would be good to unpick participants' beliefs around sleep and to identify bad habits. Could make better use of problem solving for this.</p> <p>Consider including discussion on acceptance as part of this session as this was an issue for several people</p>

Session number	Comments	Ideas for improvements
4	<p>Good discussion regarding planning daily physical activity</p> <p>Pedometers were well received</p> <p>Participants continue to engage well with practical session</p>	<p>For future delivery:</p> <p>Need to modify content relating to 'apps'/technology based self-monitoring and balance this with options for non-tech savvy participants</p>
5	<p>Really good session</p> <p>Good use of flipcharts to capture ideas from the group</p> <p>Good examples from participants of successful planning/pacing</p> <p>Excellent feedback from participants regarding the benefits of a group format</p>	<p>For future delivery:</p> <p>Consider including information about RA support groups such as NRAS in future support materials</p>
6	<p>Good active participation from all members of the group</p> <p>Participants continuing to use activity diaries and find them very helpful</p> <p>Helpful to recap on previous sessions</p>	<p>For future delivery:</p> <p>Could allow more time for planning long-term physical activity within the session rather than just as a homework task</p> <p>Ensure focus on solutions rather than just identifying barriers to physical activity</p>
7	<p>Participants came up with good ideas for solutions to barriers to physical activity</p> <p>Group shared ideas and advice</p> <p>Many participants have set plans for continued exercise</p>	<p>For future delivery:</p> <p>Repeat goal setting and ask participants to rate confidence that they will continue physical activity in the long-term</p>

NRAS=National Rheumatoid Arthritis Society; RA=rheumatoid arthritis

8.9 Discussion

Findings from this study suggest that the processes, format and content of a PA self-management intervention for RA fatigue were acceptable to the study population. High attendance (mean: 6.5 out of 7 sessions) and low attrition (n=1) rates, high rating scores for the patient experience questionnaire and positive responses to open questions provided evidence of acceptability.

The majority of patients (n=18) who were interested in this study were recruited via mailshot, suggesting that this was the most effective recruitment strategy. However, as face-to-face recruitment was conducted by members of the healthcare team and not the research team it is not known how many patients were invited to take part using this strategy. Time pressures of a busy clinic might mean that recruitment was a low priority for clinicians, suggesting that potential participants might have been missed. Recruitment in clinic by a member of the research team or a dedicated research nurse might have improved this strategy and should be considered for future studies.

Acceptability must also take into account reasons for declining participation. The majority of people who were interested were unable to attend due to work commitments or logistical issues. This echoes previous focus group findings (chapter 6) where concerns regarding attendance for those in employment were raised. The intervention might appeal in terms of its aims and content, but the delivery might be considered unacceptable to these patients. Although time constraints and logistics, such as transport and travel, are known barriers to participation in PA interventions (de Jong *et al*, 2004a, Vervloesem *et al*, 2012), the issue of accessibility of PA and fatigue management interventions for patients in employment warrants further exploration. A survey of work and RA conducted by NRAS in 2010 reported that 81.1% of 119 respondents in employment cited fatigue as a major barrier to remaining in work (NRAS, 2010). The lack of attendance by those who work was evident in the demographic data, with only two participants reporting that they were in employment. One of these participants withdrew after session one, citing work as the reason. The majority of participants were retired and aged over 60 (n=5). The inclusion of larger numbers of retired participants might suggest that patients who are not working are more able to prioritise attendance at such interventions. Previous qualitative findings have reported that RA patients of working age (20 to 60 years) often prioritised work over other activities, including physical exercise (Feldthusen *et al*, 2013).

Participants in this study were predominantly female, indicating an under-representation of men (n=1), even though seven (31.8%) of the 22 participants who expressed an interest in the study were male. Of these, two were ineligible as they reported a BRAF severity score of less than 6/10. The other five were unable to attend,

with four citing work as the main reason. Previous research noted an over-representation of men amongst patients who were unwilling to participate in an exercise programme (de Jong *et al*, 2004a, Vervloesem *et al*, 2012). Men with RA appear to have differing preferences for support needs and management strategies (Flurey *et al*, 2015), which may indicate a need for particular attention to improving recruitment and research participation in this group. Similarly, the literature review by Flurey *et al* (2015) noted that men seem to value paid work more highly than women, suggesting that they might be less likely to prioritise participation in healthcare interventions.

Demographic data indicated the presence of other conditions where fatigue is frequently a major symptom, such as fibromyalgia and hypothyroidism. Inclusion criteria for this study did not eliminate patients with other health conditions. This was a pragmatic decision to reflect the nature of clinical practice, where RA patients often have additional health problems. This was not an issue in this study, as it did not aim to evaluate the effectiveness of the intervention for reducing fatigue. If a future trial wished to evaluate the true effect of the intervention on RA fatigue then the exclusion of fatigue syndromes may need to be considered to minimise confounding effects. However, for a pragmatic trial it would be appropriate to include them in order to provide evidence of clinical benefit and be more representative of clinical practice.

8.9.1 Patient experience questionnaire

High scores recorded by participants on the patient experience questionnaire also suggested acceptability of the intervention in terms of content, format and delivery processes. However, these data must be interpreted with caution as only eight participants completed the intervention. Attempts were made to minimise bias, such as use of anonymised questionnaires, an independent researcher facilitating completion in the absence of the course leaders, and encouraging participants to give honest feedback to help improve the intervention. Nonetheless, participants' knowledge that one of the course leaders had developed the intervention and was undertaking a PhD may have influenced their feedback, as they may have been concerned about causing offence. Participants in this study had also volunteered to take part in the knowledge that it was a PA intervention. As a result they are likely to have been interested in PA and approached the programme with a positive attitude. As previously discussed, this is a common problem in PA trials (Neuberger *et al*, 2007, Nordgren *et al*, 2014). Additionally, mean Modified Health Assessment Questionnaire scores were 1.1 suggesting only mild functional loss in the participant group. Indeed, all participants were mobile and only one occasionally used a walking aid. Nonetheless, they all met inclusion criteria for fatigue severity so it is argued that they were an appropriate group to receive the intervention.

Responses to open questions were also positive, although participants did provide suggestions for future improvements to the programme. Similarly, deductive analysis using the COM-B behavioural model (Michie, van Stralen and West, 2011) employed during intervention development provided some insight into possible influences of the intervention on components of PA behaviour.

Analysis suggests that the programme potentially influenced participants' physical and psychological capability through encouraging PA practice and enhancing self-management and coping skills. Tools for planning and self-monitoring PA, such as activity diaries and pedometers, were particularly well received. The identification of key BCTs (action planning, goal setting, problem-solving and self-monitoring) that have been shown to increase PA in previous research was encouraging (Michie, *et al* 2009a, Bird *et al*, 2013). Influences on capability may also be indicative of enhanced self-efficacy, as described by Bandura's self-efficacy theory (1977), or competency as a component of motivation in SDT (Ryan and Deci, 2000).

It is clear from the analysis that the intervention provided a physical opportunity for participants, offering the necessary time, environment and resources to undertake PA. What is less clear is whether participants sought out their own opportunities outside of the sessions. The suggested improvements for the intervention mostly related to a desire for ongoing support with more sessions available and a longer programme. Nonetheless, some comments were suggestive of the intention to continue PA after the intervention. The absence of further detail highlights a limitation of this form of evaluation, as a focus group or interview study would have enabled the candidate to further unpick details about this element of the programme. These alternative methods of qualitative evaluation should be considered in future studies. Initially a focus group was considered for evaluating the programme in the current study. This would have allowed the intervention participants to reflect on and share their experiences of taking part and generate ideas for improvement (Kitzinger, 2005). However, this method was rejected due to the risk of bias involved if the moderator was the same person who had delivered the programme.

The social opportunity provided by the intervention was highly valued by participants. The group format appeared to be a key factor in enhancing self-management and coping skills, and provided peer support and encouragement. These findings emphasise that this was a vital element of the intervention. Comments that the peer support would be missed by some participants suggests that there may need to be more emphasis on helping participants to identify and access other support networks following the intervention. This is supported by social network theory that proposes that networks can influence health behaviours and psychological status through provision of social

support, social influence, social engagement and access to resources (Berkman *et al*, 2000). Although identifying other networks was discussed in the intervention it could have been reiterated in the final session.

The suggestion for an additional 6-month follow-up reiterates participants' desire for ongoing support. Some HCPs delivering PA interventions for fatigue in other conditions reported incorporating a follow-up session (chapter 5). This was also debated by rheumatology AHPs during intervention development. Logistics of implementation and concerns regarding attendance would need to be considered when incorporating a follow-up session. However, the apparent high value placed on both peer and professional support for enhancing motivation for PA justify its consideration in future iterations of this intervention.

Participants explicitly noted that motivation was influenced by the intervention. Similarly, other determinants of motivation, such as beliefs about capability, increased confidence and improved mood following PA were also implied. The availability of choice within practical sessions enabled participants to feel more in control of their PA. This could be interpreted as enhancing autonomous motivation as described by SDT (Ryan and Deci, 2000).

A further theme from the inductive qualitative content analysis reiterated that the intervention process was acceptable. This appeared partly to be due to the support and encouragement of the course leaders. It is likely that the course leaders could influence the effectiveness of the intervention. This is an important factor to consider not only for future larger scale evaluation, but also for application in clinical practice where different people might deliver the intervention. It is difficult to control for this effect, but future evaluation should consider ways to enhance treatment fidelity and therapist competence. Whilst delivery of a protocol-based intervention might increase adherence to the protocol, it does not account for therapist competence that might also affect the treatment effectiveness (Nezu and Nezu, 2005). It has been suggested that this might be achieved by increasing competence through use of a detailed manual, enhanced training and regular supervision (Nezu and Nezu, 2005).

The intervention structure of discussion and practical sessions was acceptable to participants. This helps to dispel concerns expressed by some AHPs in previous focus groups that two hours might be too long for RA patients (chapter 6), although concerns relating to service delivery may still be valid and important. Similarly, the intervention was delivered in a hospital gym in this study which remains a potential problem for some services that do not have access to suitable premises. However, practical sessions could

be adapted if a room was available, as specific gym equipment is not essential for delivery.

Other resources, such as handouts and support materials provided during the intervention also appeared to be acceptable, suggesting that these are appropriate for use in future testing of the intervention. No other modifications or refinements to these resources or content were suggested at this stage of development. However, alternative formats for support materials, including multi-media must be considered in future development as this was raised as an important preference by patients in the focus group study (chapter 6).

8.9.2 Outcome measures

As well as exploring the acceptability of the intervention process, content and delivery, this study aimed to explore the acceptability of completing potential outcome measures for use in future research.

Results suggest that, overall, the measures were acceptable to participants, as reflected by high rating scores in the patient experience questionnaire and 100% completion rate. However, it should be noted that mean rating scores for this component were the lowest on the questionnaire and received the most negative comments in the open responses. These comments suggested that too much writing was problematic for participants. Scales with tick boxes or numeric rating scales were preferred. The main outcome measure that involved writing was the patient experience questionnaire. This lends support to the recommendation that future evaluation should include other methods, such as focus groups and/or interviews to eliminate the need for writing. These methods would also enable researchers to tease out further detail and understanding related to patients' experiences of the intervention.

Whilst changes in outcomes from pre- to post-intervention must not be over-interpreted, all outcomes changed in the direction of improvement. It is worth noting that mean baseline Hospital Anxiety and Depression Scale scores for both anxiety and depression appeared to be higher than other baseline data for RA patients. It could be argued that this was due to the selection of patients who experienced fatigue, as fatigue in RA has been shown to be associated with anxiety and depression (Stebbing *et al*, 2010). However, the scores still appear high when compared to other data for RA patients selected for the presence of fatigue (Nicklin *et al*, 2010b). In the study by Nicklin *et al* (2010b), where inclusion criteria specified fatigue severity of at least 5cm on a 10cm visual analogue scale, mean anxiety scores measured by the Hospital Anxiety and Depression Scale were 7.7 (SD 3.8) compared with 9.9 (SD 2.5) for this study. Similarly mean depression scores were 8.7 (SD 4.3) versus 9.8 (SD 3.0) in this study. The higher

Hospital Anxiety and Depression Scale scores here are most likely explained by the small number of participants in this study (n=8 versus n=229 (Nicklin *et al*, 2010b)). High scores for just one or two participants would have affected the mean score in the current study.

Range scores for the Self-Efficacy and Health Beliefs Questionnaire and Multi-dimensional Outcome Expectations for Exercise Scale appear to be high at baseline assessment. This might confirm the assumption that participants in this study were more motivated and interested in PA. Alternatively, it might suggest a ceiling effect for these scales. However, these scales have been shown to be reliable in an arthritis population (Gecht *et al*, 1996) and in older adults with physical and functional comorbidities (Wojcicki, White and McAuley, 2009, Hall *et al*, 2012). Identification of suitable measures for capability and motivation components of the COM-B model require further consideration for future evaluation of this intervention.

Another issue with outcome measurement related to the IPAQ-SF. The scoring protocol for this questionnaire (IPAQ, 2005) was complicated and the exclusion of 'don't know' responses meant that two cases had to be removed from the analysis. This could be problematic for future trials, as it appears that this outcome measure is not suitable for use in this type of study. It is in fact noted by the developers that the IPAQ was designed for large population studies and is not recommended for use in small intervention studies such as this (Craig *et al*, 2003). Nevertheless, other researchers have used this questionnaire in studies to measure PA in RA, (for example, Nordgren *et al*, (2012), John *et al*, (2013)), as it is a validated tool. It was chosen for this study for ease of comparison with other PA data in RA patients. However, an assessment of criterion validity has highlighted limitations for its use for estimating energy expenditure in RA (Tierney, Fraser and Kennedy, 2014). A review of other validation studies noted that IPAQ-SF overestimated PA levels by 46-173% when compared with objective measures (Lee *et al*, 2011). Other tools are available, such as the 7-day Physical Activity Recall (Sallis *et al*, 1985) and the Nord-Trøndelag Health Study PA questionnaire (Kurtze *et al*, 2008), although validity and reliability in RA are not known. Nonetheless, other measures should be considered for future evaluation of this intervention.

Lastly, although fatigue scores all showed a trend towards improvement, data suggest that one participant was confused by the BRAF-NRS Coping response option. This is reverse scored (higher scores are better) compared to the other NRS responses for severity and impact (Nicklin *et al*, 2010b). Therefore, while seven of the eight participants demonstrated improved BRAF-NRS Coping scores, one participant had a worse score (6 points difference) despite the fact that all their other outcomes improved.

This issue has been noted in other validation studies for this outcome measure (Nicklin *et al*, 2014).

8.9.3 Reflective practice

Course leaders' reflections indicate that the sessions generally worked well, although some minor alterations are required to improve session content. The main issues arose in early sessions, particularly in the first session where the time taken to complete pre-intervention assessments had been underestimated. Participants reported feeling tired after doing this and the course leader was required to adapt the session to incorporate an additional comfort break. This meant that session content was hurried. Another issue raised in this session was the need for a second person to assist the course leader. This was predominantly to aid with room set-up for the discussion and practical session. It was also beneficial to have a second person present to improve individual attention during small group work and when goal-setting in the practical. Although it is not believed that two people would always be required to deliver the intervention, it should be considered for larger groups ($n>6$) and where there are any concerns regarding safety for participants or course leaders.

8.9.4 Limitations of the study

Recruitment to the study was straightforward, perhaps indicating a desire for interventions for fatigue management in RA. However, reasons for declining participation and demographic information are likely to have influenced recruitment. It is apparent that men were under-represented in the study. This is important, as there runs a risk of developing an intervention that is not acceptable to men if their views are not considered during development. The one male participant may not have felt comfortable voicing some of his opinions if he felt that he would be ignored or misunderstood by the rest of the group.

Voluntary participation will have resulted in self-selection of participants who are likely to be more interested and motivated to engage in PA. It must also be noted that participants' travel expenses were reimbursed in this study, possibly adding an incentive to take part. Had this not been the case it is possible that transport costs would have prohibited some participants from attending.

Evaluation of the acceptability of the intervention was by questionnaire only. Further exploration of free-text responses to open questions was not possible. Other methods of evaluation should be considered in future studies, paying due attention to minimising researcher influence or bias to reduce the likelihood of false positive results.

This intervention was implemented and delivered as part of a research study, therefore there were minimal constraints on resources. This may not be a realistic reflection of clinical practice in the current UK healthcare climate. Equally, no cost data were collected for this study. Cost implications must therefore be considered in future testing of this intervention.

8.10 Conclusions

The format and content of this carefully designed PA self-management intervention and its associated support materials were acceptable to group participants. The intervention appeared to incorporate content that could address capability, opportunity and motivation required for changing PA behaviour, although the study did not explicitly aim to investigate changes in these components.

The intervention processes were well received by participants, who reported suitable structure and appropriate delivery of content and materials. The group format was considered invaluable for peer support and enhanced learning. Suggested improvements related to ongoing support and follow-up to the intervention. Other changes to the intervention include identifying a suitable subjective PA outcome measure and improved methods for programme evaluation.

This intervention should now be considered for further evaluation in a pilot study prior to full scale testing in an RCT.

Chapter 9: Summary and discussion of research findings and implications for research and clinical practice

The preceding chapters 4 to 8 have discussed the studies and development processes undertaken in this research. This chapter summarises the main findings from these studies and discusses their implications for future research and clinical practice.

9.1 Thesis aims

The overall aim of this thesis was to develop a PA intervention to support RA patients to self-manage symptoms of fatigue. The thesis objectives were:

1. To identify the evidence for the use of PA for fatigue management in RA and other long-term conditions
2. To understand the experiences of HCPs using PA for fatigue management in clinical practice
3. To explore RA patients preferences and opinions relating to the intervention format, content and delivery
4. To identify the thoughts of rheumatology AHPs regarding practicalities of implementing and delivering a PA intervention in clinical practice
5. To develop an outline PA self-management intervention to manage RA fatigue informed by a theoretical framework of behaviour change
6. To model intervention processes in order to determine acceptability to RA patients and to inform further development.

These aims were addressed using a step-by-step approach as recommended by the MRC guidance for developing and evaluating complex interventions to improve health (MRC, 2000, MRC, 2008, Craig *et al*, 2008).

As discussed in chapter 1, the complexity of an intervention relates to the numerous dimensions that might influence the process and outcomes (MRC, 2008). For this intervention these might include:

- the number of and interaction between programme elements, for example, session structure and content, support materials, mode and style of delivery
- the number and complexity of behaviours and skills that participants undertake, for example, self-management skills such as pacing and self-monitoring, participating in PA

- the number and complexity of behaviours required by those delivering the intervention, for example, knowledge of RA, fatigue and PA, knowledge of PA/GET delivery, training in BCTs and addressing psychosocial issues
- the number and variability of outcomes, for example, changes in type, amount, duration and/or intensity of PA, changes in fatigue severity, effect and coping, changes in general RA self-management skills
- the degree of flexibility or tailoring of the intervention permitted, for example, different group sizes, time of day, location and resources

These interacting components are likely to influence the practical effectiveness of the intervention, and whether it would work in every day practice (MRC, 2008).

An iterative development process was conducted via a series of studies including a systematic literature review (chapter 4), qualitative interviews (chapter 5) and focus groups (chapter 6), intervention development (chapter 7) and a proof-of-concept study (chapter 8).

9.2 Contributions to knowledge

A PA self-management intervention was developed using a rigorous, systematic method, drawing together theory, preferences and practical considerations that aim to support adults with RA with managing fatigue. To the candidate's knowledge, this is the first such intervention to be developed in this way for managing this symptom.

The studies presented in this thesis contributed to knowledge in a variety of ways. These will be discussed in more detail but can be summarised as follows:

1. There is support from existing evidence, RA patients and rheumatology AHPs for the use of PA for fatigue management in RA. However, existing programmes lack an explicit theoretical basis for facilitating PA behaviour change.
2. Preferences for intervention components were expressed by RA patients and AHPs:
 - a. Preferred intervention format included group sessions delivered over several weeks, consisting of discussion topics and practical PA. RA patients would like a choice of PA and an opportunity to practice PA within the sessions.
 - b. RA patients would prefer intervention delivery to be face-to-face, delivered by someone with knowledge of RA, fatigue and PA.

- c. RA patients would like support with enhancing motivation for PA within the context of their fatigue, by addressing psychosocial issues and barriers to engagement.
 - d. Practical considerations for implementing interventions require the availability of appropriate resources, such as staffing and equipment, and a flexible approach to accommodate local needs.
3. Time of day and location of sessions are important, but individual variation needs to be considered. Occupation and employment may be a major barrier to participation in these interventions if sessions are held during the working day.
 4. A PA self-management intervention based on preferences expressed by RA patients and professionals, informed by a theoretical framework for HBC, appears to be acceptable to RA patients.

9.2.1 Support for the use of PA for fatigue management

The studies presented in this thesis indicate that PA is beneficial for fatigue management in a range of long-term conditions (chapter 2 and 3) and suggest that PA might be effective for managing RA fatigue. However, it is difficult to understand the processes by which they might be effective due to the large degree of heterogeneity between interventions and inconsistent reporting of intervention components. These might include the mode and style of delivery, the type, intensity, duration and frequency of PA and the number and variability of outcomes and how these are measured. Absent or inconsistent reporting of these details, makes it difficult to identify the mechanisms by which an intervention might be effective. For example, poor reporting and lack of consistency of delivery mode, format, content and outcome measurement, and variability in the type, duration, intensity and frequency of PA made it impossible to know which of these variables contributed to the effectiveness of the interventions. As the mechanism of effect is unknown it is difficult to predict whether these interventions will work in other conditions. As a result, the ideal parameters for a successful RA intervention cannot be determined from existing research reports. In order that the variables that make up a complex PA intervention are better understood these interacting components need to be identified and defined to begin to understand causal mechanisms. This lends support to the development of a new PA intervention designed to manage RA fatigue.

Interpretation of intervention effectiveness might be enhanced by knowing the effects on outcome measures over time. Unfortunately, lack of follow-up outcome data for the RCTs discussed in chapters 2 and 3 limits this understanding. This has been acknowledged as a limitation in systematic reviews of PA interventions for fatigue management in long-term conditions (Edmonds, McGuire and Price, 2004, Cramp and

Byron-Daniel, 2012). Interviews with HCPs suggested that they were also unaware of lasting effects on outcomes such as fatigue and PA after the end of the intervention (chapter 5). These findings emphasise the importance of including long-term follow-up when designing future studies to evaluate intervention effectiveness.

Despite these concerns, HCPs believed that PA was a useful tool for fatigue management and supported its use (chapter 5). However, interview findings highlighted large variation in programme structure and implementation, even within the same health condition. Whilst there seemed to be more consistency between CFS programmes based on PACE (White *et al*, 2011) or FINE (Wearden *et al*, 2010) trials there was still considerable disparity. For example, differences in format (group versus individual), programme duration, methods of behaviour change and implementation of follow-up therapy sessions were still evident. Some variation may be explained by the apparent lack of guidelines for implementing existing PA fatigue management interventions in clinical practice. HCPs were adapting programmes to suit their own service requirements. There was no evidence of patient involvement in the development or modification of the interventions at a research (chapter 4) or service level (chapter 5), although this was not specifically asked during the interviews. The variation between programmes highlighted by interviewees and lack of guidelines for implementation add support for the development of an evidence-based intervention that meets the needs of RA patients. These also negate the option of adapting and delivering an existing programme.

Part of the issue for poor implementation may result from the way in which interventions have been developed. RCTs are often designed to test the effectiveness of the intervention, and are frequently delivered as tightly controlled, standardised programmes to a narrow target population (Glasgow, Lichtenstein and Marcus, 2003). These interventions may not translate easily into clinical settings if due consideration has not been given to implementation or participation issues, including stakeholder engagement, during development (Glasgow, Lichtenstein and Marcus, 2003, Glasgow *et al*, 2012). It must also be acknowledged that intervention implementation in clinical practice involves a complex process of adoption and adaptation to fit local context and needs. This has been termed 're-invention' (Rogers, 2003). Adoption of evidence-based practice in clinical settings must recognise the active role of adopters who are likely to interpret and reconstruct the local utility of the intervention (Fitzgerald *et al*, 2002). Consequently, evidence will be weighed up against contextual factors, for example financial incentives and concordance from other professionals. Therefore, it is necessary to recognise that implementation will not represent the original intervention. Instead,

development must consider how much change is acceptable without excessively diluting effectiveness.

RA patients and rheumatology AHPs gave further support for a PA intervention to aid fatigue management, believing it would be a useful strategy (chapter 6). However, the definition of PA may need clarification for patients and AHPs alike to ensure that it is understood that this is not a prescriptive exercise intervention. Focus group data suggested that for some patients the idea of having to fit in more exercise would be off-putting. Some AHPs focussed on resistance exercise and therefore may not have recognised the potential value of more general PA. The emphasis on PA as any activity that involves bodily movement and expends energy, as defined by Caspersen (1985), must be clarified to avoid misunderstanding by AHPs and patients, and to encourage patient participation. The definition by the Department of Health (2011) is useful in this regard:

“Physical activity includes all forms of activity, such as everyday walking or cycling to get from A to B, active play, work-related activity, active recreation (such as working out in a gym), dancing, gardening or playing active games, as well as organised and competitive sport.” (p. 6, Department of Health, 2011)

In the context of this intervention, RA patients should be encouraged to find ways of incorporating PA into their daily lives as a long-term fatigue management strategy. For some, this might mean managing their current PA to achieve a better balance of rest and activity, as opposed to an increase in PA per se. The ability of some patients to engage in PA may be altered by BCTs such as reframing an increase in PA as a decrease in sedentary behaviour.

While AHPs were supportive of intervention development, some expressed uncertainty as to the demand for a specific fatigue management programme (chapter 6). Instead they suggested boosting fatigue information in current self-management and PA interventions. As discussed in chapter 6, this may reflect a lack of awareness by AHPs of the prevalence and severity of RA fatigue, or a lack of reporting of fatigue by patients, as noted in previous research (Hewlett *et al*, 2005). Alternatively, as RA patients sometimes found it difficult to separate fatigue from other RA symptoms (chapter 6) it may indeed be more appropriate in the future to consider combining a programme for fatigue with a more generic PA self-management programme. This may need to be investigated further in future research.

9.2.1.1 Use of theory to support intervention development

Engagement with and maintenance of PA may be particularly difficult for those with long-term conditions who have pain and other limitations (Wilcox *et al*, 2006, Jack *et al*, 2010). Therefore any intervention that aims to improve PA must also employ techniques to facilitate ongoing participation. It is recognised that techniques to increase motivation and self-efficacy for PA, including CBT approaches, are likely to support behaviour changes and improve activity levels in patients with RA (Knittle *et al*, 2011, Dures *et al*, 2012, Lee *et al*, 2012, Larkin and Kennedy, 2014).

As discussed previously, Iversen and colleagues (2010) recommended that all self-management programmes for rheumatic diseases should be based SCT or CBT and should include exercise. However, the evidence for the use of HBC theory in existing long-term condition PA-based fatigue management programmes (chapter 3) or for promoting PA in RA generally (chapter 4) is limited. Existing PA programmes (chapter 3) lacked an explicit theoretical basis for explaining PA behaviour change or enhancing long-term adherence. This was further evidenced by the apparent lack of awareness by HCPs of a behaviour change theory underpinning the programmes that they were delivering (chapter 5). Some participants identified the deconditioning model to explain the cause of fatigue. However, application of these programmes without a clear understanding of how the intervention might bring about behavioural outcomes is likely to limit the effectiveness of the intervention. Using the deconditioning model to explain the cause of fatigue only allows therapists to determine that PA might reduce fatigue. It does not enable them to explain the mechanisms by which PA might be changed in order to reduce fatigue. Additionally, this model over-simplifies the causal mechanisms of fatigue and does not account for psychosocial or personal factors that are proposed to influence RA fatigue (Hewlett *et al*, 2011b).

The similar lack of evidence of an explicit theory in interventions to promote PA in RA (chapter 4) made it difficult to identify HBC interventions. This reiterates the importance of using an explicit theoretical basis during development of the intervention in this thesis. However, despite the lack of named theory, it was possible to identify implicit use of some BCTs in these interventions. Although some of these, such as goal setting and review, problem-solving, action planning and self-monitoring, have previously been noted as effective for promoting PA (Michie *et al*, 2009a, Bird *et al*, 2013) their use in the interventions identified in chapters 3 and 4 was inconsistent and infrequent. Similarly, some of these BCTs were used by some HCPs (chapter 5), but not by all of them. Their inconsistent use by HCPs did not always appear to be tied to specific professional training

but more from tacit knowledge. Integration of BCTs from a recognised taxonomy (Michie *et al*, 2013) aims to improve the consistency of their use.

The current intervention was developed using the BCW as a theoretical framework, with the COM-B model as the central behavioural system to explain behaviour change (Michie, van Stralen and West, 2011). Using such frameworks and incorporating implementation and participation issues within intervention development is likely to improve the strength of future effectiveness research and, if appropriate, subsequent uptake and dissemination (Glasgow *et al*, 2012).

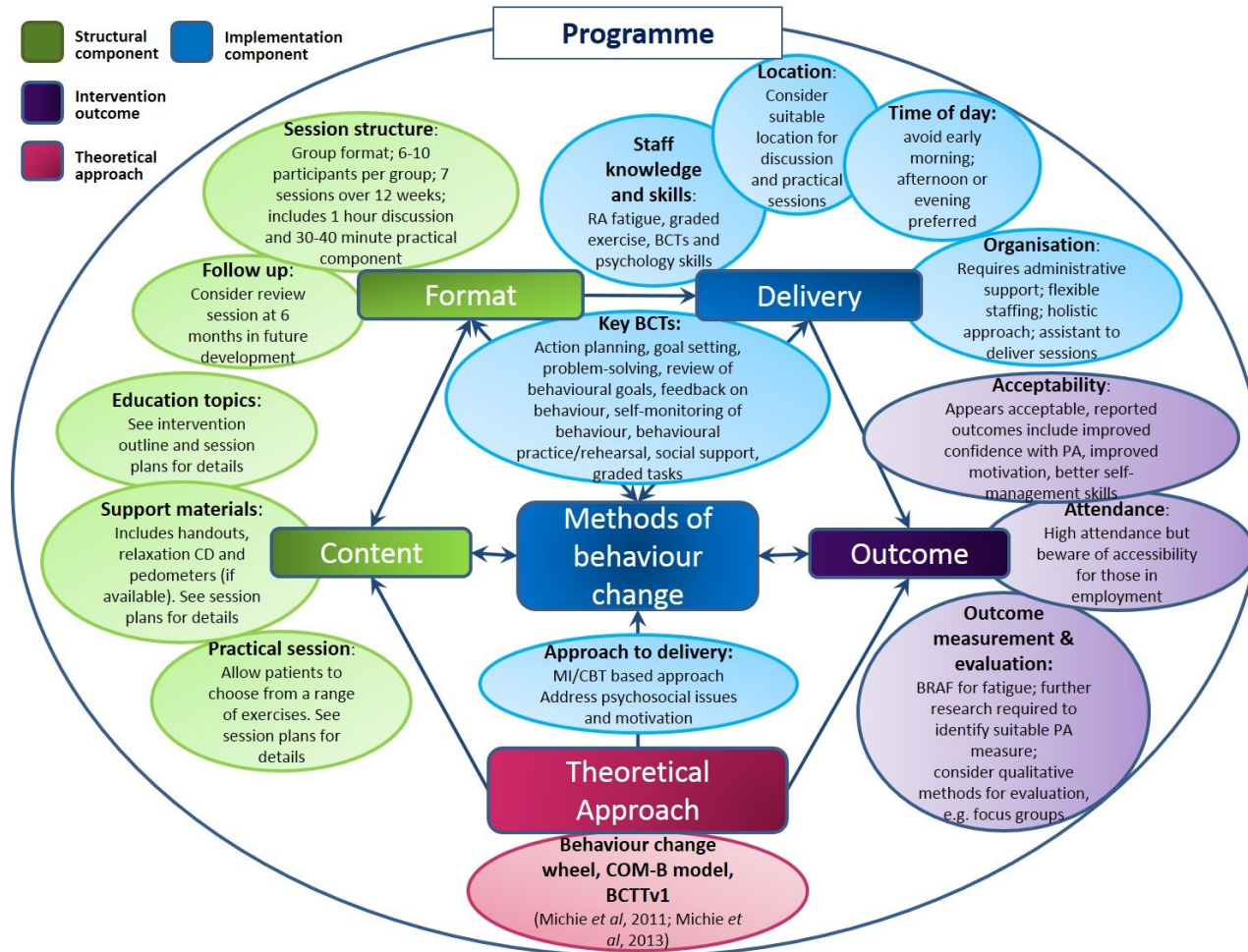
9.2.2 Preferences for intervention components

RA patients and HCPs expressed a range of ideas and preferences for intervention components. The model of components derived from interview data (chapter 5, figure 5.1) has been modified to reflect proposed acceptable parameters for intervention structure, implementation, outcome and theory. This is presented in figure 9.1.

9.2.2.1 Format and content

Group interventions were highly valued by RA patients and AHPs (chapters 5 and 8). Findings from the proof-of-concept study (chapter 8) indicated that group format was acceptable to participants, providing peer and professional support, enhanced learning and increased motivation. As there was an apparent predominance of individual programmes for managing CFS both in the literature (chapter 3) and in interviews (chapter 5), the finding that an RA population would prefer a group format adds further justification for developing an RA specific intervention. Adapting existing programmes without due consideration of RA patient preferences or experiences of rheumatology clinical staff could have neglected to recognise this important finding. Additionally, evidence that programmes based on SCT are useful for self-management (Iversen, Hammond and Betteridge, 2010) further supports the group format, as this is a key principle of this theory (Bandura, 1998).

Figure 9.1: Suggested components for intervention structure, implementation, outcome and theoretical approach



BCT=behaviour change technique; BCTTv1=behaviour change technique taxonomy version 1; BRAF=Bristol Rheumatoid Arthritis Fatigue Scale (Nicklin *et al*, 2010b); CBT=cognitive behavioural therapy; MI=motivational interviewing; PA=physical activity; RA=rheumatoid arthritis

AHP focus group participants suggested the potential for group programmes to reduce service delivery costs (chapter 6). However, an economic analysis was not included in these early stages of development of this intervention. Comparison of the costs and health effects of an intervention can aid decision-makers when choosing where to allocate resources (Phillips, 2009). Choices between different treatment options will depend on additional benefits offered by a new intervention and the associated costs. This is particularly pertinent in the current healthcare climate where NHS managers are under pressure to reduce spending and allocate scarce resources carefully. Therefore a cost-effectiveness analysis should be included in the next phases of development and testing of the intervention. Inclusion of cost-effectiveness studies and economic evaluations of interventions can aid the translation of research into practice (Glasgow, Lichtenstein and Marcus, 2003).

Despite support for a group format, it must be recognised that this is unlikely to be suitable for every patient. RA patients participating in this research volunteered to take part in a focus group study and a group intervention; therefore one might assume they are already interested in participating in a group. Consequently, the views of patients who do not like groups are unlikely to have been represented. This is a limitation of the research, and future adaptation of the intervention for those who do not want to or cannot attend a group programme must be investigated. Alternative data collection methods such as interviews should be utilised to ensure that the views and preferences of these patients are understood.

RA patients indicated a preference for a long programme. The intervention presented in this thesis was held over 12 weeks. This programme was longer than a traditional model of six weeks described by AHPs (chapter 6). More than half of RA patients consulted during development indicated a preference for a longer programme, as they felt they would benefit from the ongoing support. Indeed, participants who took part in the intervention (chapter 8) expressed a desire for the programme to continue beyond 12 weeks. Longer programmes are supported by the literature, with self-management programmes for rheumatic diseases recommended to be greater than six weeks (Iversen, Hammond and Betteridge, 2010). The current intervention used a staggered approach, reducing the frequency of sessions with a gradual withdrawal of professional support. AHPs believed that this could improve self-management and encourage independence with PA. This idea is supported by the literature for SCT to enhance self-efficacy (Bandura, 1977). Interventions of at least six weeks duration are thought to improve maintenance and engagement with PA (Fjeldsoe *et al*, 2011), potentially through a

change in PA-related cognitions such as increased self-efficacy (Knittle *et al*, 2011, Knittle, De Gucht and Maes, 2012).

The current intervention design does not include a follow-up therapy review session. Participants in the proof-of-concept study suggested that this would be beneficial to enhance motivation for continuing PA (chapter 8). Although some existing programmes did offer follow-up sessions, HCPs acknowledged that this was variable and inconsistent (chapter 5). As a result, it was difficult to know whether PA was maintained after the end of the programmes. Ideas and options for follow-up sessions for the current intervention should be considered in future development. These might include an additional review session at six months or telephone follow-up to check progress. Comments from participants in the proof-of-concept study suggested that they would benefit from meeting up again as a group, suggesting that telephone follow-up may not be suitable. This could be explained by the apparently high importance of peer support for RA patients (chapters 6 and 8). Format and delivery of follow-up sessions needs further consideration and investigation.

RA patients approved a combination of discussion topics and practical PA within each session (chapter 6), as suggested by interview participants (chapter 5). This structure appeared to be acceptable to participants undertaking the intervention (chapter 8). Initial concerns by some AHPs raised in the focus groups regarding the length of sessions (2 hours) were allayed after others reported success with longer sessions (chapter 6). Certainly, none of the participants taking part in the intervention commented that the sessions were too long. However, qualitative evaluation of a CBT programme for RA fatigue that had weekly two hour sessions noted that session length and timing may present a barrier to engagement and progress (Dures *et al*, 2012). Yet it should be noted that the format of these sessions consisted of group discussion only (Hewlett *et al*, 2011a). The balance of discussion and practical PA in the current intervention might be less mentally demanding and therefore more tolerable. Similarly, the tapered frequency over the 12 weeks might reduce the burden of a weekly commitment for the entire intervention duration.

Ideas for intervention content were largely driven by interview data (chapter 5) that were presented to RA patients in the focus groups (chapter 6). RA patients indicated that inclusion of topics such as sleep, occupation, stress and relaxation and their influence on fatigue was important. This reflects the multi-factorial nature of this symptom in RA (Hewlett *et al*, 2011b). Although participants in the proof-of-concept study infrequently acknowledged specific topics, comments in the evaluation suggested that all discussion

topics were useful and recognising emotional aspects of fatigue were reported to be helpful.

Content aimed to address self-management skills, as RA patients highlighted a need to improve competence in this area to reduce reliance on external support (chapter 6). Participants noted that self-management skills training was often neglected over time, with those with longer disease duration feeling that they had less access to support in this regard. A Dutch survey of self-management support needs of chronically ill patients found that these needs were not related to illness duration (van Houtum *et al*, 2013). Rather, needs change according to patients' perceptions of their illness and changes in their subjective health status irrespective of the time since diagnosis. The findings from this survey challenge the traditional model of patient education and self-management training predominantly in the first few years of having RA. This suggests that HCPs need to offer support throughout the course of the illness. This has implications for the current intervention in clinical practice, suggesting patients should have access to the programme at any stage after diagnosis.

The content of practical sessions was predominantly based on exercises used in an RCT of a PA self-management intervention for chronic pain (with permission, Walsh *et al*, 2013), with additional upper limb exercises adapted from the EXTRA intervention for upper limb strengthening in RA (with permission, Manning *et al*, 2014). The large number of PA options in the practical sessions was important to patients and appeared to enhance their enjoyment of the intervention (chapter 8). PA included aerobic and strengthening exercises. Evidence for PA for CRF seems to suggest that aerobic exercise might be most important for fatigue management (Cramp and Byron-Daniel, 2012). Many of the CFS programmes described in the literature (chapter 3) and by HCPs (chapter 5) advocated walking. Although findings from this research do not indicate a clear preference for a particular type of PA, AHPs and RA patients supported the use of a graded approach to PA (chapter 6). Similarly, the optimal intensity for PA could not be determined from the literature, but there was some suggestion that starting at a low-intensity was key to engaging fatigued patients in PA to avoid exacerbation of their symptoms (chapter 3). This was also advocated by HCPs using PA in clinical practice (chapter 5) and supported by AHPs working in rheumatology (chapter 6).

Support materials were well-received by participants in the proof-of-concept study and provided a valuable resource for future reference (chapter 8). Self-monitoring of PA behaviour using the activity diaries and/or pedometers was particularly valued. Use of colour for the activity diaries provided a useful visual aid. These have previously been found useful for managing RA fatigue (Dures *et al*, 2012).

9.2.2.2 Delivery of the intervention

Figure 9.1 illustrates considerations for optimal intervention delivery, including where and when to hold the sessions and who should deliver them. The findings in this thesis demonstrate there is a preference for face-to-face intervention delivery by someone with knowledge of RA, fatigue and PA. This has implications for the knowledge, skills and training needs of course leaders.

Various issues have been identified relating to perceived expertise required to deliver a PA self-management intervention. Findings from interviews with HCPs suggested that training requirements for delivery were not clearly defined, with differing opinion about who could deliver these programmes (chapter 5). Some HCPs seemed unable to recognise that skills and knowledge requirements might be addressed with appropriate training, enabling any HCP to deliver a PA programme. Findings implied that physiotherapists believed they could deliver the psychosocial components with some additional training, yet a psychologist would not have the necessary skills to deliver the PA component. This highlights cultural issues around perceptions of professional boundaries. These beliefs may inhibit the ability of an organisation to deliver PA self-management interventions in a flexible and cost effective manner if specialist professionals are always required. Perceptions of professional boundaries and specialist knowledge may be encountered even during core training of physiotherapists. An investigation of the psychology content of UK physiotherapy education reported that psychology training offered to undergraduate physiotherapists is often non-specific and delivered by non-specialist physiotherapy staff (Heaney *et al*, 2012). Some participants in the study by Heaney and colleagues (2012) had concerns that psychology specialists would not be able to offer contextual relevance and instead would only be able to provide theoretical teaching in psychology. However, others acknowledged that physiotherapy staff qualified to teach psychology would have the ideal balance of physiotherapy and psychology knowledge and skills (Heaney *et al*, 2012). This might suggest the opposite is also likely to be true, where psychology staff with a sound understanding of physiotherapy and training in GET would be able to deliver a PA intervention. It should be noted that the qualifications to teach psychology were not specified in the research article by Heaney *et al* (2012).

Similar thoughts about knowledge and skills training were identified related to GET. Some physiotherapists did not feel that GET required specialist training, believing this was a core skill of their profession. However, a survey of Dutch health professionals' educational needs for promoting PA in RA indicated that 72% of expert physical therapists expressed a need for additional education in this area (Hurkmans *et al*, 2011). Similarly, a

survey investigating the educational needs of rheumatology nurses and AHPs in the UK has noted a need to develop knowledge and skills for the provision of PA advice (Lillie, Ryan and Adams, 2013). Some AHP focus group participants in the current study reported that they would like additional training in GET (chapter 6). It is interesting to note the lack of competence and confidence for this core skill.

The intervention was initially designed for delivery by one therapist. However, it became apparent following delivery of the first session during the proof-of-concept study that an assistant would be needed (chapter 8). This second person was not required for co-delivery, but facilitated small group discussion and helped supervise PA in the practical sessions. The addition of another person has implications for the cost of a future intervention, even though the assistant would not need to be a qualified professional. Similarly, some AHPs in the focus group study noted that they were the sole physiotherapist in their department (chapter 6). The requirement for an additional person could prohibit intervention delivery in those services. It may be that the intervention could be modified in those circumstances with a smaller group size ($n < 8$), enabling one therapist to deliver the programme. This raises the question of whether an extra person should be optional to facilitate the logistics of setting up rooms and equipment, and managing a larger group, or if an assistant is essential for health and safety, providing help should an incident arise. This is likely to depend largely on local needs where the intervention is delivered. A full risk assessment should be undertaken prior to implementation to ensure that health and safety concerns are addressed, as recommended by the National Patient Safety Agency (2006). It is worth noting that similar interventions in other patient groups are being successfully delivered by one therapist (Hurley *et al*, 2007, Walsh *et al*, 2013).

9.2.2.3 Enhancing motivation and engagement with physical activity

The selection of topics such as sleep, stress and relaxation by RA patients (study 3) reflects the need for a biopsychosocial approach to managing fatigue. As these issues may present barriers to PA, they must be tackled to enhance engagement. Addressing PA alone is not enough. Techniques to enhance self-efficacy for PA should also be included, such as goal setting, action planning and self-monitoring of behaviour. This is supported by the literature demonstrating that higher self-efficacy is associated with increased likelihood of attaining PA goals in RA (Knittle *et al*, 2011). Use of a biopsychosocial approach to self-management is supported by evidence in other conditions, such as chronic back pain, where positive outcomes are related to changes in psychological distress, fear avoidance beliefs and self-efficacy for coping and pain control (O'Sullivan, 2012). This was emphasised by HCPs (chapter 5) who recommended that course leaders

delivering interventions must think holistically and assist patients with identifying individual barriers to engagement with PA.

Some AHPs were tentative regarding the ability to engage fatigued patients in PA, as fatigue is often cited as a barrier (chapter 6). They emphasised the need to highlight other benefits of PA that might reduce fatigue as a secondary outcome, such as improved sleep. The role of exercise for improving sleep quality in RA has not been clearly established. However, a recent RCT investigating the effect of a home exercise programme on sleep quality and fatigue in RA claimed a significant and clinically important improvement in both outcomes ($p=0.04$) (Durcan, Wilson and Cunnane, 2014b). However, this must be interpreted with caution given the poor methodological quality of this study, discussed in chapter 2. Nonetheless, as RA fatigue has been attributed to unrefreshing sleep (Hewlett *et al*, 2005), improvements in sleep quality as a result of PA may well encourage participation. This reiterates findings from interviews with HCPs (chapter 5) and focus groups with RA patients (chapter 6) that sleep is an important topic to address.

AHPs in the focus groups (chapter 6) mainly reported offering education on the benefits of PA in RA for strengthening and general fitness. The function of the intervention and method of delivery is a key factor here. Provision of information may be necessary to address some gaps in knowledge, but education alone is unlikely to be sufficient to change behaviour. This has been demonstrated in a review of education programmes for RA (Riemsma *et al*, 2004). In fact, addressing PA knowledge may not be a primary concern, as existing evidence suggests that many patients are already aware of the benefits of PA (Law *et al*, 2010, Law *et al*, 2013). Instead, there is a need to facilitate patients in identifying and addressing barriers to engaging in PA, and enabling development of skills for problem solving and self-management. Rather than offering solutions, course leaders need to encourage patients to explore their own ideas and discover suitable resolutions through discussion with other group members. This has been reported to be helpful to RA patients in a CBT-based self-management intervention for managing fatigue (Dures *et al*, 2012). These principles of guided discovery are central to CBT (Sage *et al*, 2008) and motivational interviewing (Rollnick, Mason and Butler, 1999). Additionally, problem-solving has been identified as a core BCT for promoting a change in PA behaviour in adults (Michie *et al*, 2009a, Bird *et al*, 2013). The candidate, who delivered the intervention in this proof-of-concept study, had training in CBT skills and knowledge of the theory and principles of motivational interviewing. Therefore a facilitatory, biopsychosocial approach was utilised. Findings from this study indicate that participants found the course leaders supportive and motivating, suggesting that this

delivery style was acceptable. This has implications for the knowledge and skill requirements of those delivering the intervention.

The principles of guided discovery were extended to the practical sessions through the provision of a range of exercises for patients to choose from. The element of choice was greatly appreciated by participants in the proof-of-concept study (chapter 8). Participants felt comfortable with the PA because they could select a level to suit their own ability and did not feel pressurised to do more. This is an important finding as it demonstrates that rather than patients not doing enough, as feared by some AHPs (chapter 6), they felt more confident and motivated to do more through their own volition rather than as a result of external pressure (chapter 8). This notion demonstrates the importance of intrinsic rather than extrinsic motivation to enhance autonomous behaviour, as proposed by SDT (Ryan and Deci, 2000). Allowing patients a choice places them at the centre of decision-making regarding using PA to manage their fatigue. This may be a fundamental component of enhancing motivation to engage in PA.

9.2.2.4 Practical considerations for implementation

Several practical considerations were raised by HCPs delivering existing PA fatigue management programmes in clinical practice (chapter 5), such as time of day and location of sessions. RA patients confirmed concerns that sessions should not be held first thing in the morning, as many described finding it difficult to get ready in time (chapter 6), with RA symptoms often worse at this time (Sierakowski and Cutolo, 2011). Other considerations related to external demands such as work and caring responsibilities (chapter 6). From an AHP perspective session timings may be constrained by resource factors, such as room and staffing availability (chapter 6). Whilst optimal delivery time may be in the afternoon or evening, this may not be possible for some services. Indeed, room availability meant that the sessions in the proof-of-concept study started at 11.15am.

The proof-of-concept study was held in an outpatient therapy department in a specialist rheumatology centre, with access to a seminar room and therapy gym containing equipment including exercise bikes and a treadmill. The location of these sessions appeared to influence intervention attendance, as travel distance was cited as a reason for declining participation. This is a well-recognised barrier to participation in exercise programmes (de Jong *et al*, 2004a, Mayoux-Benhamou *et al*, 2008, Vervloesem *et al*, 2012, Nordgren *et al*, 2014). Although face-to-face group delivery was preferred by RA patients (chapter 6) and considered a strength of the intervention (chapter 8) it is evident that alternatives need to be investigated for those who cannot or do not wish to attend. Alternative locations and mode of delivery, such as community based programmes and internet-delivered interventions, should be investigated in future research to improve

accessibility for all patients. The use of multi-media, such as internet or telephone, for distance intervention delivery was rejected by focus group participants (chapter 6) who felt that face-to-face delivery was preferable. However, participants who are unable to travel to attend group sessions held in the daytime, and hence who might have chosen these alternative delivery options, are likely to have declined an invitation to take part in the focus groups. Therefore their views may not have been represented. It is possible that alternative modes of delivery, such as web-based or telehealth interventions, would be more acceptable for these patients.

In a recent interview study, RA and psoriatic arthritis patients particularly endorsed the advantages offered by internet-based CBT interventions of no travel time, choice of when to take part and no waiting for the therapist (Ferwerda *et al*, 2013). Interestingly, male participants noted reduced travel time and costs as an advantage of internet-based interventions more frequently than females in the same study. Travel time and costs might partially explain under-representation of men participating in the current intervention (chapter 8) and in other face-to-face exercise programmes (Vervloesem *et al*, 2012).

9.2.3 Employment as a barrier to participation

Throughout this thesis, many RA patients experienced employment as a major barrier to participating in interventions (chapter 6 and 8). Of the 12 RA patients in the focus groups and nine in the proof-of-concept study, seven were in paid work. Employment was reported as a reason for declining participation in the proof-of-concept study. Given that many employed RA patients have cited fatigue as a barrier for continuing to work in a recent survey (NRAS, 2010), it is important that accessibility is improved for this patient group. Of 2,029 respondents to the NRAS survey, 24% reported changing jobs because of their fatigue and 71% of unemployed respondents attributed their inability to work to their fatigue (NRAS, 2010).

Organisations need to have the flexibility to adjust their delivery to accommodate practical considerations alongside patient preferences. This was recognised by some AHPs in the focus groups (chapter 6), who were able to offer a range of start times for their self-management classes, including evening sessions that may be suitable for employed patients. However, this is not always feasible and some patients reported that they would be too tired to attend evening sessions (chapter 6). Research is required to discover what alternative means of delivery, if any, would be acceptable. It may also be beneficial to develop information about RA fatigue for employers so that they might better understand this symptom, as RA patients report a lack of understanding of their condition by colleagues and employers (chapter 6). Additionally, patients and employers might

require support with prioritising PA and self-management. This is likely to be mutually beneficial in terms of improved health and productivity.

PA prioritisation might also need to be addressed on an individual basis prior to attending a group programme. Some HCPs assessed patients' readiness to change before they were referred to a PA intervention (chapter 5). This pre-assessment was not included in the current intervention but might be worth considering in future development to aid engagement. It may be that some patients assume that work demands or their employers will prevent them from attending. They may be unable to envisage how investing time into participating in an intervention might improve their work and productivity in the longer term. An individual assessment prior to starting an intervention might address concerns and problem-solve barriers to participation.

9.2.4 Acceptability of a PA self-management intervention

Participants in the proof-of-concept study suggested that the intervention was acceptable, with high attendance rates and low attrition also reflecting this. Similarly, evaluation scores for the intervention were positive. However, these findings must be interpreted with caution given the very small numbers in this study (n=8 completing the intervention, n=1 withdrew due to work commitments). Also, it must be noted that some RA patients who were interested in taking part were unable to attend. It could be argued that the format of the intervention in terms of location and timing was not acceptable to these patients. This should be explored further in future development studies to further our understanding of intervention acceptability.

During evaluation of the intervention, participants spontaneously described elements of the COM-B model that were central to the programme development. Findings suggest that the intervention has the potential to enhance physical capability through the development of physical skills in practical sessions and between sessions. Psychological capability may be influenced through enhanced self-management skills and improved decision-making when selecting and implementing appropriate PA without exacerbating fatigue. However, the influence on fatigue can only be postulated here, as changes in fatigue were not explicitly mentioned by patients in the evaluation.

Participants valued both the physical and social opportunities offered by the intervention, with supervised practical sessions boosting confidence and motivation, and interaction with other RA patients providing peer support and vicarious learning. However, participants would have liked ongoing support. There was minimal evidence within the evaluation that they had independently sought opportunities for long-term PA in the four weeks between sessions 6 and 7, despite discussing options for ongoing PA in session 6. The lack of supporting evidence in the questionnaires may reflect a limitation with this

method of evaluation. This might be improved by adding an additional question, or amending existing ones, or further probing in an interview or focus group setting could have clarified this. Future evaluation of the intervention must consider alternative methods to ensure data are adequately captured. Follow-up therapy sessions should be considered to enhance opportunity, including options for telephone and web-based follow-up support.

Participants experienced the intervention as motivating and it encouraged them to increase their PA. Elements of reflective motivation were described, such as altered beliefs in capability and a desire to achieve personal PA goals. The potential for the intervention to influence automatic motivation was suggested by descriptions of positive emotional responses to PA, such as improved mood.

Specific changes in PA behaviour cannot be determined from this thesis. However, subjective feedback did suggest an increase in PA.

9.3 Implications for research

9.3.1 Methodology

9.3.1.1 Using the Behaviour Change Wheel for intervention design

A key strength of the intervention developed in this thesis is its systematic development informed by an underpinning theory of behaviour change. As discussed in chapter 7, the TREND statement recommends an explicit description of intervention theory (Des Jarlais *et al*, 2004), and MRC guidance advocates identification of appropriate theory during intervention development (MRC, 2008).

The BCW offered a comprehensive framework for intervention design based on theoretical constructs of behaviour change (Michie, van Stralen and West, 2011). Mapping data from HCP interviews and RA patient and AHP focus groups onto the framework allowed a detailed understanding of possible mechanisms for changing PA behaviour in patients with fatigue. Incorporating preferences and practical considerations with theory has hopefully resulted in an intervention that is more likely to be acceptable to the target population and will be suitable for implementation in clinical practice in the future.

The accompanying BCW guide provided a step-by-step approach to building an intervention using these data (Michie, Atkins and West, 2014). However, it should be noted that this guide was not regarded as a rigid procedure; rather it ensured that different components of the intervention were carefully considered and addressed throughout the design phase.

At the centre of the BCW is the COM-B model of behaviour (Michie, van Stralen and West, 2011). This was used to analyse and understand behaviour change in the current intervention, as described in chapter 7. Previous research has recommended the use of SCT as a basis of self-management interventions (Iversen, Hammond and Betteridge, 2010) and SDT appears to have been used to target autonomous motivation (Knittle *et al*, 2013). The advantage of the COM-B model over these individual theories is the explicit inclusion of context in the form of physical and social opportunity. The theoretical constructs of self-efficacy and motivation can still be incorporated into the model, and therefore COM-B provides an all-encompassing behavioural system as the basis of intervention development (Michie, van Stralen and West, 2011).

NICE has recommended this model in their public health guidelines for individual-level behaviour change interventions (NICE, 2014b). However, the BCW framework is sufficiently flexible to allow other behaviour change theories and models to be used as the central behavioural system. The framework would still be applicable should an intervention developer have a particular interest in using or evaluating a specific theory.

Although there are currently no other known rheumatology interventions that have been developed using the BCW, recent interventions have selected BCTs for changing PA behaviour using earlier versions of the BCT taxonomy (for example, Heine *et al*, 2012a, Manning *et al*, 2014, Knittle *et al*, 2013). Use of the BCT taxonomy (Michie *et al*, 2013) when developing the current intervention allowed selection of evidence based techniques that are most likely to be effective. This facilitates comparison with similar interventions through use of standardised terminology, and deepens our understanding of which interventions might bring about behaviour change. The BCT taxonomy is recommended within the NICE guidance in addition to the BCW (NICE, 2014b). This thesis demonstrates that using the BCW theoretical framework combined with the BCT taxonomy can provide a comprehensive, structured method for developing and evaluating behaviour change interventions in rheumatology.

9.3.1.2 Use of interactive polling software

The workshop with RA patients in chapter 6 used an interactive polling system (TurningPoint technology) to enable real-time voting on preferences for intervention components. This technology allowed the candidate to present a large volume of data to study participants for them to indicate preferences for intervention content. No published evidence for the use of this technology in rheumatology or other health research has been identified.

There were concerns that RA patients with hand disabilities would find the keypads difficult to use, but only minor adaptations were required for one participant. The

advantages of using this technology were that it enabled presentation of a large amount of data in a short timeframe. Real-time data could be collected anonymously, and this could be reviewed and discussed with participants immediately to clarify any uncertainty or ambiguity. The keypad voting system enabled participants to select their preferred options and then ask questions or discuss the topics within the group. These data were recorded using the software and transferred into Microsoft Excel 2007 for subsequent analysis.

9.3.2 Further development of the current intervention

9.3.2.1 Multi-media support materials

This research has identified that RA patients have different preferences for the format of educational support materials. For some participants paper-based information was preferred, whilst others found reading difficult and preferred audio-visual materials such as a DVD to supplement the intervention. It was emphasised that multi-media materials would be required to meet different preferences and needs. Some AHPs in the focus group (chapter 6) provided anecdotal evidence that using technology can help engagement with exercise and PA in general, such as use of 'apps' for self-monitoring or prompts for PA.

The materials developed in this thesis were all traditional paper-based handouts. The use of 'apps' to enhance motivation was discussed during the intervention in the proof-of-concept study (chapter 8), but the majority of participants reported they did not have access to smartphone technology.

9.3.2.2 Follow-up

Participants in the proof-of-concept study identified that they would like further input beyond the 12 weeks of the current programme (chapter 8). The addition of a review session as part of the intervention may improve motivation for ongoing PA and would allow therapists to review progress over a longer time period. This session might also be made available to all participants who had previously completed the intervention, rather than just the last group, thus improving access to ongoing support. Alternatively, telephone review might be considered more suitable. Other options might include improved links with community-based leisure services to provide ongoing support outside of the health sector. These ideas should be explored in future development work to identify the most appropriate options.

Long-term follow-up of research outcomes should also be included in future evaluation of the intervention. These data are frequently unavailable in existing published evidence, preventing an understanding of the effects of current interventions over time, such as longer term maintenance of PA (chapter 2, 3 and 4).

9.3.2.3 Alternative mode of delivery

The issue of accessibility, for example, for those who work, needs further investigation, including exploring alternative means of delivering a PA fatigue management programme. The internet is increasingly used to deliver health interventions (Webb *et al*, 2010), and this may present an alternative mode of delivery for those who are unable to access face-to-face sessions. Although this would reduce the learning and support offered by a face-to-face group format, online interventions could include access to group forums providing support from other patients and HCPs. Indeed, research has suggested that RA patients are prepared to take part in internet-based CBT interventions, therefore this may also be true for lifestyle and behaviour-change interventions (Ferberda *et al*, 2013). Potential advantages of ease of access and time saved for travel were particularly noted by participants in the study by Ferberda *et al* (2013), although lack of face-to-face contact was a concern. Other research has suggested that internet-based delivery of the established Arthritis Self-Management Program provided a potential alternative to the group format (Lorig *et al*, 2008). Significant improvements in health status (health distress, activity limitation, self-reported global health and pain) and self-efficacy for managing arthritis were noted at one year after baseline. However, these results should be interpreted with caution due to methodological concerns, as discussed in chapter 4.

In the workshop study, participants (n=12) were asked delivery preferences for follow-up sessions. The majority (n=10) indicated that they would prefer face-to-face delivery rather than via telephone (chapter 6, figure 6.18). The remaining two patients did not mind. However, they were not asked about internet-delivery. Web-based support materials were put forward in the workshop and none of the participants selected this option (figure 6.20).

Other delivery options might include supplementing face-to-face sessions with telephone support to reduce the amount of attendance time. This option was not suggested to patients during the workshops, but may be worth exploring in future research.

As well as specific fatigue, PA and self-management support patients should be signposted to additional sources of peer support such as NRAS. This could be incorporated into the intervention.

9.3.3 Further evaluation of the intervention

9.3.3.1 Feasibility of an RCT

The next step for evaluation of the current intervention is to design and carry out a study to determine the feasibility of conducting an RCT; that is, is it appropriate for further testing (Bowen *et al*, 2009)? A feasibility study might adopt several areas of focus, for example, further investigation of acceptability, implementation and practicality of the intervention. A focus on acceptability of the intervention to study participants and those involved in implementation and delivery might consider outcomes such as satisfaction, appropriateness, possibility of continued use and the effects on the organisation. A focus on implementation would include determining whether the intervention can be put into practice as proposed. Additionally, a focus on practicality would explore how the intervention might be delivered if resources, training of course leaders, time, commitment, or some combination thereof were in any way limited. Examples of outcomes of interest might include treatment fidelity, resource requirements, factors affecting implementation, efficiency of implementation, effects on participants, ability of participants to participate in the intervention and an analysis of intervention costs (Bowen *et al*, 2009). Gathering cost data during future testing would aid translation of the research findings into clinical practice (Glasgow, Lichtenstein and Marcus, 2003).

A feasibility study would include identification of suitable methods for a potential RCT, such as recruitment strategies, choice of outcome measures, data analysis and cost analysis. Long-term follow-up must also be included when testing the effectiveness of the intervention. The potential addition of an intervention follow-up session must be considered here, as the intervention might still be ongoing at six months. Follow-up to the study will result in a very long research process and this needs to be taken into account.

9.3.3.2 Choice of outcome measures

Care must be taken when selecting outcome measures for use in this study. Some participants in chapter 8 commented that large amounts of writing might not be suitable for RA patients, and that rating scores were easier to complete. This should be taken into account when choosing future outcome measures to minimise the burden on the patient. E-completion, such as touch screens, might be useful to consider. Also, use of alternative qualitative methods of evaluation, such as interviews or focus groups, or quantitative using TurningPoint, might reduce this burden.

Findings from the proof-of-concept study (chapter 8) noted issues with using the IPAQ-SF. Whilst this measure is a validated tool for use in populations studies (Craig *et al*, 2003), an assessment of criterion validity has highlighted limitations for its use for

estimating energy expenditure in RA (Tierney, Fraser and Kennedy, 2014). Comparison with an objective PA measure indicated that the IPAQ-SF underestimated energy expenditure by 41%. Other validation studies have reported an overestimation of PA by an average of 84% compared with objective measures (Lee *et al*, 2011). A reliability study for self-reported PA measures should be considered prior to further testing of the current intervention. Alternative options might include the 7-day Physical Activity Recall (Sallis *et al*, 1985) and the Nord-Trøndelag Health Study PA questionnaire (Kurtze *et al*, 2008), mentioned in chapter 8. Additionally, future research should consider the use of an objective PA measure. Although pedometers were used in the intervention this was as a motivational tool rather than for the purpose of outcome measurement.

9.3.3.3 Use of qualitative methods for evaluation

As mentioned in section 9.2.4, alternative methods should be considered for future evaluation of the intervention to enhance the richness of the evaluation data. This includes acceptability for both study participants and those delivering the intervention. For example, this might be explored through qualitative focus groups. The format of a focus group would allow participants to reflect on their own experiences and discuss and debate this amongst their peers (Kitzinger, 2005). Group discussion would be appropriate for exploring a range of views and may produce ideas that would not be disclosed in a one-to-one interview (Kitzinger, 1995). However, a one-to-one interview may be suitable for exploring acceptability for course leaders, particularly as this may only include one or two people. Care must be taken to minimise bias when collecting these data. Therefore an independent qualitative researcher should conduct focus groups.

9.4 Implications for clinical practice

The research presented in this thesis confirms that there is a need for improved fatigue management in RA. This was recognised by AHPs working in rheumatology (chapter 6), who supported development of a new intervention. In the meantime, several implications for current clinical practice can be gleaned from the research findings, including timing of self-management support, clarifying the meaning of PA, giving advice related to fatigue and PA and addressing organisational issues to improve access to interventions.

9.4.1 Timing of self-management support

RA patients indicated that while education sessions are offered in the first few years after diagnosis, they often find their support needs are not met later in their disease (chapter 6). This results in feelings of isolation and uncertainty about their ability to manage their RA. HCPs need to recognise that support needs may change through the

course of the disease and offer help and advice accordingly. Other researchers have also noted a change in self-management support needs regardless of disease duration (van Houtum *et al*, 2013). Whilst RA patients expressed a need for early, preventative advice (chapter 6), these findings suggest that access to supplementary support might be required throughout the course of the disease.

9.4.2 Defining physical activity

It was noted in chapter 6 that the definition of PA versus formal or prescriptive exercise is not always clearly understood by patients. Similarly, some AHPs did not clearly differentiate between these concepts. This might lead to a tendency to prescribe formal exercises rather than encourage lifestyle PA to reduce inactivity, such as active transport or housework. Hence, as well as broadening the scope of PA advice, health professionals need to be clear on PA guidelines and definitions of PA in order to give patients appropriate advice. Reported barriers to PA often include lack of time, motivation or enjoyment (Wilcox *et al*, 2006) therefore reducing these obstacles through exploration of alternative options to formal exercise is important. For example, reassuring patients that all PA can be beneficial and reducing sedentary behaviour may be a helpful starting point for improving engagement, alongside encouraging enjoyable activities (Knittle *et al*, 2013).

9.4.3 Physical activity advice for fatigue management

Patients and AHPs reported that current PA advice is aimed at functional rehabilitation and general fitness rather than fatigue management (chapter 6). This is partly due to the lack of evidence for the effectiveness of PA for fatigue, as highlighted in this thesis. Nonetheless, AHPs did feel that they could do more to emphasise the benefits of PA beyond physical fitness, such as better sleep, which may in itself improve fatigue.

9.4.4 Improving access to self-management interventions

The need for organisational flexibility was evident to ensure implementation and delivery of self-management interventions as discussed in this thesis. Difficulties with accessing face-to-face interventions due to work commitments and travel have already been discussed in section 9.2.3. Some HCPs (chapter 5) and AHPs (chapter 6) acknowledged that flexibility was required to improve access for these patients. Similarly, patients who do not like groups would require access to interventions that can be delivered on an individual basis or by alternative means, such as web-based programmes. Current services might need to consider options for flexible working hours for staff to enable delivery of evening or other out-of-hours sessions, as described by one service (chapter 6). Other options might necessitate improved collaboration with leisure and community services for local delivery.

Some AHPs reported a lack of staffing and limited resources (chapter 6), thus reducing their ability to deliver PA interventions that require access to a gym, particularly group programmes. This highlights the need for clinicians to be innovative and adaptable to enable delivery of these programmes. For example, one HCP noted that they were able to deliver a GET programme in a small clinic room if necessary (chapter 5). Likewise, additional skills training may improve multi-professional, inter-disciplinary working. For example, a physiotherapist, OT, nurse or psychologist might deliver the same self-management PA intervention if they had adequate experience and training, as discussed in section 9.2.2.2.

9.5 Strengths and limitations

Strengths and limitations of individual studies are discussed within the preceding chapters. Overall strengths and limitations are summarised below.

The combined patient and HCP/AHP preferences, practicalities and theoretical underpinning were a key strength of intervention development. These elements appeared to be lacking in other programmes. For example, the involvement of RA patients both as participants and PRPs added rigour to this intervention, where patient involvement was not evident in other programmes. Similarly, consideration of practical issues for implementation aims to improve future translation into practice following subsequent evaluation of intervention effectiveness. Also, the research identified a lack of theory underpinning the majority of PA interventions, despite recommendations that using appropriate theory enhances intervention development (MRC, 2008). Use of the BCW (Michie, van Stralen and West, 2011) as a theoretical framework allows a comprehensive analysis of PA behaviour and will aid understanding of the potential mechanisms of behaviour change. Additionally using standardised terminology for BCTs through use of the BCT taxonomy (Michie *et al*, 2013) facilitates comparison with other interventions and aids reproducibility of the intervention processes.

Findings from existing evidence for use of PA to manage fatigue indicated that many interventions were not designed with fatigue as the primary outcome of interest. An advantage of the intervention developed in this thesis is that it has been designed to support changes in PA behaviour within the context of fatigue.

Limitations of the research predominantly relate to issues with recruitment and participant characteristics. As a result, findings from the studies must be interpreted with caution. Recruitment biases may have restricted the breadth of opinion represented. For example, in the interview study HCPs were only recruited from services where PA was used for fatigue management. Consequently, the views of those HCPs who do not believe PA is useful for managing fatigue have not been represented. Similarly, patients who are

not interested in group participation or who do not want to engage in PA are unlikely to agree to take part in research to develop a PA intervention. Attempts to minimise bias included not mentioning PA in the participant information sheet for the focus group study so that those who were not interested in PA might still have been included. Recruitment of patients who already have an interest in PA before they consent to take part is a common problem with PA research, and also with encouraging engagement with PA or exercise programmes in general. Other researchers have specifically recruited RA patients who do not meet PA guidelines to minimise the issue of including those who are already active in interventions to promote PA (Nordgren *et al*, 2012, Knittle *et al*, 2013). However, the current intervention is not designed to increase PA. In fact, excluding these active patients would limit access to the intervention for those patients with high fatigue levels who may be doing too much PA. The emphasis of the intervention is therefore to modify PA according to individual patient need, which may include increasing PA or redressing the balance between activity and rest. A potential solution to improved engagement of less active or less interested patients in PA interventions might be to complete a pre-intervention assessment of readiness to change behaviour. This was included in some of the existing fatigue management programmes in long-term conditions (chapter 5) and was suggested to patients (chapter 6) but was not included in the intervention design. This option could be revisited in future iterations of the intervention.

Demographic information from the RA patient focus group study (chapter 6) suggested an over-representation of men compared with the general RA population (50% versus 30% (Crowson *et al*, 2011)). This may reflect a particular need for fatigue management support in men. This idea is supported by previous research suggesting that men with RA may struggle to manage and that they find fatigue particularly problematic (Flurey *et al*, 2014).

Conversely, men were under-represented in the proof-of-concept study (n=1 out of 9). Although several male patients expressed interest in the study, many were unable to attend due to other commitments. Similarly, other patients who declined participation cited employment and travel as a barrier. As mentioned throughout this thesis, this has been noted in previous PA research (Vervloesem *et al*, 2012, Nordgren *et al*, 2014). Although this should not be over-interpreted here given the small sample size, care must be taken when recruiting for future evaluation studies to ensure that the views of all potential participants are considered. This includes not only a balance of gender, but also ethnicity, which was not acknowledged in this thesis. These limitations need to be considered further to determine alternative options for those who cannot attend or have specific cultural preferences, for example, gender-specific groups.

9.6 Personal reflections

Conducting this research and writing this thesis has been a hugely challenging yet rewarding process. At the start of the research project, I had only a basic knowledge of RA and its management and a keen interest in PA and behaviour change. Over the last three years this has changed considerably, as I hope is demonstrated in this thesis.

This thesis and the intervention have been greatly strengthened by the large amount of patient input into all aspects of the research, both as participants and as PRPs. I have endeavoured to reflect on my own clinical background and to acknowledge my personal and professional biases, particularly when conducting and analysing qualitative research. It is inevitable that some aspects of the intervention will reflect my own opinions and judgements, as part of the intervention development required subjective decisions. However, I have sought the support of my experienced supervision team and PRPs throughout to minimise personal biases in the programme.

Masters-level modules in conducting systematic reviews, qualitative research methods, theory of HBC and work-based learning have allowed me to develop a good grounding as a novice researcher. Similarly, training in CBT skills for clinical practice and experiences of delivering PA interventions as part of a clinical trial (Walsh *et al*, 2013) and for my own research have enhanced my clinical knowledge and skills. The research presented in this thesis has been disseminated at various local and national conferences and events, via published abstracts (appendix W1-W4) and poster and oral presentations (appendix X) and I look forward to continuing with this work.

Undertaking this research has enabled me to develop professionally, as a researcher and clinical physiotherapist, and personally. It has undoubtedly changed my clinical practice for the better and I hope it stands me in good stead for continuing to grow and develop as a clinical researcher.

9.7 Thesis summary

Fatigue is an important symptom in RA, yet existing evidence highlights a lack of effective interventions to manage RA fatigue. Interventions that use PA in other long-term conditions appear to be effective, and provide valuable lessons regarding format, content and delivery. However, these programmes are often not easily translated from research into clinical practice. This may be due to the lack of theoretical basis for explaining how to change PA behaviour as a means of reducing the impact of fatigue, as well as practical issues when integrating protracted interventions in clinical practice.

Patients and HCPs who participated in this research supported the development of new interventions to improve fatigue management in RA. An intervention was developed

based on existing evidence combined with the ideas and preferences of patients and professionals, and informed by a theoretical framework for behaviour change.

Preliminary investigations suggested that the PA self-management intervention developed in this research was acceptable to RA patients. However, further consideration of alternative modes of delivery is needed to improve accessibility for those who are not able to attend face-to-face sessions.

In conclusion, it is recommended that the current intervention is considered for further evaluation in a feasibility and pilot study prior to full scale testing in an RCT.

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Appendices

Appendix A: Cochrane MEDLINE search strategy (Cramp *et al*, 2013b)

1. exp arthritis, rheumatoid/
2. ((rheumatoid or reumatoid or revmatoid or rheumatic or reumatic or revmatic or rheumat\$ or reumat\$ or revmarthrit\$) adj3 (arthrit\$ or artrit\$ or diseas\$ or condition\$ or nodule\$)).tw.
3. 1 or 2
4. exp Fatigue/
5. fatigue\$.tw.
6. (tired\$ or weary or weariness or exhaustion or exhausted).tw.
7. ((astenia or asthenic) and syndrome).tw.
8. ((lack or loss or lost) adj3 (energy or vigo?r)).tw.
9. (apath\$ or lassitude or weak\$ or letharg\$).tw.
10. (feel\$ adj3 (drained or sleep\$ or sluggish)).tw.
11. vitality.tw.
12. or/4-11
13. randomized controlled trial.pt.
14. controlled clinical trial.pt.
15. randomized.ab.
16. placebo.ab.
17. drug therapy.fs.
18. randomly.ab.
19. trial.ab.
20. groups.ab.
21. or/13-20
22. (animals not (humans and animals)).sh.
23. 21 not 22
24. and/3,12,23

\$=used to identify all words beginning with the stem

Appendix B: Chapter 2 data extraction form**FATIGUE REVIEW - DATA SCREENING SHEET**

Title:

Report ID:

Study ID:

Reviewer:

Eligibility

	Yes / No / Unclear	Notes/Evidence
Is it an RCT?		
Are participants adults with RA?		
Is fatigue reported separately for RA patients?		
Does it include fatigue as an outcome measure?		
Does it investigate a PA intervention?		
Include study in review?		

ACTION/NOTES – (Email authors, arrange translation etc)

FATIGUE REVIEW - DATA EXTRACTION SHEET

Description of study

Objectives													
Design (eg randomized crossover)													
Recruitment (eg primary care, secondary care, postal advert, database)													
Inclusion criteria													
Exclusion criteria													
Participants :	<table> <tr> <td>N required for intervention sample size:</td> <td>Control:</td> </tr> <tr> <td>N entered for intervention:</td> <td>Control:</td> </tr> <tr> <td>N completed to primary endpoint for intervention:</td> <td>Control:</td> </tr> </table>	N required for intervention sample size:	Control:	N entered for intervention:	Control:	N completed to primary endpoint for intervention:	Control:						
N required for intervention sample size:	Control:												
N entered for intervention:	Control:												
N completed to primary endpoint for intervention:	Control:												
Was study powered sufficiently to detect a change in fatigue?	Yes / No / Unclear												
Age (Range / mean / sd per group and overall):	<table> <tr> <td>Overall</td> <td>Mean:</td> <td>SD:</td> </tr> <tr> <td>Intervention group</td> <td>Mean:</td> <td>SD</td> </tr> <tr> <td>Intervention group</td> <td>Mean</td> <td>SD</td> </tr> <tr> <td>Control group</td> <td>Mean</td> <td>SD</td> </tr> </table>	Overall	Mean:	SD:	Intervention group	Mean:	SD	Intervention group	Mean	SD	Control group	Mean	SD
Overall	Mean:	SD:											
Intervention group	Mean:	SD											
Intervention group	Mean	SD											
Control group	Mean	SD											
Gender (per group and overall):	<table> <tr> <td>Overall</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Intervention group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Intervention group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Control group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> </table>	Overall	F= % (n=)	M= % (n=)	Intervention group	F= % (n=)	M= % (n=)	Intervention group	F= % (n=)	M= % (n=)	Control group	F= % (n=)	M= % (n=)
Overall	F= % (n=)	M= % (n=)											
Intervention group	F= % (n=)	M= % (n=)											
Intervention group	F= % (n=)	M= % (n=)											
Control group	F= % (n=)	M= % (n=)											
Diagnosis: (✓)	RA according to Arnett criteria RA verified by a clinician Self-report RA Other												

Co-morbidities:													
Ethnicity:													
Disease duration (mean / sd per group and overall):	<table> <tr> <td>Overall</td> <td>Mean:</td> <td>SD:</td> </tr> <tr> <td>Intervention group</td> <td>Mean:</td> <td>SD</td> </tr> <tr> <td>Intervention group</td> <td>Mean</td> <td>SD</td> </tr> <tr> <td>Control group</td> <td>Mean</td> <td>SD</td> </tr> </table>	Overall	Mean:	SD:	Intervention group	Mean:	SD	Intervention group	Mean	SD	Control group	Mean	SD
Overall	Mean:	SD:											
Intervention group	Mean:	SD											
Intervention group	Mean	SD											
Control group	Mean	SD											
Fatigue scales used	Name: Possible range of scale High good or bad?												
Interventions Was the main intention of the intervention to reduce fatigue?	Yes / No / Unclear												
Treatment Group Details of i/v:													
Duration of i/v:													
Dose eg. no. of sessions or drugs intended:													
Adherence ie no. of sessions attended/doses taken:													
Other details:													
Comparison Group(s): Details of control condition/alternative i/v													
Duration of control:													
Dose eg. no. of sessions or drugs intended:													

Adherence ie no. of sessions attended or doses taken																																	
Possible contamination between groups																																	
Other details:																																	
Outcome measures																																	
Fatigue scores : Fatigue scale 1 (eg VAS) Mean change + sd per group Mean + sd per group + time point	<table border="1"> <thead> <tr> <th>Name</th> <th>Mean change</th> <th>sd</th> <th>Mean score (pre)</th> <th>sd (pre)</th> <th>Mean score (post)</th> <th>sd (post)</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other	Group								Group								Group							
Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other																										
Group																																	
Group																																	
Group																																	
Fatigue scores : Fatigue scale 2 (eg MAF) Mean change + sd per group Mean + sd per group + time point	<table border="1"> <thead> <tr> <th>Name</th> <th>Mean change</th> <th>sd</th> <th>Mean score (pre)</th> <th>sd (pre)</th> <th>Mean score (post)</th> <th>sd (post)</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other	Group								Group								Group							
Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other																										
Group																																	
Group																																	
Group																																	
Other outcomes (identify which measure was the primary outcome if this was indicated)																																	
Pain	Included? Yes / No If included, what was main result?																																

Anxiety	Included? Yes / No If included, what was main result?
Depression	Included? Yes / No If included, what was main result?
Adverse effects (where available include Total Adverse Events and Total Serious Adverse Events)	
Leaving the study early (record any info about why patients did not complete the study)	
Primary end point + measurement time points	
Notes	

DOMAIN	JUDGEMENT (YES, NO, UNCLEAR)	REASON FOR JUDGEMENT (copy and paste directly from text of trial)
Sequence generation Was the allocation sequence adequately generated?		
Allocation concealment Was allocation adequately concealed?		
Blinding of participants, personnel & outcome assessors <i>For each main outcome</i> Was knowledge of the allocated interventions adequately prevented during the study?		
Blinding of personnel		
Blinding of participants		
Blinding of outcome assessors		
Incomplete outcome data <i>For each main outcome</i> Were incomplete outcome data adequately addressed?		
Selective outcome reporting Are reports of the study free of suggestion of selective outcome reporting		
Other sources of bias Was the study apparently free of other problems that could put it at a risk of bias?		

Appendix C: Narrative review search strategy

Generic search strategy (Medical Subject Heading used where applicable):

1. fatigue
2. cancer related fatigue
3. chronic fatigue syndrome
4. 1 OR 2 OR 3
5. Physical* activit* OR Exercise* OR Walk* OR Cycl* OR Swim* OR gym* OR Aerobic exercise* OR Yoga OR Tai chi OR Physical exercise* OR Sport* OR fitness OR Fitness level* OR Activity level* OR Nordic walking OR exercise therapy OR exercise intervention
6. Long term condition*
7. Chronic disease*
8. Chronic condition*
9. Chronic illness*
10. 6 OR 7 OR 8 OR 9
11. 4 AND 5 AND 10

*=used to identify all words beginning with the stem

Appendix D: Chapter 4 data extraction form

HBC REVIEW - DATA SCREENING SHEET

Title:

Report ID:

Study ID:

Reviewer:

Eligibility

	Yes / No / Unclear	Notes/Evidence
Is it an RCT?		
Are participants adults with RA?		
Is physical activity reported separately for RA patients?		
Does it use a theoretical approach to HBC?		
Does it include physical activity as an outcome measure?		
Include study in review?		

ACTION/NOTES – (Email authors, arrange translation etc)

HBC REVIEW - DATA EXTRACTION SHEET

Description of study

Objectives													
Design (eg randomized crossover)													
Recruitment (eg primary care, secondary care, postal advert, database)													
Inclusion criteria													
Exclusion criteria													
Participants :	<p>N required for intervention sample size: Control:</p> <p>N entered for intervention: Control:</p> <p>N completed to primary endpoint for intervention: Control:</p>												
Was study powered sufficiently to detect a change in physical activity levels?	Yes / No / Unclear												
Age (Range / mean / sd per group and overall):	<table> <tr> <td>Overall</td> <td>Mean:</td> <td>SD:</td> </tr> <tr> <td>Intervention group</td> <td>Mean:</td> <td>SD</td> </tr> <tr> <td>Intervention group</td> <td>Mean</td> <td>SD</td> </tr> <tr> <td>Control group</td> <td>Mean</td> <td>SD</td> </tr> </table>	Overall	Mean:	SD:	Intervention group	Mean:	SD	Intervention group	Mean	SD	Control group	Mean	SD
Overall	Mean:	SD:											
Intervention group	Mean:	SD											
Intervention group	Mean	SD											
Control group	Mean	SD											
Gender (per group and overall):	<table> <tr> <td>Overall</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Intervention group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Intervention group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> <tr> <td>Control group</td> <td>F= % (n=)</td> <td>M= % (n=)</td> </tr> </table>	Overall	F= % (n=)	M= % (n=)	Intervention group	F= % (n=)	M= % (n=)	Intervention group	F= % (n=)	M= % (n=)	Control group	F= % (n=)	M= % (n=)
Overall	F= % (n=)	M= % (n=)											
Intervention group	F= % (n=)	M= % (n=)											
Intervention group	F= % (n=)	M= % (n=)											
Control group	F= % (n=)	M= % (n=)											
Diagnosis: (✓)	<p>RA according to Arnett criteria</p> <p>RA verified by a clinician</p>												

	Self-report RA Other
Co-morbidities:	
Ethnicity:	
Disease duration (mean / sd per group and overall):	Overall Mean: SD: Intervention group Mean: SD Intervention group Mean SD Control group Mean SD
Physical activity scales used	Name: Possible range of scale High good or bad?
Interventions Was the main intention of the intervention to promote physical activity?	Yes / No / Unclear
Treatment Group Details of i/v:	
Duration of i/v:	
Dose eg. no. of sessions intended:	
Adherence ie no. of sessions attended:	
Other details:	
Comparison Group(s): Details of control condition/alternative i/v	
Duration of control:	
Dose eg. no. of sessions intended:	

Adherence ie no. of sessions attended																																	
Possible contamination between groups																																	
Other details:																																	
Outcome measures																																	
Physical activity scores : PA scale 1 Mean change + sd per group Mean + sd per group + time point	<table border="1"> <thead> <tr> <th>Name</th> <th>Mean change</th> <th>sd</th> <th>Mean score (pre)</th> <th>sd (pre)</th> <th>Mean score (post)</th> <th>sd (post)</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other	Group								Group								Group							
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Group																																	
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Group																																	
Physical activity scores : PA scale 2 Mean change + sd per group Mean + sd per group + time point	<table border="1"> <thead> <tr> <th>Name</th> <th>Mean change</th> <th>sd</th> <th>Mean score (pre)</th> <th>sd (pre)</th> <th>Mean score (post)</th> <th>sd (post)</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Group</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other	Group								Group								Group							
Name	Mean change	sd	Mean score (pre)	sd (pre)	Mean score (post)	sd (post)	Other																										
Group																																	
Group																																	
Group																																	
Other outcomes (identify which measure was the primary outcome if this was indicated)																																	
Aerobic Capacity	Included? Yes / No If included, what was main result?																																

Quality of Life	Included? Yes / No If included, what was main result?
Self-efficacy	Included? Yes / No If included, what was main result?
Pain	Included? Yes / No If included, what was main result?
Anxiety	Included? Yes / No If included, what was main result?
Depression	Included? Yes / No If included, what was main result?
Fatigue	Included? Yes / No If included, what was main result?
Disease Activity	Included? Yes / No If included, what was main result?
Adverse effects (where available include Total Adverse Events and Total Serious Adverse Events)	
Leaving the study early (record any info about why patients did not complete the study)	
Primary end point + measurement time points	

Notes	

DOMAIN	JUDGEMENT (YES, NO, UNCLEAR)	REASON FOR JUDGEMENT (copy and paste directly from text of trial)
Sequence generation Was the allocation sequence adequately generated?		
Allocation concealment Was allocation adequately concealed?		
Blinding of participants, personnel & outcome assessors <i>For each main outcome</i> Was knowledge of the allocated interventions adequately prevented during the study?		
Blinding of personnel		
Blinding of participants		
Blinding of outcome assessors		
Incomplete outcome data <i>For each main outcome</i> Were incomplete outcome data adequately addressed?		
Selective outcome reporting Are reports of the study free of suggestion of selective outcome reporting		
Other sources of bias Was the study apparently free of other problems that could put it at a risk of bias?		

Appendix E: Participant information sheet and reply slip (interviews)



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

Expert opinion on the use of physical activity for fatigue management in long term conditions

Participant Information Sheet

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Ask us if there is anything that is not clear, or if you would like more information.

What is the purpose of the study?

The purpose of the study is to identify the physical activity content of fatigue management programmes for long term conditions (LTCs). The study will explore clinicians' opinions and experiences of delivering this intervention, and identify any barriers and facilitators to implementation and delivery.

It is hoped that hearing about clinicians' experiences of using physical activity for fatigue management will enable us to identify key components and to understand the practicalities and obstacles relating to delivery and acceptability of this intervention. Findings from the study will inform the development of a programme for rheumatoid arthritis.

Why have I been chosen?

You have been chosen because you have been identified as a health professional who is, or has been, involved in delivering a physical activity intervention as part of a fatigue management programme for a long term condition.

We are writing directly to clinicians to invite them to take part. Your views are important to us - it doesn't matter whether you feel you are not now delivering the physical activity component, only doing so on occasion, or delivering it a lot.

Do I have to take part?

No, taking part is voluntary. If you decide not to take part, you do not have to give a reason. If you decide to take part we will ask you to sign a consent form, and give you a copy of this information sheet and the consent form to keep. We will also ask for your verbal permission to collect some information about the physical activity sessions that you run prior to the interview.

What if I wish to withdraw at a later stage?

You are free to withdraw at any time, and with no explanation, up until the point of publication of any data. If you do withdraw any data you provided will be removed from the study.

What will I be asked to do if I take part?

You will be asked to take part in an interview to discuss your experiences and views relating to the use and delivery of physical activity for fatigue management in long term conditions, both positive and negative. The interview will take place at your workplace, it should last about one hour. We will ask your permission to audio-record the interview, which we will later type up (transcribe) using the actual words spoken.

Will my taking part in this study be kept confidential?

Yes. When the interviews are transcribed, all identifying information (such as people's names, locations, or specific descriptions of a clinical setting) will be replaced with code numbers, or a generalised summary. Therefore, anything you say will not be able to be linked to you or the clinical setting you work in, in any report or publication. We are not evaluating individual fatigue management programmes.

What will happen to the results of the research study?

Research team members will analyse the transcripts systematically and independently, then discuss their findings to see if common themes emerge. The findings will be written up as part of a PhD thesis and may be used in conference presentations or published in a journal. It is anticipated that the results from this study will inform the design and development of a physical activity intervention to reduce the impact of fatigue for patients with rheumatoid arthritis; by identifying the key components of physical activity programmes, such as type, duration, location, and implementation issues that might be relevant to delivery and acceptability of such programmes in a rheumatology setting. It forms part of the first of 3 phases of a PhD project on this topic.

Who is organising and funding the research?

This study is part of a doctoral research project registered with the University of the West of England, Bristol (UWE) and based at the Academic Rheumatology Unit at the Bristol Royal Infirmary. It is funded by University Hospitals Bristol NHS Foundation Trust, and has been approved by the UWE Research Ethics Committees.

What do I do now?

Thank you for considering taking part in this research. Please complete the reply slip and return it in the reply-paid envelope to **Victoria Salmon** (PhD Student). Victoria will contact you in a few days. You can ask any questions you have and let her know your final decision.

Study team

Victoria Salmon, UH Bristol Doctoral Research Fellow, University of the West of England, Bristol

Dr Fiona Cramp, Associate Professor in Musculoskeletal Health, University of the West of England

Professor Sarah Hewlett, Professor of Rheumatology Nursing, University of the West of England

Dr Nicola Walsh, Arthritis Research UK Fellow, University of the West of England

Professor John Kirwan, Consultant Rheumatologist & Professor of Rheumatic Diseases, University of Bristol

Marie Urban, Patient Research Partner, University Hospitals Bristol

Maria Morris, Patient Research Partner, University Hospitals Bristol

Contact: **Victoria Salmon 0117 342 4972**



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

Expert opinion on the use of physical activity for fatigue management in long term conditions

Reply Slip

1. I have read and understood the information sheet for this study. Please circle:

Yes, I would be interested in being contacted to discuss participation in this study
No, thank you, I would prefer not to be involved

2. If you answered **yes** to question 1, please circle:

Yes, I would be happy for a message to be left on my answer machine
No, I would prefer not to have messages left on my answer machine

Please return this slip using the self-reply envelope provided

Name: -----
Phone: -----
Email: -----
Signature: -----
Date: -----

Victoria Salmon
Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Appendix F: Pre-interview case report form



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

Expert opinion on the use of physical activity for fatigue management in long term conditions

Pre-interview Information Case Report Form

Thank you for agreeing to take part in this study.

It would be helpful to gather some information about you and the programme that you run prior to carrying out the interview by answering the questions below. Don't worry if you are unable to provide this information in advance as we will be able to discuss this at the start of the interview instead if necessary.

Background information

1. Age
2. Sex Male
 Female
3. Profession _____
4. Year of qualification in this profession
5. Clinical role _____
6. How long have you been running the physical activity sessions for this programme?

Programme information

If you have a programme information booklet that contains all or some of the information below, and that you are willing to share with the research team, please do provide a copy. Otherwise please complete the information below.

7. What long term condition(s) is the fatigue management programme for?

8. Is the programme run in groups or individually?

9. What is the minimum group size for the programme to run?

And maximum group size?

10. How is physical activity (PA) included in the fatigue management programme?

11. If PA is only one component, briefly outline what other components are included in the programme?

12. How long (number of weeks) is the whole programme?

13. How many sessions are provided in total and how often do these take place (for example, 8 sessions in total, x1 per week)?

14. Please outline how many sessions and what proportion of each session are dedicated to PA.

Please provide any further information about the programme content and delivery that you feel would be useful:

Thank you for completing this information. Please either return this to the researcher in the pre-paid envelope provided, or bring it along to the interview.

Victoria Salmon, Principal Investigator

Appendix G: Example of deductive coding

	1. Goals and planning				
Participant ID	<i>Goal setting (behavior)</i>	<i>Problem solving</i>	<i>Action planning</i>	<i>Review behavior goal(s)</i>	<i>Discrepancy between current behavior and goal</i>
INV-004-2C	<p>We'll look at goals, and say to people, what do you want to do? And they say, I'd really like to play the piano, but I haven't got the energy. So, I say, okay, that's great, let's think about you starting to play the piano for five minutes a day, and see how that goes. (pp6)</p> <p>INT: Okay. And, um, so, do you, do you ... How do you help to encourage physical activity between sessions, if you like? So, how do you motivate, um, people to continue between times?</p> <p>INV-004-2C: Um, yeah, I don't know how ... I mean, what we're doing is we're setting them,[.] a goal for each week. (pp11)</p>	<p>INT: So, you relate back to previous weeks?</p> <p>INV-004-2C: Yes, relate back to where they've got to. And people say, oh I didn't do my stretches this week, you know, so it's trying to encourage ... Oh well, you did well, what did you do? That's really good, considering you had that set-back, you know, that's great, what can you, how can you build on that?</p> <p>So, a lot of it is about set-back management, and trying ... I suppose it's just trying to encourage people. (pp.11/12)</p> <p>There's a session on overcoming obstacles (pp24)</p>	<p>they say, I'd really like to play the piano, but I haven't got the energy. So, I say, okay, that's great, let's think about you starting to play the piano for five minutes a day, and see how that goes. (pp6)</p>	<p>, so if they say they use walking, it's the easiest exercise to use, we'd start off walking one or two minutes a day, say, if that was their baseline. Build it up to thirty minutes, and when they get it to thirty minutes, then we increase the intensity of it. (pp.1)</p> <p>so we'd get people to write down their goals, and what they're going to do, and then maybe get, you know, put it on a flip chart, and keep getting that out to remind them. (pp. 23)</p>	0

	1. Goals and planning				
Participant ID	<i>Goal setting (behavior)</i>	<i>Problem solving</i>	<i>Action planning</i>	<i>Review behavior goal(s)</i>	<i>Discrepancy between current behavior and goal</i>
INV-006-4E	<p>Number four is, is values and erm, values and goals [...] And setting ... setting short term goals at that point,[...], in week five we catch up on that and we're going for the long term goals then. (pp6)</p> <p>INT: Is that how you get them to engage? INV-006-4E: Very much. [...] But it's very much around goal setting and, and erm, practical strategies, things that are linked with their values in life ... (p11)</p>	<p>Number four is, is values and erm, values and goals. [...] And setting ... setting short term goals at that point, talking about barriers (pp6)</p>	0	<p>...setting short term goals at that point, talking about barriers and then in erm, in week five we catch up on that and we're going for the long term goals then. INT: Right. So you're doing ... so reviewing it and ... INV-006-4E: Reviewing it, yeah. (pp6)</p>	0

	1. Goals and planning				
Participant ID	<i>Goal setting (behavior)</i>	<i>Problem solving</i>	<i>Action planning</i>	<i>Review behavior goal(s)</i>	<i>Discrepancy between current behavior and goal</i>
INV-007-5F	... setting some goals with them if they can at that stage, (pp2) the direction that the therapy then kind of goes in is erm dependent on what the patient's goals are (pp3)	so I may very well be touching to a certain degree on any challenges and barriers to their implementation of the therapy [...] we can look at the individual helping them problem solve, ... (pp4) ... if a patient comes in and they've had a sudden setback or they're going to a wedding then I would stop, and we would look at where they are in that setback, look at setback planning and how to think about and learn from that setback. (pp5)	... I will focus on looking at you know looking at activity analysis to enable them to reduce the energy expenditure on that goal, getting them to think about planning their day so that they've got, you know rest and erm activity, erm and.. but also a balance between cognitive and physical, and then exploring, so that's very global isn't it, that's looking at a global day, but then you go into the finite parts of activity analysis whereby you're looking at particularly any high activities, cognitively, physically or emotionally that we can sort of look at how they might sequence that task or how they might work with any environmental demands. (p3)	...if they're kind of moderately you know they're hearing the strategies but actually they're not coming back they've not done their home work or they've not tried it, you know we look at the pros and cons of where they are now and getting them to understand, you know, are they moving forward, where they are now and look at maybe reducing some of their goals or looking at it in a different remit for them. (pp6)	if they're kind of moderately you know they're hearing the strategies but actually they're not coming back they've not done their home work or they've not tried it, you know we look at the pros and cons of where they are now and getting them to understand, you know, are they moving forward, where they are now and look at maybe reducing some of their goals or looking at it in a different remit for them. (pp6)

Appendix H: Patient participant information sheet (focus groups)



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Participant information sheet

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Ask us if there is anything that you do not understand, or if you would like more information.

What is the purpose of the study?

Fatigue, or extreme and persistent tiredness, is often a big problem for people with rheumatoid arthritis. At the moment there are not very many programmes available to help people manage their fatigue.

The purpose of this study is to find out how patients with rheumatoid arthritis would like to receive help and advice for managing their fatigue, and to see whether you feel that a physical activity programme may or may not be helpful. We would also like to find out your views on what advice and information to include in a fatigue management programme, and how you think it should be delivered.

Hearing and understanding patients' views about fatigue management will help us to discover the important elements to include in future programmes, and to understand how practical or difficult it might be to offer these as an intervention. Findings from the study will help with the development of future interventions for managing fatigue in RA.

Why have I been invited?

You have been invited because you have rheumatoid arthritis and have experienced extreme tiredness (fatigue) since your diagnosis.

Do I have to take part?

No, taking part is voluntary. If you decide not to take part, you do not have to give a reason. If you decide to take part we will ask you to sign a consent form, and give you a copy of this information sheet and the consent form to keep. We will also ask for your permission to collect some information about your medical history.

What if I wish to withdraw at a later stage?

You are free to withdraw at any time, and with no explanation, up until the point of publication of any data. If you do withdraw any data you provided will be removed from the study.

What will I be asked to do if I take part?

You will be invited to come to a half day workshop in Bristol. During the day you will be asked to take part in a group discussion (focus group) with the researcher (Victoria Salmon) and a patient research partner. There will be between 5 and 7 other people like yourself in the group. Before the focus group starts you will be asked to read and sign a consent form and answer some questions about your medical history.

During the group discussion you will be asked to discuss your thoughts about fatigue management, and whether you think physical activity would or would not help you to manage fatigue in rheumatoid arthritis. You can say as much or as little as you want and there are no right or wrong answers. This discussion will last about an hour. We will ask your permission to audio-record the discussion, which we will later type up (transcribe) and analyse.

Following the focus group there will be a break for refreshments. Then during the second part of the morning everyone will be shown some ideas about what content has been included in interventions for fatigue management in other long term conditions. These are themes and ideas that have come from our analysis of published research and interviews with health professionals delivering these interventions in other patient groups. All participants attending the workshop will discuss which of these components might be acceptable and appropriate to include in a similar intervention for RA. Ideas will be recorded on flip charts and notes will be made by the researcher and patient research partners/facilitators.

Will my taking part in this study be kept confidential?

Yes. When the discussions are transcribed, all information that would allow you to be identified (such as people's names, locations, or specific descriptions) will be replaced with code numbers, or a generalised summary. Therefore, anything you say will not be able to be linked to you in any report or publication. In the unlikely event of disclosure of any misconduct during the focus group this will be passed to the appropriate authority.

Reports from the study will include quotations from the discussion but names will not be used. Recordings are kept securely for 6 years and then destroyed in accordance with guidelines for best practice in research.

What will happen to the results of the research study?

Research team members will analyse the transcripts systematically and independently, then discuss their findings to see if common themes emerge. The findings will be written up as part of a PhD thesis and may be used in conference presentations or published in a journal. It is anticipated that the results from this study will inform the design and development of an intervention to reduce the impact of fatigue for patients with rheumatoid arthritis by prioritising the key components of future programmes, and implementation issues that might be relevant to delivery and acceptability of such programmes in a rheumatology setting. It forms part of the second of 3 phases of a PhD project on this topic.

Who is organising and funding the research?

This study is part of a doctoral research project registered with the University of the West of England, Bristol (UWE) and based at the Academic Rheumatology Unit at the Bristol Royal Infirmary. It is funded by University Hospitals Bristol NHS Foundation Trust, and has been approved by the NHS Research Ethics Committee (NRES Committee East Midlands – Nottingham 1. Reference 13/EM/0331).

What do I do now?

Thank you for considering taking part in this research. Please complete the reply slip and return it in the reply-paid envelope to **Victoria Salmon** (PhD Student). Victoria will contact you in a few days. You can ask any questions you have and let her know your final decision.

Study team

Victoria Salmon, UH Bristol Doctoral Research Fellow, University of the West of England, Bristol

Dr Fiona Cramp, Associate Professor in Musculoskeletal Health, University of the West of England

Professor Sarah Hewlett, Professor of Rheumatology Nursing, University of the West of England

Dr Nicola Walsh, Arthritis Research UK Fellow, University of the West of England

Professor John Kirwan, Consultant Rheumatologist & Professor of Rheumatic Diseases, University of Bristol

Marie Urban, Patient Research Partner, University Hospitals Bristol

Maria Morris, Patient Research Partner, University Hospitals Bristol

Contact: **Victoria Salmon 0117 342 4972**



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Reply Slip

1. I have read and understood the information sheet for this study. Please circle:

Yes, I would be interested in being contacted to discuss participation in this study

No, thank you, I would prefer not to be involved

2. If you answered **yes** to question 1, please circle:

Yes, I would be happy for a message to be left on my answer machine

No, I would prefer not to have messages left on my answer machine

Please return this slip using the self-reply envelope provided

<p>Name:</p> <p>-----</p> <p>--</p> <p>Phone:</p> <p>-----</p> <p>--</p> <p>Email:</p> <p>-----</p> <p>--</p> <p>Signature:</p>

Victoria Salmon
Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Appendix I: Recruitment advertisement (allied health professionals)



Department of Allied Health Professions



Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Rheumatoid arthritis: physical activity and fatigue management **CPD afternoon and research event**

Are you a specialist rheumatology physiotherapist?

Or

Do you have at least 12 months experience working in this clinical area?

If so, we would like to invite you to take part in a research focus group and CPD afternoon related to rheumatoid arthritis (RA), physical activity (PA) and fatigue management.

What will the afternoon involve?

Session 1: Focus group

This research focus group offers an opportunity to contribute to future practice in the management of RA fatigue. We would like to hear your thoughts and ideas about using PA to manage fatigue in RA. This group discussion will identify and explore key elements of a PA intervention, and will help us to understand the practicalities and obstacles relating to its delivery and acceptability in clinical practice.

Refreshment break: Coffee/tea/snacks will be provided

Session 2: CPD event

This CPD lecture will present an update of the current evidence relating to physical activity and exercise in RA. This interactive session will include an opportunity for discussion and questions relating to this topic.

Event details*:

London

Date: Monday 9th December 2013

Location: The Chartered Society of Physiotherapy, 14 Bedford Row, London, WC1R 4ED

Time: 2.00-5.00pm

South West

Date: Wednesday 11th December 2013

Location: Clinical Rheumatology, Bristol Royal Infirmary, Lower Maudlin Street, Bristol, BS2 8HW

Time: 3.00-6.00pm

*Travel expenses up to £20 can be provided on submission of receipts/tickets

Further information and contact details:

Please contact Victoria Salmon if you are interested in finding out more about this event. Please forward this invitation to any colleagues that might also be interested in attending.

Email: Victoria.salmon@uwe.ac.uk

Telephone: 0117 342 4972

Appendix J: AHP participant information sheet (focus groups)



Rheumatology Research
 Faculty of Health and Life Sciences
 Based at:
 Academic Rheumatology
 Bristol Royal Infirmary
 BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Participant information sheet

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Ask us if there is anything that is not clear, or if you would like more information.

What is the purpose of the study?

Fatigue is often a big problem for people with rheumatoid arthritis. At the moment there are very few programmes available to help people manage their fatigue.

The purpose of this study is to explore the acceptability and deliverability of a physical activity (PA) intervention for the management of fatigue in rheumatoid arthritis (RA), and to discuss and identify key components of this intervention. The study will explore RA patients' and physiotherapists' opinions about PA as a fatigue management intervention, and identify any barriers and facilitators to implementation and delivery.

Hearing and understanding patients' and clinicians' opinions about using PA for fatigue management will help us to identify key components and to understand the practicalities and obstacles relating to delivery and acceptability of this intervention. Findings from the study will inform the development of a PA intervention for managing fatigue in RA.

Why have I been chosen?

You have been chosen because you are a rheumatology healthcare professional.

Do I have to take part?

No, taking part is voluntary. If you decide not to take part, you do not have to give a reason. If you decide to take part we will ask you to sign a consent form, and give you a copy of this information sheet and the consent form to keep. We will also ask for your verbal permission to collect some information about your professional background.

What if I wish to withdraw at a later stage?

You are free to withdraw at any time, and with no explanation, up until the point of publication of any data. If you do withdraw any data you provided will be removed from the study.

What will I be asked to do if I take part?

You will be asked to attend a one hour group discussion (focus group) either in Bristol or London. The discussion will be guided by the researcher (Victoria Salmon) and a member of the research team, and the group will include between 5 and 7 other people like yourself. Before the focus group starts you will be asked to read and sign a consent form and answer some questions about your professional background.

During the group discussion you will be presented with some ideas that RA patients have about what components might make up a PA intervention for fatigue management in RA. These are themes and ideas that have come from our analysis of focus groups with RA patients. You will be invited to discuss your thoughts about fatigue and PA, and how you think this might be delivered as an intervention to manage fatigue in rheumatoid arthritis. You can say as much or as little as you want and there are no right or wrong answers. This discussion will last about an hour. We will ask your permission to audio-record the discussion, which we will later type up (transcribe) and analyse.

Will my taking part in this study be kept confidential?

Yes. When the discussions are transcribed, all identifying information (such as people's names, locations, or specific descriptions) will be replaced with code numbers, or a generalised summary. Therefore, anything you say will not be able to be linked to you in any report or publication. In the unlikely event of disclosure of any misconduct during the focus group this will be passed to the appropriate authority.

Reports from the study will include quotations from the discussion but names will not be used. Recordings are kept securely for 6 years and then destroyed in accordance with guidelines for best practice in research.

What will happen to the results of the research study?

Research team members will analyse the transcripts systematically and independently, then discuss their findings to see if common themes emerge. The findings will be written up as part of a PhD thesis and may be used in conference presentations or published in a journal. It is anticipated that the results from this study will inform the design and development of a PA intervention to reduce the impact of fatigue for patients with rheumatoid arthritis by prioritising the key components of PA programmes, such as type, duration, location, and implementation issues that might be relevant to delivery and acceptability of such programmes in a rheumatology setting. It forms part of the second of 3 phases of a PhD project on this topic.

Who is organising and funding the research?

This study is part of a doctoral research project registered with the University of the West of England, Bristol (UWE) and based at the Academic Rheumatology Unit at the Bristol Royal Infirmary. It is funded by University Hospitals Bristol NHS Foundation Trust, and has been approved by the NHS Research Ethics Committee (NRES Committee East Midlands – Nottingham 1. Reference 13/EM/0331).

What do I do now?

Thank you for considering taking part in this research. Please complete the reply slip and return it in the reply-paid envelope to **Victoria Salmon** (PhD Student). Victoria will contact you in a few days. You can ask any questions you have and let her know your final decision.

Study team

Victoria Salmon, UH Bristol Doctoral Research Fellow, University of the West of England, Bristol

Dr Fiona Cramp, Associate Professor in Musculoskeletal Health, University of the West of England

Professor Sarah Hewlett, Professor of Rheumatology Nursing, University of the West of England

Dr Nicola Walsh, Arthritis Research UK Fellow, University of the West of England

Professor John Kirwan, Consultant Rheumatologist & Professor of Rheumatic Diseases, University of Bristol

Marie Urban, Patient Research Partner, University Hospitals Bristol

Maria Morris, Patient Research Partner, University Hospitals Bristol

Contact: **Victoria Salmon 0117 342 4972**



Rheumatology Research
Faculty of Health and Life Sciences
Based at:
Academic Rheumatology
Bristol Royal Infirmary
BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Reply Slip

1. I have read and understood the information sheet for this study. Please circle:

Yes, I would be interested in being contacted to discuss participation in this study

No, thank you, I would prefer not to be involved

2. If you answered **yes** to question 1, please circle:

Yes, I would be happy for a message to be left on my answer machine

No, I would prefer not to have messages left on my answer machine

Please return this slip using the self-reply envelope provided

<p>Name: -----</p> <p>Phone: -----</p> <p>Email: -----</p> <p>Signature: -----</p> <p>Date: -----</p>
--

Victoria Salmon
Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Appendix K: Patient case report form (focus groups)



Rheumatology Research
 Faculty of Health and Life Sciences
 Based at:
 Academic Rheumatology
 Bristol Royal Infirmary
 BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Case Report Form

Thank you for agreeing to take part in this study.

It would be helpful to gather some information about you and your experiences of physical activity and fatigue prior to carrying out the focus group by answering the questions below. Your answers are confidential and your name will not be linked to the answers that you give on this form.

Background information

1. Gender (please tick)

Male

Female

2. Date of birth (day/month/year)

3. Please indicate your current work status:

Paid work

Student

Homemaker

Unemployed

Retired

Receiving incapacity benefits

Other (please specify): _____

4. When were you diagnosed with rheumatoid arthritis?

5. Since being diagnosed with RA have you experienced extreme tiredness/fatigue?
(please tick)

Yes

No

Thank you for completing this information. Please either return this to the researcher in the pre-paid envelope provided, or bring it along to the interview.

Victoria Salmon, Principal Investigator

Appendix L: Workshop questions

When we spoke to health professionals about the physical activity element of fatigue management programmes they are delivering, they gave us information about the content and how it is delivered. Please use your handsets to vote for the statement that you most agree with for the following questions.

Section A

1. I would prefer a fatigue management programme to be delivered:
 - a. At the hospital clinic
 - b. At my GP clinic
 - c. In the local community, e.g. leisure centre, community centre, village hall
 - d. Via written support materials for me to follow at home
 - e. Via online support materials for me to follow at home
 - f. Don't mind

2. I think referral to the programme should be from:
 - a. My consultant
 - b. My specialist nurse or therapist
 - c. My GP
 - d. I should be able to request to attend the programme directly
 - e. Any of the above

3. Before starting the programme we would want to assess the participants. This assessment should take place:
 - a. Face to face
 - b. By telephone
 - c. Don't mind

4. The total length of the fatigue management programme should be:
 - a. Less than 5 weeks
 - b. 5-6 weeks
 - c. 8-10 weeks
 - d. 12-14 weeks
 - e. Don't mind

Section B – hospital based therapy only

If participants identify that they are happy to attend a hospital or local clinic, or don't mind (1a or b or e above), then continue with these questions. If participants specify that they only want a programme to follow at home, proceed to section C.

5. Travel arrangements for getting to the hospital are an important consideration for me when deciding whether to attend the programme:
 - a. Yes
 - b. No

-
6. For a hospital based programme I would need to travel by
 - a. Car
 - b. Bus
 - c. Walk
 - d. Hospital transport would need to be arranged for me
 - e. Combination

 7. I would prefer to attend the programme
 - a. On my own
 - b. With a relative, friend or carer
 - c. Don't mind

 8. Programme sessions in the clinic or hospital should be held:
 - a. Twice a week
 - b. Once a week
 - c. Every 2 weeks
 - d. Don't mind

 9. I would prefer a programme that was delivered:
 - a. In groups
 - b. One to one
 - c. A combination of group and one to one
 - d. Don't mind

 10. Each session should last:
 - a. Up to 60 minutes
 - b. Up to 2.5 hours (including a break)
 - c. Don't mind

 11. The time of day for the sessions should be:
 - a. Mid morning
 - b. In the afternoon
 - c. Don't mind

 12. Sessions should include:
 - a. **50% education** and **50% physical activity** practical session (e.g. gentle exercises with instruction and opportunity to practice)
 - b. **Mainly education** with a small practical session
 - c. **Education and discussion only** (no practical exercise)
 - d. Don't mind

13. The programme should be delivered by

- a. Any **allied health professional** with appropriate training (e.g. occupational therapist, psychologist, physio)
- b. Any **health professional** with appropriate training (e.g. any therapist or clinical nurse specialist)
- c. Any **therapy assistant or exercise professional** with appropriate training (e.g. therapy technical instructor, specialist fitness instructor)
- d. Don't mind

14. Practical sessions should include:

a. Demonstration of exercises	Yes	No	Don't mind
b. Practice/rehearsal of exercises	Yes	No	Don't mind
c. Stretching	Yes	No	Don't mind
d. Relaxation	Yes	No	Don't mind
e. Gentle seated exercises	Yes	No	Don't mind
f. A range of exercises to choose from	Yes	No	Don't mind

15. Homework should be set between sessions, e.g. completing activity diaries, goal setting:

- a. Yes
- b. No
- c. Don't mind

16. Follow up to the programme should be

- a. At 6 months
- b. At 12 months
- c. At 6 and 12 months
- d. At my request

17. Follow up sessions should be:

- a. In groups
- b. One to one
- c. A combination of groups and one to one
- d. Don't mind

18. I would prefer the follow up session to be

- a. Face to face
- b. Via telephone or skype
- c. Don't mind

Section C – Home and hospital based therapy

19. I would like to be able to access professional support during the programme:

- a. By email
- b. Via telephone
- c. Using Skype
- d. Don't mind

20. The following education topics should be included in a physical activity fatigue management programme:

a. Activity analysis and management – includes activity planning, pacing and prioritising	Yes	No	Don't mind
b. Goal setting and problem solving about physical activity	Yes	No	Don't mind
c. Review and progression of activity/exercise goals	Yes	No	Don't mind
d. Managing setbacks	Yes	No	Don't mind
e. Physical activity education – includes effects of exercise, physical activity and fatigue, type of activity	Yes	No	Don't mind
f. Graded activity or graded exercise therapy	Yes	No	Don't mind
g. How to maintain physical activity in the long term	Yes	No	Don't mind
h. Discussing and modifying thoughts and feelings around physical activity and fatigue (CBT based)	Yes	No	Don't mind

i. Sleep management	Yes	No	Don't mind
j. Mindfulness (includes acceptance and commitment therapy)	Yes	No	Don't mind
k. Relaxation – various techniques	Yes	No	Don't mind
l. General self-management	Yes	No	Don't mind
m. Diet	Yes	No	Don't mind
n. Occupation and activity	Yes	No	Don't mind
o. Posture and positioning	Yes	No	Don't mind
p. Balance and prevention of falls	Yes	No	Don't mind
q. General education about fatigue	Yes	No	Don't mind

21. Programme support materials should include:

a. A presentation to support education topics	Yes	No	Don't mind
b. Sheet of exercises performed in the session	Yes	No	Don't mind
c. Programme information booklet/manual	Yes	No	Don't mind
d. Information regarding local exercise groups and facilities	Yes	No	Don't mind
e. Record charts, such as activity diaries, record for exercises	Yes	No	Don't mind
f. Relaxation materials, e.g. CDs	Yes	No	Don't mind
g. Individual education topic handouts	Yes	No	Don't mind
h. Pictures and diagrams	Yes	No	Don't mind

22. I would like programme support materials to be delivered:

- a. Using paper-based information, e.g. information booklet, programme manual
- b. Online via a website
- c. Via email
- d. A combination of the above
- e. Don't mind

Continued exercise

23. After the programme I would prefer to continue exercising:

- a. At home
- b. In my local community/leisure centre
- c. Don't mind

Appendix M: AHP case report form



Rheumatology Research
 Faculty of Health and Life Sciences
 Based at:
 Academic Rheumatology
 Bristol Royal Infirmary
 BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Case Report Form

Thank you for agreeing to take part in this study.

It would be helpful to gather some information about you and your current clinical role prior to carrying out the focus group by answering the questions below. Your answers are confidential and your name will not be linked to the answers that you give on this form.

Background information

1. Gender (please tick)

Male

Female

2. Date of birth (day/month/year)

 /

3. Profession _____

4. Year of qualification in this profession

5. Current clinical role _____

Rheumatology experience

6. How long have you been working in a rheumatology setting (years)?

Thank you for completing this information. Please either return this to the researcher in the pre-paid envelope provided, or bring it along to the interview.

Victoria Salmon, Principal Investigator

Appendix N1: Session 1 lesson plan

Session 1: Introduction to the programme

18/09/14	11.30-12.30	FRAPA Education 1	VS	RNHRD
18/09/14	12.45-1.30	FRAPA Practical 1	VS	RNHRD

Aims

To introduce participants to:

- ♦ The aims and expectations of the course.
- ♦ The concepts of fatigue and physical activity (in the context of RA)
- ♦ Activity analysis
- ♦ Practical session format and exercises

Objectives

The participant should be able to:

1. Outline fatigue experiences and identify how these might influence their daily life
2. Differentiate between PA and exercise, and be aware of the recommendations for PA in RA
3. Describe the potential consequences of using PA to manage fatigue and understand the possible mechanisms for how this might work
4. Use activity diaries to analyse their own physical activity

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Pens with grip suitable for RA patients
- ♦ Post-it notes
- ♦ Handouts

Aims – practical session

To introduce participants to:

- ♦ The gym equipment and a range of exercises to choose from.
- ♦ Reinforce potential benefits of PA for managing fatigue
- ♦ Address safety considerations

Objectives

The participant should be able to:

1. Recognise the gym equipment that they can use in future sessions and how to use it
2. Understand the purpose of modifying PA to manage fatigue

Equipment

- ♦ Gym equipment
- ♦ Theraband
- ♦ Handout of exercises

SESSION PLAN

DISCUSSION SESSION

1. Introduction/objectives (10)

- Participants write preferred name on white sticky label (first name only)
- Introduce self as course tutor and give brief explanation that the course aims to help people with RA manage their fatigue using physical activity. This will be discussed in more detail during the session.
- Ask participants to introduce themselves, how long they have had RA
- Explain any housekeeping and ground rules:
 - Confidentiality and privacy for others in the room
 - Respect others views, even if they are different from your own
 - Try to let others speak and don't all talk at once
 - Arrive 10 mins early
 - Let us know about missing appointments
- Encourage participation and interaction to make the most from the course. Participants are encouraged to establish a shared experience and to work together throughout the education sessions. There will, however, be an emphasis on working at an individual level during the practical sessions so that participants can work to their own level of confidence and ability
- Emphasise that this is not a curative programme – this is not a cure for fatigue, but is a means of managing this symptom. It is natural that fatigue symptoms will continue to fluctuate.
- Ask about participants' expectations from the course

Handout 1: Introduction to the course

2. What is fatigue? (15)

Outline fatigue experiences and identify how these might influence their daily life

Discuss what is understood by fatigue.

Note that there is a broad spectrum of fatigue experiences and that this varies greatly between individuals, therefore everyone's experience is valid and relevant for this discussion

- How would you describe it to others?
- How does this affect your everyday life?

What do we know about fatigue?

- Discuss potential causes of fatigue:
 - What do you think might cause fatigue for you?
 - Any other things that might cause fatigue?
- Discuss what makes fatigue better:
 - Do you have any strategies at the moment for addressing your fatigue?

- Grouping ideas into RA, personal and cognitive factors – write these on flipchart
- Handout: causes of fatigue. Encourage participants to reflect on and identify their own causes according to these groupings (note: emphasise that filling in the handout is optional. It is just there as a tool for reflection if they find it useful)

Handout: ARUK fatigue booklet

Handout 2: Causes of fatigue

Make notes using flipchart to summarise what patients have discussed

3. PA and exercise in RA (15)

Differentiate between PA and exercise, and be aware of the recommendations for PA in RA

Describe the potential consequences of using PA to manage fatigue and understand the possible mechanisms for how this might work

Discuss PA and exercise:

- What do you understand by PA/exercise?
- What are experiences of PA?
- How do you feel about modifying PA levels? What are the pros and cons?

Discuss fears/beliefs about safety of exercise. (Note: barriers to PA will be discussed in further detail with goal setting. Acknowledge that barriers are common and is overcoming them is part of the whole course)

Outline PA recommendations in NICE/BSR guidelines:

- All RA patients should have access to PT for advice about tailored exercise programmes
- All RA patients should improve general fitness and undertake regular exercise.

Benefits in RA:

- Is anyone aware of benefits of PA in RA?
- General benefits include a reduced risk of coronary heart disease, diabetes, hypertension, and some cancers
- Specific health benefits for RA include improved functional ability, with improved cardiovascular fitness, strength, increased muscle mass, decreased fat mass, better joint mobility, load bearing exercise is required to reduce bone loss
- Exercise can reduce pain and stiffness and may reduce fatigue in RA

Discuss the potential effect of PA on fatigue (positive and negative) – relate back to handout 2 (fatigue diagram). Discuss how PA might influence the factors identified. Include known research evidence.

Handout 3: PA in RA

4. Introduction to activity analysis (10)

Use activity diaries to analyse their own physical activity

Hand out activity diaries and instructions. Discuss how to fill these in. For week 1, diaries will include a record of symptoms. However, subsequent weeks will just use the standard diary.

- Useful to get an idea of what is happening in everyday life
- Helps to see patterns of sleep and activity
- We will use these more next time to help set a baseline for physical activity
- Being able to analyse activity can help increase confidence and allow you to feel more in control
- The instruction sheet has space for examples. Note that the intensity does not depend on the task. The same task, e.g. washing up, could be low energy one day and high energy the next therefore this same task would have a different colour.
- Try and fill in the diary every day, rather than doing several days at once
- Record your fatigue symptoms for each day
- Any questions?

Handout 4: Activity diaries – modified to include PA

5. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15)

PRACTICAL SESSION

1. Demonstration of gym equipment and exercises

Recognise the gym equipment that they can use in future sessions and how to use it
Understand the purpose of modifying PA to manage fatigue

Tutor to demonstrate exercises and gym equipment

Explain that participants can choose which exercises they might like to try:

- Each exercise has ideas for progression
- Please ask the tutor if you are unsure about anything
- Note: aerobic exercise has been shown to be particularly important for reducing fatigue. Point out which are aerobic vs strengthening

Try out exercise (time permitting)

Handout 5: list of exercises included in practical

Handout 1: a new programme to support fatigue management in RA

You might be wondering what to expect over the next 12 weeks so here is some information that may help:

Session dates and times

The first four sessions will be held once a week on consecutive weeks. Every session will start at 11.30am and will last for 2 hours:

Session 1	Thursday 18 th September
Session 2	Thursday 25 th September
Session 3	Thursday 2 nd October
Session 4	Thursday 9 th October

The next two sessions will be held every other week:

Session 5	Thursday 23 rd October
Session 6	Thursday 6 th November

The last session will be four weeks after session 6:

Session 7	Thursday 4 th December
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What does the course involve?

Aims of the course:

- To introduce you to skills and ways that might help you manage your RA fatigue and carry out day-to-day physical activities with more confidence
- To encourage you to develop further knowledge of the benefits of physical activity and how it might help improve the impact of fatigue
- To assist you with planning your physical activity and setting goals so that you feel more motivated to continue with your physical activity in the long term

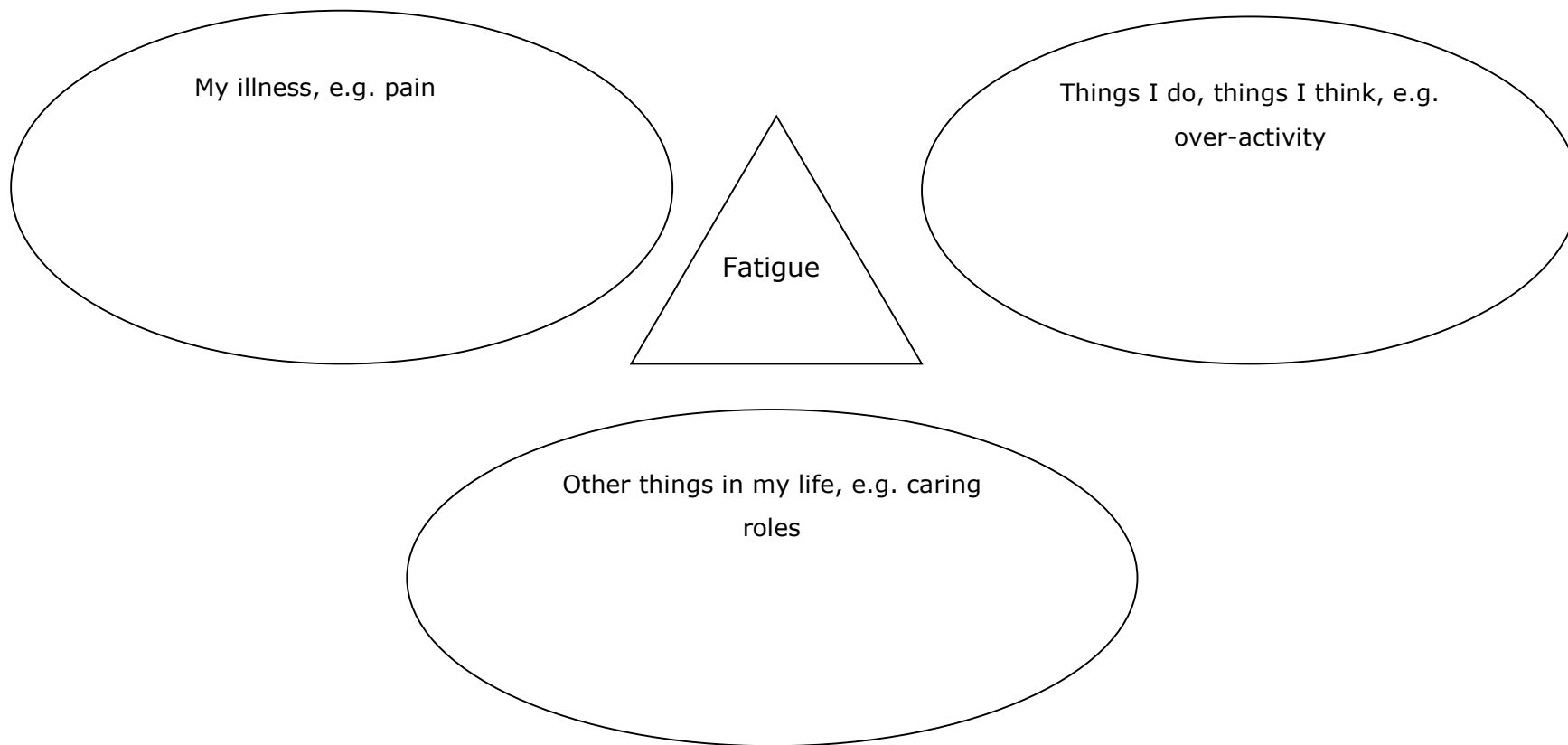
The course will look at how someone might change their physical activity in a way that will help manage fatigue. Each session will start with a group discussion session that will focus around a particular topic. This will be guided by the course tutor and will last up to 60 minutes.

The discussion session will be followed by a 15 minute break for tea/coffee and a snack if you wish. After the break you will have an opportunity to have a go at some simple physical activity of your choice.

The course involves taking part in the sessions and also trying out some of the different ideas about managing your fatigue and physical activity in between sessions. It is hoped that this will help people work out ways to plan their physical activity so that they can cope with their fatigue and improve their quality of life.

Handout 2: What causes fatigue?

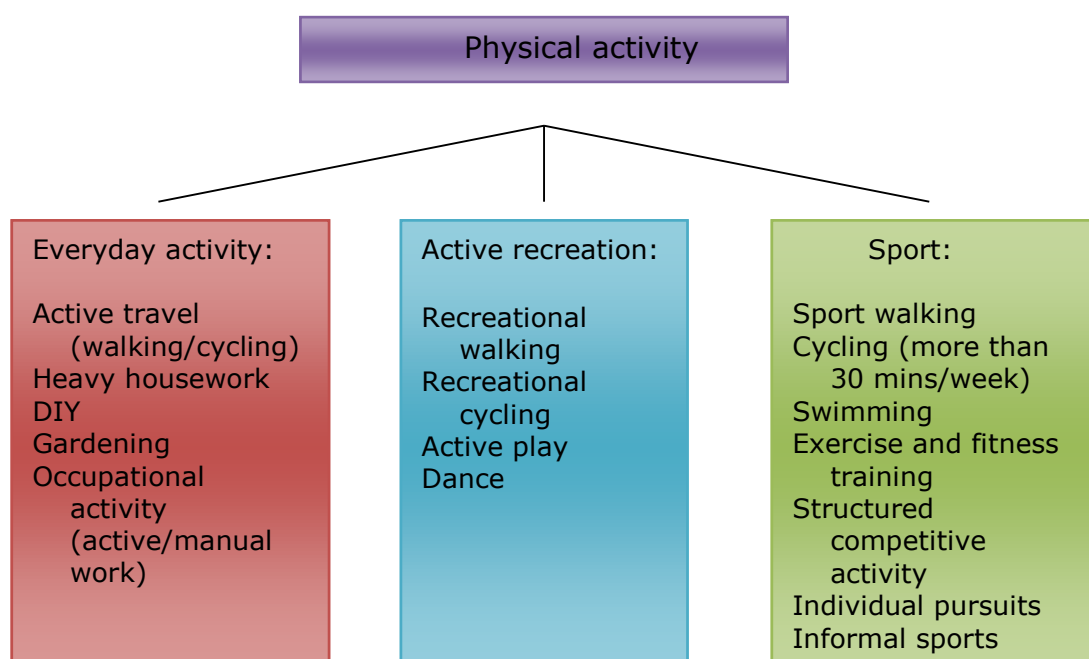
Think about what makes your fatigue worse and how this fits in the diagram below:



Handout 3: Physical activity in rheumatoid arthritis

What is physical activity?

Physical activity can be any sort of activity that gets you moving! This might be walking or cycling, physical activity related to work, recreational activity (for example, gardening or DIY), as well as organised sports or more formal exercise.



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Benefits of physical activity

It is well known that physical activity is good for people with rheumatoid arthritis (RA), and research has shown that it can help relieve symptoms, such as pain and stiffness, and generally improve your health. As well as improving muscle strength and joint mobility, being active can help reduce anxiety, improve sleeping patterns and help you feel more in control of your day to day life. It can also help reduce the risk of other health problems.

What activity should I do?

Anything that you enjoy!

The British Society for Rheumatology and British Health Professionals in Rheumatology (BSR/BHPR) and the National Institute for Health and Care Excellence (NICE) have produced guidelines for the management of RA. These guidelines recommend physical activity/exercise to help improve muscle strength, endurance and fitness levels. If you find your balance is poor or you might be at risk of falling you should also include exercises to improve your balance.



Physical activity for fatigue

There is some evidence that RA fatigue may be helped by physical activity and research also shows that physical activity can significantly reduce fatigue in other long term health conditions. There is plenty of evidence that shows physical activity can improve muscle strength, reduce anxiety and depression and improve overall mood and well-being. All these factors can be associated with fatigue, therefore improvements in physical activity are likely to result in less impact of fatigue on your daily life.

It is a good idea to break activities up into smaller amounts if you have fatigue and to build up the amount you do very slowly.

You might want to start with a short amount of physical activity so that you don't make your symptoms worse. It is important that you start with an amount that you can manage to do every day, even on a bad day. For example, if you can only manage 5 minutes a day on a bad day start with this and do it every day. Once you can manage this baseline

amount, you can increase it by one or two minutes the following week. This is known as graded activity or exercise. We will discuss this further in session 2.

Finally, and importantly, try to limit the amount of time you spend sitting or lying down for long periods at once during waking hours. This includes sitting at work or home, watching television or driving a car. Recent research has suggested that too much sitting increases the risk of health problems such as diabetes. Take regular breaks to stand up and move around. This will also help to stop your joints getting stiff and seizing up.

Will physical activity damage my joints?

No. Research shows that physical activity will not damage your joints. All physical activity, including high intensity exercise, is safe in rheumatoid arthritis. Moreover, research shows that those who are active have the same if not better joint health than those who are not.

It is important to remember that doing any new physical activity or any activity that you haven't done for a while is likely to result in some muscle soreness during and/or for a few days afterwards. This is a normal response and will get less over time as your body gets used to the activity. As you get more experienced with your physical activity you will start to learn how your body responds and what level is right for you.

We have developed this new programme to support fatigue management in RA and this research study is looking to see if you find physical activity useful for managing your RA fatigue.





Your health professional, such as your GP or rheumatology team, should be able to help you to take part in physical activity and advise you on how you can manage physical activity as part of your daily life.



El Portil. Walking on the Beach. Sunset. Huelva. Andalusia. Spain, Creator: Tomas Fano, Source: <https://www.flickr.com/photos/tomasfano/4480795941>; Creative Commons Licence: Attribution-ShareAlike 2.0 Generic (CC BY-SA 2.0)

Handout 4a: Activity diary instructions

Instructions for Use:

-  High Energy Physical Activity (PA) - Colour Red
 -  Low Energy PA - Colour Yellow
 -  Sedentary Activity - Colour Black
 -  Rest/Chill Out Time - Colour Green
 -  Sleep - Colour Blue
-  Crash - Mark with a cross

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<u>Examples of high energy PA may be:</u>	<u>Examples of low energy PA may be:</u>
<u>Examples of sedentary activity may be:</u>	<u>Examples of rest or chill out time may be:</u>

However, whether they are low or high really depends on you and how involved you get with these activities

Handout 4b: Activity diary template

Week 1	Morning - am											Afternoon/evening - pm												
__/__/__	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11
Day 1																								
Day 2																								
Day 3																								
Day 4																								
Day 5																								
Day 6																								
Day 7																								

Week 2	Morning - am											Afternoon/evening - pm												
__/__/__	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11
Day 1																								
Day 2																								
Day 3																								
Day 4																								
Day 5																								
Day 6																								
Day 7																								

Key


High Energy PA	<input type="checkbox"/>	Low Energy PA	<input type="checkbox"/>	Sedentary time	<input type="checkbox"/>	Rest or Chill Out Time	<input type="checkbox"/>	Sleep	<input type="checkbox"/>	Crash
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Handout 5: Exercises included in the practical session


Exercise	Instructions	
Walking	<ul style="list-style-type: none"> • Walking on the treadmill <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it harder increase the time that you walk for 2. If you have reached your target time, increase the speed that you are walking at 	
Cycling	<ul style="list-style-type: none"> • Pedal using the stationary bicycle or the pedals <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it harder increase the time that you cycle for 2. If you have reached your target time, increase the resistance to make it harder 	
Step ups	<p>Level 1:</p> <ul style="list-style-type: none"> • March on the spot • Hold on to a rail for balance if you feel unsteady <p>Level 2:</p> <ul style="list-style-type: none"> • Stand in front of a step • Step up and down onto the step • Hold on if you need to • Change legs halfway through 	
Wall slides	<ul style="list-style-type: none"> • Lean back against a wall, feet shoulder width apart, feet one stride away from the wall • Slide your back down the wall until your knees are bent no more than 45 degrees • Return to standing 	

Exercise	Instructions	
Sit to stand	<ul style="list-style-type: none"> • Stand up from a chair and sit down again slowly <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it easier use a higher chair 2. To make it harder don't use your hands to push up 	
Hip out	<ul style="list-style-type: none"> • Place foot in a band • Hold onto a support • Feet shoulder width apart • Take leg out to the side then slowly return to start position <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it easier try without a band 2. To make it harder use a different colour band 3. Try with an ankle weight instead if you prefer 	
Hip back	<ul style="list-style-type: none"> • Place foot in a band • Hold onto a support • Feet shoulder width apart • Take leg out behind you then slowly return to start position <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it easier try without a band 2. To make it harder use a different colour band 3. Try with an ankle weight instead if you prefer 	

Exercise	Instructions	
Clam	<ul style="list-style-type: none"> • Lie on your side with your knees bent • Gently lift the upper knee whilst keeping hips still • Return to the starting position 	
Knee straight	<ul style="list-style-type: none"> • Sit in a chair with your knees bent • Place your foot into band in a figure of eight • Straighten knee against resistance of the band • Slowly lower to the start position <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it easier try without a band 2. To make it harder use a different coloured band 3. Try with an ankle weight instead if you prefer 	
Leg alphabet	<ul style="list-style-type: none"> • Sit on the edge of a chair • Keep your leg straight and write the alphabet with your leg <p>Progression:</p> <ul style="list-style-type: none"> • To make it harder add an ankle weight 	
Trampette	<ul style="list-style-type: none"> • Walk on the spot on the trampette, trying not to hold on to test your balance 	
Wobble cushion	<ul style="list-style-type: none"> • Test your balance on the wobble cushion • Hold on for balance as required 	

Exercise	Instructions	
<p>Push ups from a chair</p>	<ul style="list-style-type: none"> • Place your hands on the arms of a chair • Push up half way to standing, just so that your elbows are straight • Slowly lower to the start position <p>Progression:</p> <ol style="list-style-type: none"> 1. To make it easier bring your feet closer to the chair and use your legs to help push up 2. To make it harder move your feet away from the chair 	
<p>Push ups against a wall</p>	<ul style="list-style-type: none"> • Place your hands on the wall, shoulder width apart • Bend your elbows and lean into the wall. Keep your back straight • Return to the start 	

Exercise	Instructions	
Wall wash squares	<ul style="list-style-type: none">• Stand or sit in a chair• Place an exercise band under your feet and hold the other end in your hand• Draw an imaginary square on the wall in front of you <p>Progression:</p> <ol style="list-style-type: none">1. To make it easier try without a band or use a lighter resistance2. To make it harder use a stronger band or fold your band in half	 

Exercise	Instructions	
Reaching the shelf	<ul style="list-style-type: none">• Stand in front of a wall and take a step forward with one foot• Stand in the middle of your exercise band and hold the ends in each hand• Start with your arms by your side• Reach both hands up above your head as if you were reaching for a shelf• Reach as high as you can, then slowly return to the start <p>Progression:</p> <ul style="list-style-type: none">• To make it easier reach without a band or use a lighter resistance• To make it harder use a stronger resistance	 A photograph showing a person from behind, standing in a room with a light-colored wall. The person is wearing a white t-shirt and dark shorts. They are holding a green resistance band with both hands, reaching their arms straight up towards a horizontal metal bar or shelf mounted on the wall. The band is taut, indicating resistance.

Appendix N2: Session 2 lesson plan

Session 2: Graded exercise and goal setting

25/09/14	11.30-12.30	FRAPA Education 2	VS	RNHRD
25/09/14	12.45-1.30	FRAPA Practical 2	VS	RNHRD

Aims

To review activity diaries from session 1

To introduce participants to:

- ♦ Activity analysis
- ♦ Balancing activity and rest for energy management
- ♦ The principles of graded exercise therapy

Objectives

The participant should be able to:

1. Analyse their activity diaries and recognise patterns, e.g. boom and bust
2. Recognise how balancing activity and rest, and modifying activity could affect their own fatigue and energy levels
3. Understand how to modify their individual physical activity using a graded approach
4. Set a baseline physical activity specific to them that they can do on at least five days a week

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Handouts – Balancing activity and rest, GET

Aims – practical session

To introduce participants to:

- ♦ Goal setting
- ♦ Self-monitoring exertion using Borg scale
- ♦ Choosing their own exercises

Objectives

The participant should be able to:

3. Identify an individual physical activity goal
4. Make a plan for implementing the specified goal including identifying and problem solving potential barriers and assessing optimism for carrying out the plan
5. Use Borg scale for monitoring their own exertion
6. Select exercises to try out within the practical session

Equipment

- ♦ Gym equipment
- ♦ Handout for goal setting
- ♦ Handout for Borg scale

SESSION PLAN

DISCUSSION SESSION

1. Activity analysis

Review activity diaries:

Ask participants to share diaries if they are happy to do so, and to talk through what they see.

- Discuss experiences of filling in the diary
- Can you see any patterns to your week?
- Are you doing more/less physical activity than you thought?
- What is your sleep pattern?
- How much rest are you getting?

2. Energy management: balancing activity and rest (GET Step 1) (20)

Analyse their activity diaries and recognise patterns, e.g. boom and bust

Recognise how balancing activity and rest, and modifying activity could affect their own fatigue and energy levels

Introduce over-/under-activity cycle.

Draw this on the board.

- Do you recognise cycle of over-/under-activity?

Discuss how 'boom and bust' can cause gradual decline in fitness.

- Draw boom and bust wave on flipchart and illustrate downward fitness level

Look at your activity diary again:

- Is there a 'boom and bust' pattern?
- What can you do to change this pattern?

Introduce the idea of a graded approach to changing physical activity.

- Has anyone come across graded exercise or graded activity before?

Step 1 – stabilise activity by balancing activity and rest

Balancing activity

- What does balancing activity/pacing mean to you?

Highlight that balancing activity helps to stabilise the pattern. Note that from this point it is then possible to start to increase physical activity:

- Re-draw activity wave to show how someone might be able to increase fitness through balancing activity and rest.

Balancing activities, or pacing, is not easy to apply - barriers/challenges to implementing should be discussed:

- What are the challenges when trying to balance activities and rest? (E.g. too much to do, need to finish task etc)

Acknowledge that the high of a peak during 'boom' activity, where someone might be feeling really good, can be hard to give up, even if you know the sacrifice is how terrible you feel during the 'low' of a bust. Also note that before the peak of the boom activity, you have a choice – try to recognise this and make a decision to either a) carry on and be prepared for the low, or b) stop the activity and try to limit the subsequent low.

3. Graded activity/exercise progression

Understand how to modify their individual physical activity using a graded approach
Set a baseline physical activity specific to them that they can do on 5-7 days a week

Step 2 – Set a goal, and establish a baseline for the chosen PA

- What is a goal?
- Think of a physical activity that you would like to work on
- This will be discussed individually during the practical session
- Discuss SMART goal setting

Think about chosen goal.

Establish frequency of activity, and gradually build up to target (e.g. 5/6 days out of 7)

Discuss national guidelines:

- The Department of Health has outlined recommended levels of activity for adults
- Does anyone know what the recommended amount of PA is for adults?

Write up suggestions on the board and fill in answers:

How long?	30 minutes of moderate intensity activity. Note: This can be all in one go or broken up into short bouts of throughout the day
How often?	At least 5 days a week, if not all
What is moderate intensity?	You should get warmer and breathe harder during the activity Your heart will beat faster, but you should still be able to carry on a conversation
What should I do?	Anything you like (see 'what is physical activity' in last week's handout) Examples might include walking, dancing, gardening, swimming Try and choose something you enjoy and that you can fit into your daily routine

This is a recommended amount, but key is to build up to this SLOWLY. Start with light to moderate intensity and gradually build up to target duration before increasing intensity to moderate. Better to under do it at the start than over-do it and make symptoms worse.

Emphasise that doing something is better than not doing any physical activity. 30 minutes is a guideline but don't be put off if it seems unachievable as working towards it is a good start. Also, it is not a limit so if someone is there already they can do more than 30 mins/day – don't just get to 30 and stop.

Step 3 – Gradually build up the duration of PA. Stabilise at new level before next step

Draw graded PA curve on the activity/time graph to show stepped approach

Step 4 – Gradually increase intensity of chosen PA

Once you have achieved desired duration, try increasing intensity

Handouts – A graded approach to PA, Graded activity planner

4. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting

Identify an individual physical activity goal

Make a plan for implementing the specified goal including identifying and problem solving potential barriers and assessing optimism for carrying out the plan

Encourage each person to choose something that is important to them and that they will enjoy

Note: long-term goal may not be achieved within the 12 weeks, but should be able to make significant progress towards it in this time.

- Make sure the goal is important to you
- Break down into weekly targets
- Rate how confident you are that you will complete the short-term goal

Confidence needs to be 7 or above – if less then explore which bits they are confident about, then which bit is keeping it below 7. Try to problem solve. If it

appears that the goal is unrealistic, rethink and change the target to something more realistic

- Task: write down your goal before next session
- Think back to GET: you may want to use the planner to break down your goal into graded steps/weekly targets

Handout – goal setting

2. Borg scale

Use Borg scale for monitoring their own exertion
--

Give out Borg scale cards

Explain the scale and how it can help to monitor level of exertion when changing intensity or duration of physical activity

- Widely used in sports and health
- Rating of perceived exertion
- 15 points from 6 (no exertion at all) to 20 (maximal exertion)
- Use to monitor progression
- If you find you increase more than 2-3 points when you progress PA, you have probably made too big a change. Think about dropping back a level to avoid making symptoms worse

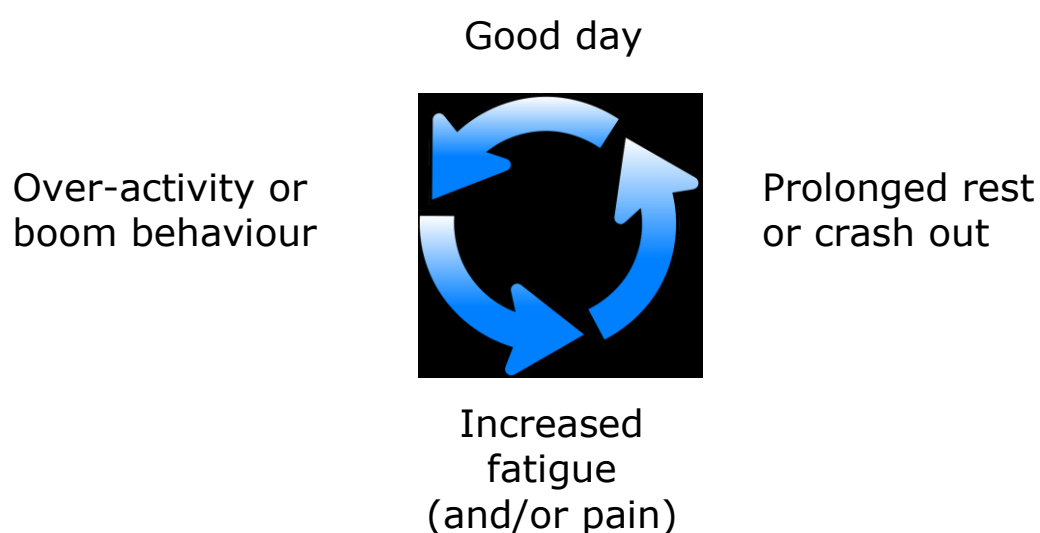
3. Try out selected exercises

Select exercises to try out within the practical session
--

- Have a go at any of the exercises that were demonstrated last time, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes
- **You can leave when you have achieved your goal for this session. DO NOT BE TEMPTED TO CARRY ON FOR THE WHOLE TIME, even if others are still exercising**

Handout 6: Balancing activities and rest

Many people with RA find that energy levels can vary from day to day, or even within the same day. This change in energy often means that people try to get as much done as possible on a better day, but then have to spend several days recovering. This cycle is sometimes referred to as boom and bust:



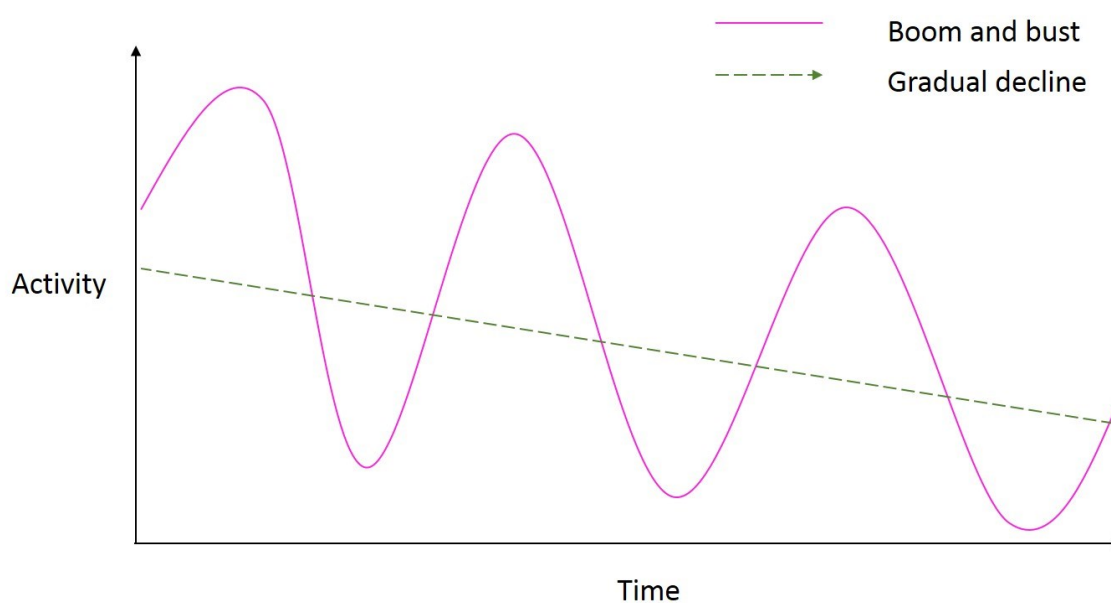
People often experience lower amounts of energy and/or pain during or after certain daily activities, such as walking or gardening. Sometimes people link their fatigue or pain with these activities, but usually it is the *intensity* and/or *duration* that the activity is performed at rather than the actual task.

If, on a good day, you continue with an activity until you have to stop due to fatigue or pain this leads to over-doing it and feeling much worse later or the next day(s). This in turn leads to prolonged fatigue, frustration, pain and anxiety which forces longer periods of rest. Overall, this leads to a less active lifestyle. Also, you may start to avoid certain activities for fear that they will make fatigue or pain worse or do damage to your joints.

Negative consequences of boom and bust:

- Prolonged set backs or crashes with fatigue
- Gradual decline in fitness and stamina, stiffer joints and weaker muscles as a result of reduced activity over several days
- Easier to overdo activities next time due to less fitness
- Fatigue controls what you do, not you!
- Feelings of frustration and failure

Boom and bust pattern:

**How can I progress my physical activity without making my symptoms worse?**

By balancing activity and rest you can start to break the cycle of over- and under-activity. It is about doing everyday activities without making your fatigue worse. Everyone should pace their daily activities, but it is particularly useful if you have RA to make the best use of your lower energy stores.

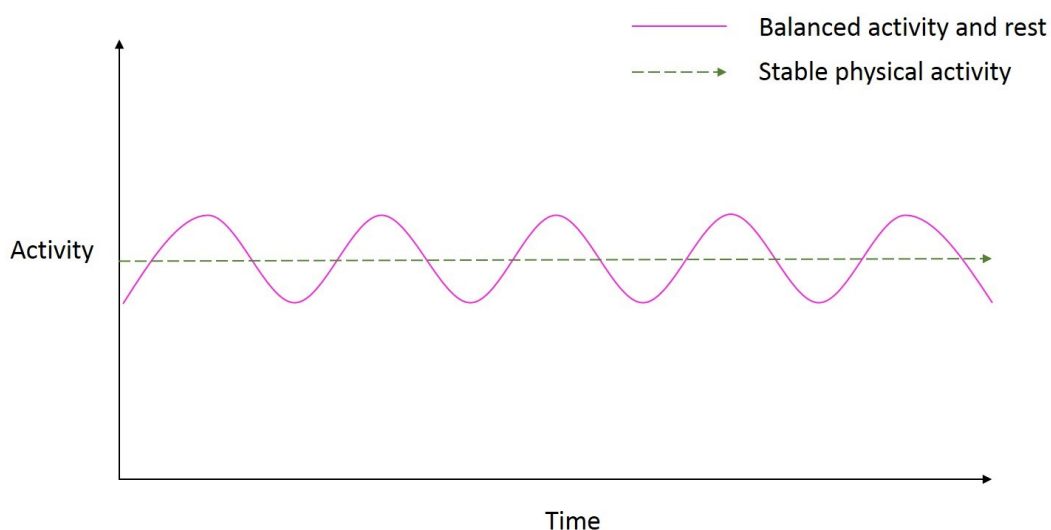
If you are able to balance your activities more effectively, over time you will become fitter. If you are fitter you can do more without making your fatigue worse. This puts you in control of your fatigue rather than fatigue controlling you.

During this programme you will develop an activity plan to help you modify your physical activity levels. You have already made a start by keeping an activity diary which allows you to identify and analyse patterns in your current activity.

Look at your activity diary and think about the following:

- Is there a 'boom and bust' pattern?
- Does there seem to be a particular activity that triggers your symptoms?
- Are you doing more/less physical activity than you thought?
- What is your sleep pattern?
- How much rest are you getting?

Balanced activity and rest:

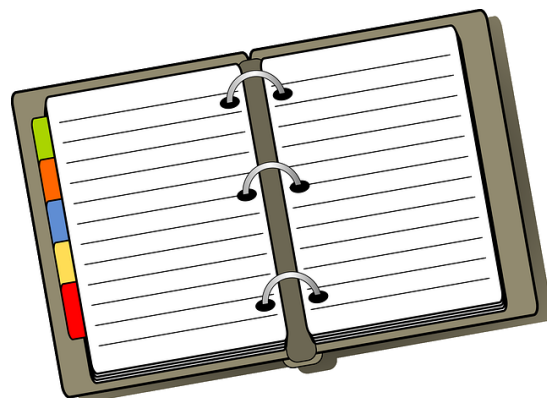


Think about how you can:

- Spread activities more evenly – alternate high energy activities with low energy or rest
- Do shorter bouts of activity interspersed with short periods of rest. Think about how long it takes for you to feel tired and stop before this happens
- You might also want to try doing an activity at a lower intensity that does not increase your symptoms

Modifying your physical activity is not easy and requires planning and prioritising:

- Plan how to do activities through the week and days
- Think about what activities you might need to do later in the day or week and adjust your activity to accommodate this

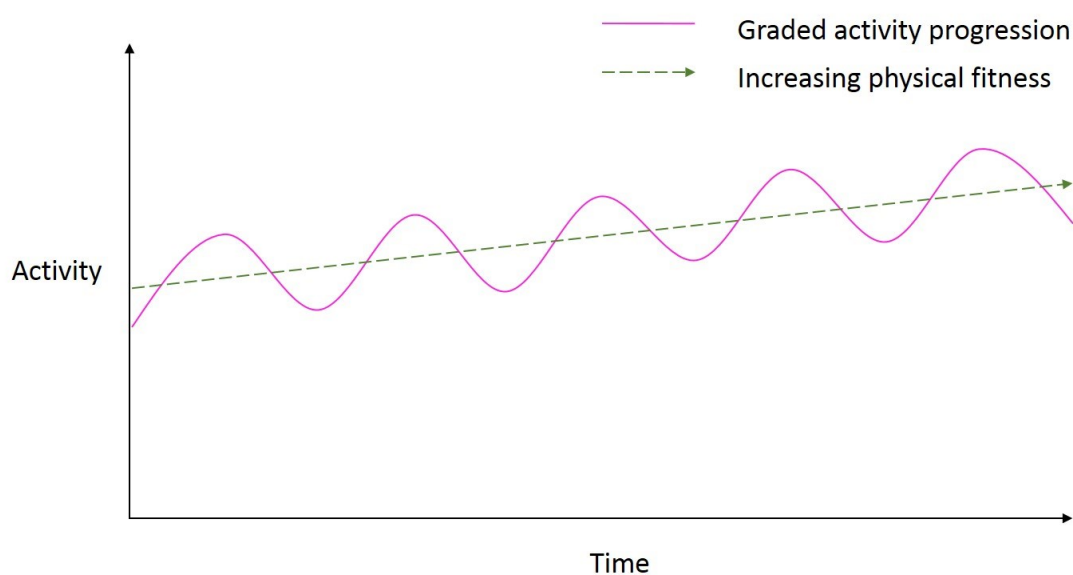


Handout 7a: Using a graded approach to modify physical activity

What is graded activity/exercise?

A graded activity or exercise approach uses physical activity to help you feel less tired and have more control over your symptoms. This is achieved by gently introducing low level physical activity into your day, or changing the activity you already do, without making your symptoms worse. Over time, it is also possible to improve your physical fitness using this approach.

Graded activity approach:



Graded activity is a step by step approach and can be applied to any activity.

Step 1 – stabilise activity by balancing activity and rest

See session 2, handout 6: Balancing activities and rest

Step 2 – establish a baseline for your chosen physical activity

Once you have a more consistent routine of balancing your current physical activity and rest you can choose an activity to increase or add in to improve your stamina and fitness.

The starting point, or baseline, for the chosen activity should be something that you can do *on a good day or a bad day*, **without** making your symptoms worse. Start by setting your time limit as what you can do on a bad day:

	Bad day	Good day	Baseline time limit
Walking	2 minutes	10 minutes	2 minutes
Housework	5 minutes	20 minutes	5 minutes
Gardening	10 minutes	30 minutes	10 minutes

Aim to build up to your target frequency gradually (e.g. start on 3 days a week and build up to 5/6 days out of 7). Start with a simple low intensity activity, e.g. slow walking or low level household chores.

The Department of Health has outlined recommended levels of activity for adults:

How long?	30 minutes of moderate intensity activity This can be all in one go or broken up into short bouts throughout the day
How often?	At least 5 days a week, if not all
What is moderate intensity?	You should get warmer and breathe harder during the activity Your heart will beat faster, but you should still be able to carry on a conversation
What should I do?	Anything you like (see session 1, handout 3: What is physical activity?) Examples might include walking, dancing, gardening, swimming Try and choose something you enjoy and that you can fit into your daily routine

Step 3 – gradually build up the duration of physical activity

When you are comfortable with your baseline activity, and can perform this on a good or a bad day, 5/6 days a week, then you can start to increase the duration of the activity.

- Aim to increase by 20%
- Stabilise your activity at this new level before you increase it again
- Keep the intensity at a low or comfortable level until you reach your target duration

Step 4 – progress the intensity of your chosen physical activity

Once you have achieved the desired duration, you can start to progress the intensity. This refers to how hard you are working during physical activity. Up until now you have been working at a comfortable low intensity. By increasing your effort to a moderate intensity you will be able to continue improving your physical stamina and fitness.

The intensity can be increased in several ways, for example, if your chosen activity is walking:

- Walk faster
- Change the route to include hill walking

If you want to progress the intensity of your strengthening exercise:

- Increase the number of repetitions of each exercise
- Increase the weight you are using, or change the colour of the exercise band

Tip: Start with small changes and stabilise your activity at the new level before you increase it any further.

Remember: Progress at your own pace, taking care not to make your symptoms worse. This will help to avoid a setback with your physical activity. Use the planner below to plan your graded activity progression.

Handout 7b: Graded activity planner

Fill in the physical activity goal for each step.
Record the date you start and complete each goal.

		Date started	Date completed
	Step 10		
	Step 9		
	Step 8		
	Step 7		
	Step 6		
	Step 5		
	Step 4		
	Step 3		
	Step 2		
	Step 1		
Baseline	<i>Example: walk for 10 minutes on 5 days of the week</i>		

Handout 8: Goal setting

It is easier to be more active if you have a goal for your physical activity. The goal that you choose will be individual to you. You may have a long-term goal in mind, but it is usually easier to start with a smaller goal so that you don't feel daunted or over-whelmed. For example, you may want to walk to work eventually. You might start off by getting off the bus one stop early, or parking slightly further away and walking the last bit. Start with small distances and slowly build up to reach your target.

Tips for setting a goal:

1. Choose something that is important to you and that you will enjoy
2. Set goals that are challenging but realistic
3. Break down the activity into smaller short-term goals
4. Make an action plan of what you want to achieve
5. Write down your goal, stick it somewhere so you will be reminded regularly, share it with family and/or friends, get support and encouragement
6. Reward yourself when you succeed!

Goals should be 'SMART':

- Specific Make your goal clear
- Measurable How will you know if you have achieved your goal?
- Achievable How likely are you to be successful?
- Realistic Do you have the resources to make this a reality?
- Time limited When do you want to achieve your goal?

Here are some things to think about when making your plan:

- What do I need to do differently to achieve the goal (e.g. walk)?
- When do I need to do it (e.g. before lunch)?
- Where will I do it (e.g. at work)?
- How much will I do/how long for (e.g. to the end of the road/10 mins)?
- How often do I need to do it (e.g. on three days)?
- Who will I do it with (e.g. with a friend)?

Long-term goal:

Short-term target:

This week I will...

..... (what)

..... (when)

..... (where)

..... (how much)

..... (how many)

How confident are you that you can do this goal?

Not at all confident	0	1	2	3	4	5	6	7	8	9	10	Very confident
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You might want to use the chart below to keep a diary of your achievements:

Day	What I did	How I felt
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Handout 9: Borg scale

Rating of perceived exertion	Exertion
6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Appendix N3: Session 3 lesson plan

Session 3: Sleep and rest, stress and relaxation

02/10/14	11.30-12.30	FRAPA Education 3	VS	RNHRD
02/10/14	12.45-1.30	FRAPA Practical 3	VS	RNHRD

Aims

To review progress

To introduce participants to:

- ♦ The relationship between sleep, fatigue and PA
- ♦ The effects of stress on fatigue and PA
- ♦ Techniques for rest and relaxation

Objectives

The participant should be able to:

1. Identify factors that might affect sleep
2. Understand the importance of quality versus quantity of sleep
3. Describe stress and its physical and emotional consequences
4. Recognise potential effects of long term stress on coping with fatigue and PA
5. Identify sources of relaxation techniques to try at home

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Handouts – Stress and relaxation, relaxation CD, sleep and rest

Aims – practical session

To review individual goals

To continue working towards own PA goal

Objectives

The participant should be able to:

7. Select exercises to try out
8. Progress exercises when appropriate

Equipment

- ♦ Gym equipment
- ♦ Pillows and mats or chairs for relaxation session

SESSION PLAN

DISCUSSION SESSION

1. Review current progress

Review activity diaries

Review progress with baseline PA

Ask participants if they are happy to share experiences so far.

- Discuss experiences of setting a goal
- How are you getting on with balancing activity and rest?

2. Sleep and rest

Identify factors that might affect sleep
--

Understand the importance of quality versus quantity of sleep

Introduce sleep topic:

Sleep is often a problem for people with RA. People also report that fatigue is not relieved by sleep or rest.

- Does anyone experience difficulty with sleeping?
- What problems do you experience?

List these on the board. Problems might include: difficulty falling asleep, waking in the night, needing to nap in the day.

- What do you think affects your sleep? What stops you getting to sleep?
- What do you think is 'normal' for sleep?

There is no set number of hours, as this varies from person to person. Instead of quantity it is the *quality of sleep* that is key. Most importantly, we need to have a consistent pattern to our sleep otherwise our body struggles to adjust.

- Has anyone ever had jet lag? Or worked night shifts? This is an example of how a disturbed pattern can affect our body
- Any tips for improving sleep?
- See handout for suggestions

Handout – sleep and rest

3. Stress and anxiety

Describe stress and its physical and emotional consequences

Recognise potential effects of long term stress on coping with fatigue and PA

Identify sources of relaxation techniques to try at home
--

- How would you describe stress?
- What might cause stress?
- What effect might it have on someone?

Write responses on the board – try to group into emotional and physical consequences. Prompts may include:

- What about effect on someone's physical activity? (less motivated, fear of failure)
- Or someone's mental activity? (e.g. hard to concentrate, hard to make decisions, forgetfulness, irritability etc – these may already been compromised by fatigue)
- Or health (headaches, nausea, etc)?

Discuss what might happen if a person experiences stress over a long period of time (e.g. prolonged tension, poor sleep etc)

- What happens to their ability to cope?
- What influence does or might this have on their PA?
- What influence might PA have on stress and someone's ability to cope?
- Think about other things that might make a person anxious, fearful, frustrated...

This may include past experiences, beliefs, fear of damage, external demands +/- support systems. Think about the following (re-emphasise don't need to share unless happy to do so)

- Might these influence fatigue and/or PA?
- Any useful stress management strategies you wish to share?

It can be helpful to break the cycle of stress and anxiety by trying to manage some of the effects of stress. For example, find ways to reduce muscle tension, seeking support from family and friends, try structured relaxation exercises. PA/exercise may also help to reduce stress/improve mood, BUT must be balanced with adequate sleep and rest especially when trying to increase fitness

Task:

- Have a listen to the relaxation CD and try some of the techniques during the week
- Look at the handout about stress and think about strategies you might use to help you when you feel stressed

There are also several online tools/apps available, such as Andrew Johnson.. does anyone know of any others?

Handout: Stress and relaxation, **Relaxation CD (RAFT)**

4. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting

Review individual goals and discuss progression as appropriate

2. Try out selected exercises

- Have a go at your chosen exercises, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes

3. Grounding exercise

Grounding exercise – from RAFT

Five minute relaxation exercise based on mindfulness - See RAFT handout

Handout 10: Sleep and rest

Many people with RA have difficulty sleeping. This can contribute to existing symptoms that are associated with this condition, such as fatigue and poor concentration. Other people feel that they need to sleep for longer than usual. Often sleep is not refreshing and does not relieve symptoms of fatigue, leaving people feeling continually exhausted.

What is normal?

The amount of sleep we need will vary from person to person, and will change as we get older. What is most important is the quality of our sleep. During the night we frequently move between different phases of sleep: rapid eye movement sleep, light sleep and deep sleep.

What causes disturbed sleep?

There are many reasons why someone might have difficulty sleeping. Although this may be partly caused by having RA, there are many other reasons why sleep might be disturbed. Often these other factors can be changed fairly easily to improve your sleep.

Sleep problems may take different forms:

- Problems getting to sleep
- Waking in the night
- Waking early and can't get back to sleep
- Despite sleeping you still feel like you haven't slept well

Often these problems mean that you want to sleep longer in the morning, go to bed earlier or sleep during the day. Over-sleeping can also increase fatigue, worsen concentration and make you feel less motivated and low in mood.

Physical activity and sleep

There are strong links between exercise and good sleep. If you are less active during the day this can make sleeping more difficult. You may well notice that as you increase your physical activity during this course, your sleep will also improve.

Exercise taken late in the evening tends to liven people up which can make it difficult to get to sleep. Some people, however, are able to do gentle exercise in the evening without disrupting their sleep.

Emotion and sleep

Many people find that they lie awake worrying at night. If you find you can't switch off it might be better to take time to think things through sitting in a chair before going to bed. You could make it part of your wind-down routine. Try using a thought diary to write down your concerns if you find it helpful. If possible, try finding time earlier in the day to think about these worries. Try to associate going to bed with going to sleep.

If you wake up early and can't get back to sleep it might be better to get up. If you still feel weary take rest in a chair instead.

Sleeping environment

Try to get the conditions right in your bedroom to suit your needs.

- The temperature of your room can have a big influence on the quality of your sleep. It is hard to sleep if the room is too hot or too cold.
- Make sure you have a comfortable mattress and pillow.
- Consider using earplugs if your bedroom is noisy. Some people find it easier to sleep with a little background noise.
- Try to minimise artificial light in your bedroom, such as street lamps or alarm clocks.

Daytime sleep

A brief rest can be helpful if it is consistent, but a long sleep in the day can make it hard to get to sleep at night.

- Try to gradually reduce the duration of your daytime sleep
- Use an alarm clock to wake you so that you can reduce your sleep time
- Consider breaking up intense activity with short rests, for example take two 15 minute breaks to rest rather than one 30 minute rest.

If you are used to sleeping in the day or keeping irregular sleeping hours remember it will take time for your body to adjust to a new routine. You may feel more tired initially, but try not to go to bed earlier. Make small, gradual changes to allow your body to adapt.

How can I improve my sleep?

Having a regular sleep pattern is the most important rule. Here are some general tips for improving your sleep:

- Establish a routine bedtime and waking time
- Gradually reduce daytime sleep and introduce more rest times
- Have a wind-down routine in the evening: don't take exercise close to bedtime, avoid caffeinated drinks or other stimulants
- Associate bed with sleep: avoid watching TV or reading in bed, checking emails or surfing the internet, eating
- If you do wake up and can't get back to sleep avoid staying in bed for long periods – get up and try to rest somewhere else instead. Try and maintain a low level of alertness: keep warm, don't eat or drink, don't focus your attention on anything. Only go back to bed when you have a good chance of falling asleep again

Handout 11: Stress

As well as the effects of the diseases process itself, the fatigue you experience with your RA can also be influenced by stress. In particular, it can affect your ability to cope with your fatigue.

Stress can have an effect on:

- Your emotions, e.g. low self-esteem, anxiety
- Your mental activity, e.g. difficulty concentrating, forgetfulness, difficulty making decisions
- Your health, e.g. headaches, nausea, high blood pressure
- Your physical reactions, e.g. muscle tension, restlessness, increased heart rate
- Your behaviour, e.g. impatience, excessive eating or loss of appetite, disturbed sleep, excessive drinking or smoking
- Your work, e.g. poor productivity, low job satisfaction

These effects can all contribute to negative feelings such as frustration, anxiety or fear which may make you feel less able to cope with your fatigue.

Stress and physical activity

Keeping active is not only helpful for your physical health. It can also help improve your mood and overall sense of well-being.

Often, however, past experiences or beliefs about capability or the consequences of physical activity can have a negative effect on your ability to cope. These beliefs can lead people to avoid physical activity out of fear of damage to joints or fear of failure. It is important to remember that physical activity is safe and beneficial for people with RA. If you balance activities with rest you will be able to enjoy a more active lifestyle and be able to manage your symptoms more easily.

Stress management strategies

Here are some examples of strategies that might help you to manage stress and cope with your symptoms:

- Recognise negative thoughts and challenge them – are they reasonable or magnified?
- Remain positive and acknowledge your successes
- If you feel overwhelmed by a task trying breaking it down into smaller chunks, set goals, accept help
- Use structured rest or relaxation that works for you
- Seek support from family or friends

Handout 12: Rest and relaxation

There are many different techniques that encourage rest and promote relaxation. The important thing is to find something that works for you. The aim of relaxation is to become more aware of changes in your body as a result of tension or stress, and to enable you to be more in control of your symptoms. Although you may try watching TV or going for a walk to help you relax, it is possible that you will remain tense during these activities. Therefore they may not help you to switch off and fully unwind.

Learning to relax is a skill and requires regular practice before it becomes helpful or you feel comfortable and confident with what you are doing.

Types of relaxation

There are many different types of relaxation. The CD provided gives you a selection of five. The first four last for approx. 20 minutes each, and the last one is five minutes. **Remember: do not listen to the CD whilst driving.**

Find a quiet, warm room where you can sit comfortably or lie down. Keep distractions to a minimum, turn off your mobile phone and ask for minimal interruption (e.g. ask family/friends that you are not disturbed for 20 minutes).

Try one technique at a time. When you find one you feel comfortable with practice it every day.

Remember it can take time to feel comfortable with relaxation at the start, but persevere as it will get easier with time!

Appendix N4: Session 4 lesson plan

Session 4: Self-monitoring PA and maintaining a healthy diet

09/10/14	11.30-12.30	FRAPA Education 4	VS	RNHRD
09/10/14	12.45-1.30	FRAPA Practical 4	VS	RNHRD

Aims

To review and discuss relaxation techniques

To introduce participants to:

- ♦ Self-monitoring of PA
- ♦ Basic principles of healthy diet and weight management in relation to PA

Objectives

The participant should be able to:

1. Be aware of a variety of methods for monitoring PA, e.g. pedometers, PA diary, apps
2. Describe components of a healthy diet
3. Recognise the relationship between diet and PA

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Handouts - self-monitoring, Diet and PA

Aims – practical session

To review individual goals

To continue working towards own PA goal

Objectives

The participant should be able to:

1. Select exercises to try out
2. Progress exercises when appropriate

Equipment

- ♦ Gym equipment

SESSION PLAN

DISCUSSION SESSION

1. Review previous session

Ask how participants got on with trying out relaxation techniques.

- What effect has this had on your activity diaries?

2. Self-monitoring of PA

Be aware of a variety of methods for monitoring PA, e.g. pedometers, PA diary, apps

How will you know if you have achieved your goal?

How will you know you have made progress?

What tools could you use to monitor this?

Discuss the following:

- Activity diaries
- Pedometers
- Apps – ask the group for suggestions, or give examples (the walk, my fitness pal (includes nutrition info) – see table below)

Tools to help prompt PA

Some people may find it difficult to remember to do their chosen PA. Using prompts can act as a reminder to do PA

- What other tools can be used for this?
- E.g. schedule as a meeting in your diary, use post-it note reminders or alarms, at work use reminders to get up from your desk or start your PA goal, Apps (e.g. workrave)

The Walk	Fitness tracker app created with the NHS and Department of Health. A bomb explodes in Inverness station, and you're given a package that could save the world. To stay alive, you'll need to walk the length of the UK! This is essentially a pedometer, but the story adds an element of challenge and adventure!
My fitness pal	This is more about monitoring your diet, but it also calculates calories burned by exercise. It is a free online food diary and calorie counter with large food database.
Catch my pain	Pain diary app allowing you to keep a diary of your pain symptoms. Additional add-on features allowing you to track stress and fatigue can be purchased.
Track and share	This app is a self-management diary to track and share your health symptoms, life goals, mood, exercise and

	habits and can be used as an action planner. The Lite version is free. There is a charge for the full version
Track and react	This tracker has been designed specifically to track the impact of your daily activities on your arthritis symptoms. Track your nutrition, fitness, sleep, medication and mood and compare it to your arthritis symptoms in the Arthritis Impact graph.

Handout – monitoring physical activity, pedometers (if anyone wants to try one)

3. Healthy eating and PA

Describe components of a healthy diet
Recognise the relationship between diet and PA

General advice for healthy eating:

- What is the link between diet and PA?
- Does this affect fatigue?

Diet and PA affect weight but also energy levels

Important to balance calories consumed with those burned through PA.

Use of a food diary can help to see if you need to make changes in your diet

- Any tips for keeping a healthy weight? (E.g. change crisps/chocolate bar for a piece of fruit, cut out dessert, reduce alcohol intake)
- Diet and fatigue – best advice is a healthy, balanced diet
- Eating frequency, weight and health – no association
- Research into diet and cancer-related fatigue in breast cancer survivors suggests a lower intake of calories from fat and a higher intake of fibre, whole grains and vegetables have been related to less fatigue
- Breakfast boosts your energy
- Keep hydrated – plenty of water and reduce alcohol intake (hydration increases metabolism)
- Make sure you eat the right amount for your activity level.

Look at NHS choices website – tiredness and fatigue – the energy diet

Handout – healthy diet

4. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting

Review individual goals and discuss progression as appropriate

2. Try out selected exercises

- Have a go at your chosen exercises, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes
- **You can leave when you have achieved your goal for this session. DO NOT BE TEMPTED TO CARRY ON FOR THE WHOLE TIME, even if others are still exercising**

Handout 13: Monitoring your physical activity

Ideas for monitoring your progress

- Keep a diary to record your physical activity. You can use your activity diary for this if you like, or keep a simple physical activity diary like the one below. Make a note of what you did and how you felt.

Day	Physical activity	How did I feel?
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

- Pedometers can be useful for setting physical activity goals and monitoring your progress. Record how many steps you do each day. Aim to match or increase your step count to maintain or increase your physical activity.

- If you have a smartphone or similar technology, there are several free apps available for monitoring physical activity and diet alongside your symptoms. The table shows a few examples, but these are by no means the only ones. Have a look and find something that works for you.

Name	Description
The Walk	Fitness tracker app created with the NHS and Department of Health. A bomb explodes in Inverness station, and you're given a package that could save the world. To stay alive, you'll need to walk the length of the UK! This is essentially a pedometer, but the story adds an element of challenge and adventure!
My fitness pal	This is more about monitoring your diet, but it also calculates calories burned by exercise. It is a free online food diary and calorie counter with large food database.
Catch my pain	Pain diary app allowing you to keep a diary of your pain symptoms. Additional add-on features allowing you to track stress and fatigue can be purchased.
Track and react	This allows you to track the impact of your daily activities on your arthritis symptoms. Track your nutrition, fitness, sleep, medication and mood and compare it to your arthritis symptoms in the Arthritis Impact graph.

Useful tips to prompt physical activity

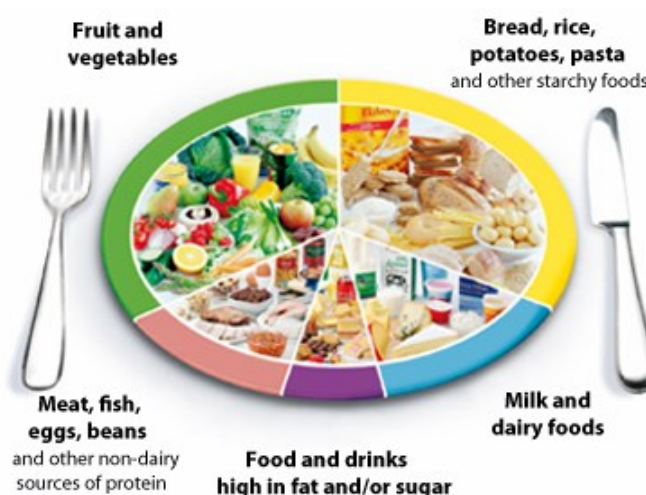
As well as monitoring your activity, it can be useful to set yourself reminders or prompts to be more active. This can help to prioritise physical activity as part of your daily routine.

- Use your diary to schedule in time for physical activity and rest
- Stick an action plan or reminder notes somewhere you will see them regularly
- Make use of technology and set alarms or reminders on your phone or computer. Free apps such as Workrave can be used to remind you to take a break.

Handout 14: Healthy eating, physical activity and fatigue

Having a healthy balanced diet alongside regular physical activity can help to keep your weight at an appropriate level. This will reduce the strain on your joints, which can also help to reduce joint pain. It can also improve your energy levels and reduce symptoms of fatigue. The best advice to achieve this is to eat a healthy, balanced diet that has limited amounts of fats and sugars.

The Eatwell Plate shows how your diet should be divided:



The eatwell plate graphic is subject to Crown copyright protection, which is covered by an Open Government Licence (<http://www.nationalarchives.gov.uk/doc/open-government-licence/version/1/open-government-licence.htm>). Source: Public Health England in association with the Welsh government, the Scottish government and the Food Standards Agency in Northern Ireland.

Other tips include:

- 5 portions of fruit or vegetables per day
- reduce alcohol intake
- drink more water
- grill food rather than fry
- choose fish or poultry as alternatives to red meat

You might find it useful to keep a food and physical activity diary for a week (see next page) to monitor what your diet consists of versus how active you are. You might also want to note how fatigued you felt.

Notice things like snacking between meals – try eating a piece of fruit instead of cake, or leave out dessert with your evening meal.

If you have concerns or difficulties with your weight discuss this with your GP.

Food, physical activity and fatigue diary

Day	Food/drink intake	Physical activity	How I felt
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

Appendix N5: Session 5 lesson plan

Session 5: Managing setbacks and external demands

23/10/14	11.30-12.30	FRAPA Education 5	VS	RNHRD
23/10/14	12.45-1.30	FRAPA Practical 5	VS	RNHRD

Aims

To review and discuss self-monitoring and healthy eating

To introduce participants to:

- ♦ Managing setbacks
- ♦ Managing PA in relation to occupation and external demands

Objectives

The participant should be able to:

1. Recognise potential setbacks and pitfalls that may prevent completion of PA goal
2. Formulate a plan to manage PA during and after a setback
3. Identify strategies for managing PA alongside external demands

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Handouts - pitfalls and setbacks, setback plan, managing external demands

Aims – practical session

To review individual goals

To continue working towards own PA goal

Objectives

The participant should be able to:

1. Select exercises to try out
2. Progress exercises when appropriate

Equipment

- ♦ Gym equipment

SESSION PLAN

DISCUSSION SESSION

1. Review previous session

Ask how participants got on with monitoring PA and any thoughts on healthy eating

Review general progress

2. Managing setbacks

Recognise potential setbacks and pitfalls that may prevent completion of PA goal

Formulate a plan to manage PA during and after a setback

- What is a setback?
- What might cause a setback? Try to identify possible triggers, if the setback is related to your RA (e.g. worsening fatigue/pain)

Write a list of potential issues that might cause fatigue to worsen, or prevent someone being able to carry out PA goal. As well as symptoms and disease factors, like pain, flares etc, encourage participants to think about other life events, priorities, emotion etc that might either trigger fatigue or create other barriers to PA.

- Can setbacks be avoided?

Explore this question further. Highlight that setbacks are normal and part of RA, but can be minimised:

- Think about looking out for signs, did you overdo PA? Are you managing to maintain your balance of PA and rest? etc...

How to manage a setback

- Remember: setback is not a failure, it does not make it pointless to keep trying
- How do you get out of a setback?

Refer back to baseline PA – remember this should be something that can be done on a good or bad day. But it may not be necessary to go back to baseline – use the graded PA planner. If someone is on step 6 when they have a flare, can they go back to 2 or 3, for example, rather than back to the bottom? It may be that they do need to go back to baseline, but then remember to step back up, don't go straight back to step 6. Work back through the steps (this may not take as long as the first time to build up, depending how long the flare/setback has lasted)

- What other steps might you use to help you out of a setback? (e.g. asking for help from friends/family, adequate rest/recovery, reducing PA (but keep moving as above))

Handout – pitfalls and setbacks, setback plan

3. Managing external demands

Identify strategies for managing PA alongside external demands

- What are the external demands on your time/energy? E.g. What other roles/responsibilities do you have?
- How can you manage these demands?

Discuss prioritising tasks and managing demands – see handout re managing energy demands and discuss.

- What is the importance of the task?
- What are your expectations of yourself for performing the task?
- What demands regularly take up lots of your energy?
- What strategies can you use to help manage this more effectively? (assertiveness – saying no, communicating needs, action planning, relaxation)

Discuss ways to include PA as part of daily life rather than as an extra thing to fit in

- How might you be able to include PA alongside these demands, particularly for those in paid employment?
- Think about options such as active travel (e.g. getting off the bus one stop early, parking further away), using the stairs for one flight, lunchtime walk with a colleague, going for a swim etc.

Handout – managing external demands

4. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting

Review individual goals and discuss progression as appropriate

2. Try out selected exercises

- Have a go at your chosen exercises, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes
- **You can leave when you have achieved your goal for this session. DO NOT BE TEMPTED TO CARRY ON FOR THE WHOLE TIME, even if others are still exercising**

Handout 15: Pitfalls and setbacks

Tips for managing setbacks

Setbacks are normal. Here are a few tips to think about when you experience a setback:

- Let people know you are having a difficult time. Be open and honest. Try to express your feelings of anger, frustration, fear to those you are close to. If you find this difficult try writing things down, talking things out loud or telling the cat!
- Focus on your achievements and resist negative thoughts. Be kind to yourself. A setback is not a failure and does not make it pointless to keep trying.
- Adapt plans – review your graded activity plan and modify your goals to accommodate the setback.
- Try using structured relaxation techniques.

Setbacks can be a learning experience. Use them to identify potential triggers and think about what you can do differently next time. This does not mean you can avoid setbacks entirely, nor should you go out of your way to do so. Instead, see if you can change anything so that you do not repeat the setback unnecessarily.

Some people find it useful to work out a setback plan. This way, you can be reminded of what you can do to manage your setback at a time when you might be feeling unwell. This may include using support from family and friends, keeping up with your physical activity but at a lower level and ensuring you balance activity with adequate rest and recovery.

Setback plan

Step	Action
1	
2	
3	
4	
5	
6	
7	
8	

Handout 16: Managing external demands

Every day we encounter demands from others (external) or ourselves (internal) to perform certain activities or tasks. Often these demands use up a lot of our energy and make it difficult to fit in other things, such as physical activity.

How can I manage these demands?

Managing demands on your time and energy often requires you to prioritise those tasks that are most important. Think about regular external demands that you encounter and ask yourself the following questions:

How important is this task?
Is this task something I enjoy?
What do I need to do to undertake this task?
What do other people expect of me?
Can any elements of this task be eliminated or delegated to someone else?

Also notice the internal demands or standards that you have for yourself in response to these external demands. These might include, for example, not wanting to let people down, finding it difficult to say no to friends or colleagues or being determined to prove you can do the job.

Here are some tips for dealing with these demands:

- Be assertive with communicating your needs – explain to family, friends or colleagues how you are feeling or why you are unable to do something and negotiate a solution if necessary. Re-arrange activities that are important to you. Remember communication is a skill and will take practice.
- Say no without excessive apology or guilt as this internal demand on your energy can cause stress and make your fatigue symptoms worse.
- Make an action plan for managing demanding tasks using your activity diary. For example, plan to break up high energy activities so that they are more manageable. Plan to intersperse activity with rest.
- Use relaxation techniques to help reduce anxiety or stress that might contribute to your fatigue. For example, schedule a rest or relaxation break after a busy meeting at work.

How can I fit physical activity into my working day?

If you are working it often feels very difficult to fit anything extra into your day, so doing more physical activity can seem impossible.

However, there are ways that you can try and incorporate your physical activity into your daily routine. For example:

- Get off the bus one stop early and walk the rest of the way
- Park a little further away from work to make your walk a little longer
- Take a walk at lunchtime
- Get out the lift one floor early and walk the last flight of stairs



London Bus route H12, Oxyman, Creative Commons Attribution-Share Alike 3.0 Unported license (https://commons.wikimedia.org/wiki/File:London_Bus_route_H12.jpg)

Appendix N6: Session 6 lesson plan

Session 6: Long term PA

06/11/14	11.30-12.30	FRAPA Education 6	VS	RNHRD
06/11/14	12.45-1.30	FRAPA Practical 6	VS	RNHRD

Aims

To review general progress

To review and discuss setback plan

To introduce participants to:

- ♦ Long term maintenance of PA

Objectives

The participant should be able to:

1. Make a plan for continuing PA long term
2. Identify useful resources to support long term adherence

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers

Aims – practical session

To review individual goals

To continue working towards own PA goal

Objectives

The participant should be able to:

1. Select exercises to try out
2. Progress exercises when appropriate

Equipment

- ♦ Gym equipment

SESSION PLAN

DISCUSSION SESSION

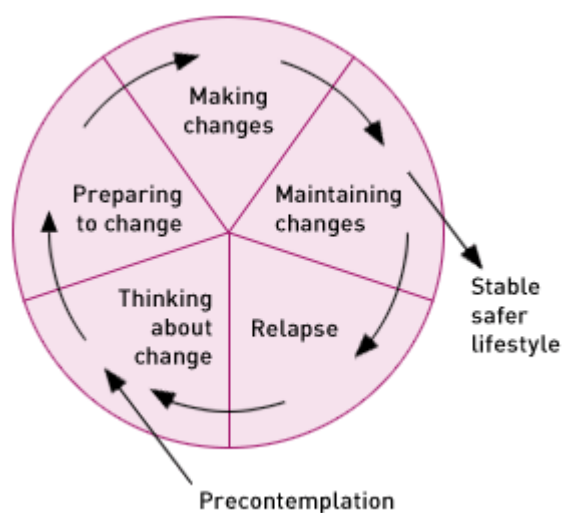
1. Review previous session

Review progress with graded PA plan
 Review setback plans
 Discuss progress with managing external demands
 Discuss any problems/barriers/concerns with programme so far

2. Long term PA

Make a plan for continuing PA long term
 Identify useful resources to support long term adherence

Discuss stages of change. Draw cycle on flipchart:



Note: Maintenance is difficult and it is common to slip into relapse, but think about how you can use skills learnt in the course to maintain changes and/or notice if you are starting to relapse. Remember also that setbacks are normal, and will not necessarily result in 'relapse'.

Discuss ideas for ongoing PA

- How will you carry on with PA long term?
- Are there any resources local to you that you can make use of?

Handout: long term plan

Task: investigate options for long term PA for next session.

Ask participants to think about options that appeal to them. These may include local classes or facilities, or might be links to websites/videos/apps etc.

Please bring details to next session, for example web address, app name, local services class timetable or contact details etc.

3. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting

Review individual goals and discuss progression as appropriate

2. Try out selected exercises

- Have a go at your chosen exercises, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes
- **You can leave when you have achieved your goal for this session. DO NOT BE TEMPTED TO CARRY ON FOR THE WHOLE TIME, even if others are still exercising**

Handout 17: Long term PA plan

<i>Resource</i>	<i>Details</i>

Appendix N7: Session 7 lesson plan

Session 7: Review

04/12/14	11.30-12.15	FRAPA Education 7	VS	RNHRD
04/12/14	12.30-1.00	FRAPA Practical 7	VS	RNHRD
04/12/14	1.00-1.30	FRAPA evaluation	FC	RNHRD

Aims

To review general progress with PA self-management

To review long term plan

Objectives

The participant should be able to:

1. Consolidate their individual PA self-management plan
2. Demonstrate a long term strategy for continuing PA post programme

Equipment

- ♦ White labels and marker pens
- ♦ Whiteboard / flipchart and markers
- ♦ Handouts - self-monitoring, pitfalls and setbacks, setback plan

Aims – practical session

To review individual goals

To continue working towards own PA goal

Objectives

The participant should be able to:

1. Select exercises to try out
2. Progress exercises when appropriate

Equipment

- ♦ Gym equipment

SESSION PLAN

DISCUSSION SESSION

1. Review previous session

Consolidate their individual PA self-management plan
Demonstrate a long term strategy for continuing PA post programme

Review long term PA plan
Review progress with PA goals as a group
Confirm ongoing long term PA strategy and long term goal
Discuss setback management
Problem solving of any ongoing barriers

2. SUMMARY/QUESTIONS (5)

TEA/COFFEE BREAK (15-20)

PRACTICAL SESSION (30-40)

1. Individual goal setting – final review

Review individual goals and discuss progression as appropriate

2. Exercise session

- Have a go at your chosen exercises, bearing in mind your personal PA goal and GET
- Work at your own pace
- When you have finished sit and rest for 10 minutes

3. Programme evaluation

Complete outcome questionnaires
Complete final programme evaluation

Handout 18: List of local resources

[Insert details of PA and exercise resources in the local area]

[Insert details of relevant local and national support groups and useful links/contacts]

Appendix O: Recruitment letter

**Royal National Hospital
for Rheumatic Diseases**
NHS Foundation Trust

Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust, Upper Borough Walls,
Bath, BA1 1RL



Rheumatology Research
Faculty of Health and Applied Sciences
Based at:
Bristol Royal Infirmary
BRISTOL BS2 8HW

[insert date]

Dear [insert name/sir/madam],

I am writing to tell you about a study being conducted at the University of the West of England. I am contacting you about this research in case you might be interested in learning more.

We are running a fatigue management course that has been designed specifically for people with rheumatoid arthritis. The course is based upon the use of physical activity as a way of managing fatigue. I have enclosed an information sheet that explains more about this study.

This course will be held in the physiotherapy department at RNHRD on the following Thursdays between 11.30am – 1.30pm (including coffee break):

18th September
25th September
2nd October
9th October
23rd October
6th November
4th December

It is important to know that this letter is not to tell you to join this study. It is your decision. Taking part is entirely voluntary. Whether or not you participate in this study will have no effect on your relationship with RNHRD as a patient.

If you are interested in learning more about this study, please review the enclosed information, complete the **enclosed reply slip**, and mail it to me in the pre-paid envelope. You can also contact the research team at 0117 342 4972 or victoria.salmon@uwe.ac.uk.

You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you about the study.

Thank you for your consideration.

Yours sincerely,

A handwritten signature in black ink on a light green background. The signature is written in a cursive style and appears to read 'Victoria Salmon'.

Victoria Salmon
MSc MSCP HCPC

University Hospitals Bristol Doctoral Research Fellow
University of the West of England

Enclosures:

Participant information sheet
Reply slip and pre-paid envelope

Appendix P: Participant information sheet (proof-of-concept study)

**Royal National Hospital
for Rheumatic Diseases**
NHS Foundation Trust

Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust, Upper Borough Walls,
Bath, BA1 1RL



Academic Rheumatology Unit
University of Bristol

Managing fatigue in rheumatoid arthritis using physical activity (FRAPA): Exploring the acceptability of a physical activity intervention

Participant information sheet

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Ask us if there is anything that you do not understand, or if you would like more information.

What is the purpose of the study?

Fatigue, or extreme and persistent tiredness, is often a big problem for people with rheumatoid arthritis (RA). Even when their RA is well controlled with medication, they can still find it difficult to manage their fatigue.

We would like to find out if a programme that helps a person to manage how physically active they are might also help them to manage their fatigue.

We do know from other research that people who have fatigue as a result of other health problems find physical activity (PA) helps to lessen the impact of fatigue. We talked to health professionals who use PA programmes to support these other patients and they said that patients find this very useful. They said that patients have less fatigue, have less fear that PA will make their symptoms worse and feel more confident with PA after attending a PA programme. They also said that patients feel that their mood improves and they are more in control of their symptoms.

We also talked to RA patients to find out what they thought about PA for managing fatigue in RA. RA patients said that they would like support and advice about how they might change their PA so that they can improve their fatigue without making their symptoms worse, and they would be interested in a programme specifically designed for managing RA fatigue.

Therefore, we have developed a new PA programme that aims to support fatigue management in RA and we would now like to invite a group of RA patients to try out this programme to see if they find it useful.

Why have I been invited to take part?

You have been invited because you have rheumatoid arthritis and have experienced extreme tiredness (fatigue) since your diagnosis.

Do I have to take part?

No, taking part is voluntary. If you decide not to take part, you do not have to give a reason, nobody will mind and it will not change the standard of care that you receive. If you are happy to let us know why you don't want to take part we would be interested to know why. If you do decide to take part we will ask you to sign a consent form, and give you a copy of this information sheet and the consent form to keep.

What if I wish to withdraw at a later stage?

You are free to withdraw at any time, and with no explanation, up until the point of publication of any data. If you have already filled in any questionnaires we would still like to use that information in our analysis as it will provide valuable information. Even if you decide that you do not wish to complete the course it is still important to us that we hear your views about the programme, therefore you will be invited to fill in a questionnaire.

What will I be asked to do if I take part?

You will be invited to attend a fatigue management course that will be held in the physiotherapy department at the Royal National Hospital for Rheumatic Diseases (RNHRD). This course will help you to look at how you might alter your PA as a way of coping with your fatigue.

Before taking part in the workshop we will ask you to fill in some questionnaires. These are filled in at the start and the end of the study. The questionnaires will ask you about your fatigue, your arthritis, and your PA.

During the fatigue management course you will be in a group of 5-8 people with RA and will attend 7 workshops. The frequency of the sessions will be:

- Sessions 1-4 will occur once a week
- Sessions 5 and 6 will occur once every two weeks
- Session 7 will occur one month after session 6

Each workshop will last up to 2 hours including a coffee break.

The course will help you to look at and change your PA in a way that will help manage your fatigue. Part of the session will be a group discussion guided by your therapist about different aspects of PA and fatigue. You will also have an opportunity to have a go at some simple PA within the session. You will be asked to try out some of the different ideas in between each session. The group will then come back after a gap of 4 weeks to review how you have all been getting on. Any set-backs or problems that may have arisen will be discussed in this session.

At the end of the final session you will be invited to complete an evaluation questionnaire about your experiences of taking part. Your name and study ID number will not be included on this questionnaire and therefore your feedback will be completely anonymous even to the research team.

I'm not sure if I'll be able to attend all the FRAPA workshops. Can I still take part?

Yes, but ideally we would like people to attend all 7 workshops.

Will my taking part in this study be kept confidential?

Yes. Any questionnaires that you fill in will be marked with a number, not your name. Your name will not be disclosed outside the research team. Your consultant or GP will be sent a letter to let them know you are taking part in the study.

What will happen to the results of the research study?

Research team members will analyse the information from the questionnaires. The findings will be written up as part of a PhD thesis and may be used in conference presentations or published in a journal. You will not be identified in any way. It is anticipated that the results from this study will inform the design and development of larger study where we can further test whether the PA programme is effective at reducing fatigue in RA. It forms the third of 3 phases of a PhD project on this topic.

Who is organising and funding the research?

This study is part of a doctoral research project registered with the University of the West of England, Bristol (UWE) and based in the Academic Rheumatology Unit at the Bristol Royal Infirmary. It is funded by University Hospitals Bristol NHS Foundation Trust, and has been approved by the Wales REC 5 (14/WA/1073) and the University of the West of England Research Ethics Committee.

If you have any concerns or complaints about the conduct of this study please contact the patient advice and liaison service (PALS) at RNHRD on 01225 465941.

What do I do now?

Thank you for considering taking part in this research. Please complete the reply slip and return it in the reply-paid envelope to **Victoria Salmon** (PhD Student). Victoria will contact you in a few days. You can ask any questions you have and let her know your final decision.

Study team

Victoria Salmon, UH Bristol Doctoral Research Fellow, University of the West of England, Bristol

Dr Fiona Cramp, Associate Professor in Musculoskeletal Health, University of the West of England

Professor Sarah Hewlett, Professor of Rheumatology Nursing, University of the West of England

Dr Nicola Walsh, Arthritis Research UK Fellow, University of the West of England

Professor John Kirwan, Consultant Rheumatologist & Professor of Rheumatic Diseases, University of Bristol

Marie Urban, Patient Research Partner, University Hospitals Bristol

Maria Morris, Patient Research Partner, University Hospitals Bristol

Contact: **Victoria Salmon 0117 342 4972**



Rheumatology Research
 Faculty of Health and Applied Sciences
 Based at:
 Academic Rheumatology
 Bristol Royal Infirmary
 BRISTOL BS2 8HW

A research study to explore the management of fatigue in rheumatoid arthritis

Reply Slip

1. I have read and understood the information sheet for this study. Please circle:

Yes, I would be interested in being contacted to discuss participation in this study

Yes, I am interested in this study but I cannot make the given dates

No, thank you, I would prefer not to be involved

It is useful for us to understand reasons why people would not like to take part so that we can make changes to improve the study in the future. If you are happy to share your reasons for not wanting to be involved please briefly state these here:

2. If you answered **yes** to question 1, please circle:

Yes, I would be happy for a message to be left on my answer machine

No, I would prefer not to have messages left on my answer machine

Please return this slip using the self-reply envelope provided

<p>Name:</p> <p>-----</p>
<p>Phone:</p> <p>-----</p>
<p>Email:</p> <p>-----</p>
<p>Signature:</p> <p>-----</p>
<p>Date:</p> <p>-----</p>

Appendix Q: Recruitment record sheet (proof-of-concept study)**Recruitment sheet**

Name: _____

Address: _____

Experience of fatigue? Yes No Please circle the number which shows your average level of fatigue during the past 7 days (**N.B. Inclusion criteria: great than or equal to 6/10**):

No 0 1 2 3 4 5 6 7 8 9 10 Totally exhausted
fatigue

Taken the information? Yes No Returned reply slip Yes No OR agreed to take part in clinic:

Phone number: _____

=====

Phoned patient following receipt of reply slip: Yes No

Date agreed?

Information pack sent: Yes No Phoned patient to remind day before: Yes No Patient attended? Yes No Other notes:_____

Appendix R: Recruitment poster (proof-of-concept study)

Royal National Hospital
for Rheumatic Diseases
NHS Foundation Trust

Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust, Upper Borough Walls,
Bath, BA1 1RL



Have you got
rheumatoid arthritis?

Do you experience
fatigue, exhaustion
or extreme
tiredness?

We are running a fatigue
management course as part of a
research study.
Please ask at reception for more
information.

Appendix S: Case report form (proof-of-concept study)



Rheumatology Research
 Faculty of Health and Life Sciences
 Based at:
 Academic Rheumatology
 Bristol Royal Infirmary
 BRISTOL BS2 8HW

Managing fatigue in rheumatoid arthritis using physical activity (FRAPA): Exploring the acceptability of a physical activity intervention

Case Report Form

Thank you for agreeing to take part in this study.

It would be helpful to gather some information about you by answering the questions below. Your answers are confidential and your name will not be linked to the answers that you give on this form.

Background information

1. Gender (please tick)

Male

Female

2. Date of birth (day/month/year)

 /

3. Please indicate your current work status:

Paid work

Student

Homemaker

Unemployed

Retired

Receiving incapacity benefits

Other (please specify):

4. How long have you been diagnosed with rheumatoid arthritis?

(years)

5. What medication are you currently taking for your rheumatoid arthritis?

6. Please let us know of any other health problems that you have.

7. [HAQ Pain VAS]

How much pain have you had because of your arthritis in the PAST WEEK? (Place a vertical line to indicate the severity of the pain)

No pain pain Severe

8. [HAQ Patient Global]

Considering all of the ways your arthritis affects you, please mark on the line to show how well you are doing:

Very well badly Very

Appendix T: Patient experience questionnaire (proof-of-concept study)

FRAPA Fatigue Programme: Patient Experience Questionnaire

We value your opinion on the fatigue programme that you have completed and would be very grateful if you could answer these few questions. This will help us make any improvements for future patients attending the programme. This answer sheet does not have your name on it. We will put everybody's answers together and see if we should make any changes to improve the course.

1a. How useful did you find the group discussion sessions?

Not useful 0 1 2 3 4 5 6 7 8 9 10 Very useful

1b. Do you have any comments about the discussion sessions? For example, was there a session or topic that was particularly helpful? Was there a session that was less helpful?

2a. How useful did you find the practical exercise session?

Not useful 0 1 2 3 4 5 6 7 8 9 10 Very useful

2b. Do you have any comments about the practical sessions to help us? For example, were any of the exercises too easy or too hard?

3a. What did you think about the course handouts you were given?

Not helpful 0 1 2 3 4 5 6 7 8 9 10 Very helpful

3b. Do you have any comments about the handouts to help us? eg. Was any one particularly useful? Were they clear?

4a. Did you find the course leaders encouraging, helping you see a way to use physical activity to manage fatigue?

Not encouraging 0 1 2 3 4 5 6 7 8 9 10 Very encouraging

4b. Do you have any comments to help us? eg. Was anything particularly good, or less good?

5a. Overall, did you find the programme well run?

No, not at all 0 1 2 3 4 5 6 7 8 9 10 Yes, definitely

5b. Do you have any comments to help us? eg. Would another way be better? Was there anything you particularly liked or disliked?

6a. How did you find completing the questionnaires?

Very difficult 0 1 2 3 4 5 6 7 8 9 10 Very easy

6b. Do you have any comments to help us? E.g. What was easy or difficult about filling in the questionnaires?

7a. Overall, how satisfied were you with the physical activity fatigue programme you have just completed?

Very dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Very satisfied

7b. Do you have any comments to help us? eg. What made you satisfied or dissatisfied?

8a. Overall, would you recommend this programme to other people with rheumatoid arthritis who experience fatigue?

No, not at all 0 1 2 3 4 5 6 7 8 9 10 Yes, definitely

8b. Do you have any comments to help us? eg. Why would you recommend it, or why would you not recommend it?

9. What changes could we make to improve the fatigue programme?

10. Do you have any further comments?

Thank you very much for completing this questionnaire

Appendix U: Session reflection form

POST SESSION REFLECTION

PERSONAL PERFORMANCE

WHAT WENT WELL

WHAT COULD BE BETTER

IDEAS FOR NEXT TIME

Appendix V1: Codes and frequencies for COM-B capability

Physical capability (TDF domains: Physical skills)		Psychological capability (TDF domains: Knowledge; Cognitive and interpersonal skills; Memory, attention and decision processes; Behavioural regulation)	
Code name	Coding frequency	Code name	Coding frequency
Exercises in practical session were good	5	Activity diary helpful	6
Practical session was appropriate level	3	Helps understanding of RA	6
Good range of exercises	2	Improved coping and self management skills	6
Provided practical help for increasing fitness	1	Pacing strategy useful	3
		Pedometer useful	3
		Self-monitoring PA was helpful	3
		Goal setting useful	2
		Managing setbacks useful	2
		Ability to choose own level was helpful	2
		Choice of exercise is good	1
		Relaxation CD helpful	1
		Would recommend to improve lifestyle management	1
		<i>Small scale recording was difficult</i>	<i>1</i>
		<i>Activity diaries hard to keep up</i>	<i>1</i>

Emboldened italics indicates negative statements or suggested improvements

TDF = Theoretical domains framework; RA = rheumatoid arthritis

Appendix V2: Codes and frequencies for COM-B opportunity

Physical opportunity (TDF domains: Environmental context and resources)		Social opportunity (TDF domains: Social influences)	
Code name	Coding frequency	Code name	Coding frequency
<i>Would like programme to continue longer</i>	5	Group is helpful	11
Grateful for opportunity	4	Hearing other experiences is reassuring	3
Practical session gave ideas for home exercises	2	Peer support	2
Handouts helpful for future reference	1	Learn tips from others for managing RA	3
Pacing handout helpful	1	<i>Will miss group support</i>	1
Exercise handout helpful	1	Enjoyed taking part	3
Practical session had good range of materials and aids	1	Programme provides good support	1
Theraband exercises were good	2		
<i>Would like follow up in 6 months</i>	1		
<i>Would like more time for practical PA</i>	1		
<i>Need more availability for more patients</i>	1		

Bold italics indicates negative statements or suggested improvements

TDF = Theoretical domains framework; RA = rheumatoid arthritis

Appendix V3: Codes and frequencies for COM-B motivation

Reflective motivation (TDF domains: Professional/social role and identity; Beliefs about capabilities; Optimism; Beliefs about consequences; Intentions; Goals)		Automatic motivation (TDF domains: Reinforcement; Emotion)	
Code name	Coding frequency	Code name	Coding frequency
Improved motivation	4	PA was mentally stimulating	1
Motivated to achieve PA in session	1	Practical session improved mood	1
Motivated to continue PA	1	Felt better after programme	1
Improved confidence	1		

TDF = Theoretical domains framework; RA = rheumatoid arthritis

Appendix W: Publications and accepted abstracts

PUBLICATIONS

- 2015** Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Morris M, Urban M, Cramp F. (accepted as a poster for Annual European Congress of Rheumatology EULAR 2015 conference): Acceptability of a novel physical activity and self-management intervention for managing fatigue in rheumatoid arthritis
- 2015** Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2015a): Development of a physical activity intervention for rheumatoid arthritis fatigue: view of patients in the United Kingdom *Rheumatology* 54 (suppl 1): i109
- 2015** Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2015b): Development of a physical activity intervention for rheumatoid arthritis fatigue: views of allied health professionals in the United Kingdom *Rheumatology* 54 (suppl 1): i109
- 2014** Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2014) The potential use of physical activity to help manage fatigue in rheumatoid arthritis: lessons from other long-term conditions *Rheumatology* 53 (suppl 1): i122
- 2007** Salmon V, Thomson D (2007): Measurement of force production during concurrent performance of a memory task. *Physiotherapy* **93**: 283-290

Appendix W1: Abstract for Rheumatology 2014

Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2014) The potential use of physical activity to help manage fatigue in rheumatoid arthritis: lessons from other long-term conditions *Rheumatology* 53 (suppl 1): i122

THE POTENTIAL USE OF PHYSICAL ACTIVITY TO HELP MANAGE FATIGUE IN RHEUMATOID ARTHRITIS: LESSONS FROM OTHER LONG TERM CONDITIONS

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Abstract Body:

Background: Fatigue is a major symptom of rheumatoid arthritis (RA) and the need for effective interventions is evident. Programmes based upon physical activity (PA) have been shown to improve patient reported fatigue in other long term conditions (LTCs). To inform the development of PA programmes for RA we aimed to identify PA components of existing fatigue management programmes for LTCs, and to explore expert opinion regarding their deliverability and acceptability.

Methods: A purposive sample of 9 health professionals (HPs) delivering PA for fatigue management in LTCs participated in semi-structured interviews. Transcripts were analysed using hybrid thematic analysis with a subset analysed independently.

Results: 5 physiotherapists, 2 occupational therapists, 1 clinical nurse specialist, 1 exercise physiologist were interviewed; age range 33-53 years; time since qualification 11-32 years; time delivering programme 7 months to 8 years. Fatigue management programmes targeted cancer-related fatigue (n=4) and chronic fatigue syndrome (n=5). Six main themes were identified:

'Format': Between 6 and 14 group or individual sessions delivered initially every 1 – 2 weeks over 6 to 52 weeks. Individual sessions tended to be shorter (45-50 minutes) than group sessions (60-120 minutes).

'Delivery': In a hospital setting by a multi-disciplinary team following referral from a HP. Key challenges to delivery included location and timing of sessions. HPs recommended that good administrative support and a flexible, holistic approach are crucial.

'Theoretical approach': Although cognitive behavioural therapy was mentioned by some HPs as the basis for their programme, application in practice was not clearly described. One participant mentioned use of a self-efficacy outcome measure. Other HPs were unaware of the theoretical basis of the programme.

'Methods of behaviour change': A range of techniques were used including instruction on performing PA, graded tasks, goals and planning, and self-monitoring. HPs reported that psychosocial and motivation issues need to be addressed to improve engagement with PA, and are integral to success.

'Content': PA and psychosocial content were described. Graded exposure to exercise without exacerbating fatigue was important. HPs emphasised that activity management, sleep management and relaxation should be included to optimise the benefits. Patient support materials included programme booklets, record charts, and relaxation CDs. Advice about long term PA was provided, including suggestions for local exercise groups.

'Outcome': HPs believed that PA and fatigue levels improve following PA interventions, although evaluation was inconsistent.

Conclusions: There are a variety of approaches to providing PA programmes for LTCs. Consistent findings included use of graded exercise therapy, the need for organisational flexibility and to address psychosocial and motivation issues. Although this might best be achieved using cognitive behavioural approaches, these were not firmly embedded within current programmes. These should be incorporated in the development of PA interventions for RA fatigue.

Appendix W2: Abstract for Rheumatology 2015

Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2015a): Development of a physical activity intervention for rheumatoid arthritis fatigue: view of patients in the United Kingdom *Rheumatology* 54 (suppl 1): i109

DEVELOPMENT OF A PHYSICAL ACTIVITY INTERVENTION FOR RHEUMATOID ARTHRITIS FATIGUE: PATIENTS' VIEWS

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Abstract Body:

Background: Fatigue is often reported as a problem by people with rheumatoid arthritis (RA). Programmes based upon physical activity (PA) have been shown to improve patient reported fatigue in other long term conditions, but RA patients' views regarding the use of PA to manage fatigue are currently unknown. This study explored patients' opinions about the use of PA for fatigue management, including support needs and delivery preferences.

Methods: A purposive sample of adults with RA who had experienced self-reported fatigue since diagnosis participated in one of two focus groups. Discussions were audio-recorded and transcripts analysed using thematic analysis.

Results: 12 patients (6 female) aged 43-66 years (mean 56.8) with disease duration 0.25-25 years (mean 8.2) took part. Three key themes were identified:

Internal factors: Various self-management and coping skills for fatigue were described but these were not applied consistently. Support for fatigue management was mainly sought from family members despite a limited understanding of the experience. Peer support from other RA patients was considered invaluable by both men and women, therefore patients supported a group intervention.

Motivation for PA: Participants reported that getting outside, being creative and enjoying a sense of achievement helped motivate them to be physically active. Internal factors such as determination and a positive attitude were also considered important. However, this positivity was often overridden by experiences of repeated failure with PA. External factors such as the physical environment affected motivation and participation in PA. Enhancing opportunities to engage in PA was suggested to facilitate motivation.

External factors: Professional support for fatigue management was rarely sought by patients. Those who had received advice found it to be limited. PA advice was

generally aimed at improving physical function rather than managing fatigue. Employment and other caring roles and responsibilities made it difficult to prioritise PA, and fatigue management was challenging as patients felt they had no choice but to soldier on in order to meet external demands. Attending a fatigue management programme would be difficult for those who work, particularly if delivered during working hours.

Conclusions: Patients supported the development of a PA intervention to improve RA fatigue. Patient perspectives regarding barriers and motivators for PA and concerns regarding implementation and delivery must be considered to support uptake and engagement with PA. These findings will inform intervention development.

Funding statement: This work was supported by University Hospitals Bristol NHS Foundation Trust.

Appendix W3: Abstract for Rheumatology 2015

Salmon V.E, Hewlett S., Walsh N, Kirwan J.R., Urban M, Morris M, Cramp F. (2015b): Development of a physical activity intervention for rheumatoid arthritis fatigue: views of allied health professionals in the United Kingdom *Rheumatology* 54 (suppl 1): i109

DEVELOPMENT OF A PHYSICAL ACTIVITY INTERVENTION FOR RHEUMATOID ARTHRITIS FATIGUE: ALLIED HEALTH PROFESSIONALS' VIEWS

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Abstract Body:

Background: There are currently few programmes available to help rheumatoid arthritis (RA) patients manage symptoms of fatigue. Programmes based upon physical activity (PA) have been shown to improve patient-reported fatigue in other long term conditions. The aim of this study was to explore rheumatology allied health professionals' (AHPs) views regarding the acceptability of a PA intervention for managing RA fatigue, to identify key components for inclusion and to discuss implementation in clinical practice.

Methods: A purposive sample of rheumatology AHPs took part in one of two focus groups. Transcripts were analysed using thematic analysis with a subset analysed independently.

Results: Seven physiotherapists and two occupational therapists took part; age range 37-50 years; time working in rheumatology 5-15 years. Five themes were identified:

Current practice: AHPs felt that healthcare professionals could do more to support patients experiencing fatigue. Fatigue management was not prioritised, although it was sometimes discussed in general RA education programmes. Current physiotherapy practice, including PA advice, focused on specific joint or mobility problems and physical function.

Attitudes and beliefs: AHPs believed that patients might not access physiotherapy to manage fatigue if they thought PA would make fatigue worse. Some participants recognised the influence of psychosocial and lifestyle factors on fatigue, whereas others believed that disease processes and other medical issues caused fatigue and required medical management. Some questioned whether there was a need for a specific PA programme for managing fatigue and thought fatigue management could be incorporated into a general PA programme.

Ideas for a new intervention: Implementing an intervention was perceived as feasible, particularly a group programme that would likely be more cost-effective than individual sessions. Groups also offer peer support for patients, although there were concerns that individualising group PA would be challenging. Lack of staffing and resources were highlighted as additional challenges for implementation and delivery. Participants supported the inclusion of goal setting and problem solving, and addressing motivation and barriers to PA. A graded approach to PA incorporating aerobic capacity and strength training was felt to be important.

Potential outcome: AHPs believed that PA could make a positive difference to fatigue in addition to having other benefits such as increased social participation, improved psychosocial wellbeing, better sleep and improved sense of control over RA.

Long term adherence: The importance of implementing strategies to facilitate ongoing PA was highlighted. Therapy input must be supplemented by PA practice at home. Improved links with community services would be needed to ensure long term continuation of PA.

Conclusions: AHPs believed that current fatigue management in RA could be improved. They supported the use of PA to manage fatigue but concerns regarding implementation and delivery must be considered during intervention development.

Funding statement: This work was supported by University Hospitals Bristol NHS Foundation Trust.

Appendix W4: EULAR 2015 accepted abstract

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Acceptability of a novel physical activity and self-management intervention for managing fatigue in rheumatoid arthritis

Background

There are few interventions available to help people with rheumatoid arthritis (RA) manage symptoms of fatigue. We designed a physical activity (PA) and self-management intervention for managing fatigue based on preferences expressed by RA patients and professionals and a theoretical framework for health behaviour change¹. The aim of this study was to explore the acceptability of this intervention.

Objectives

To explore acceptability of the intervention format, content and support materials to the study population

Methods

RA patients who experienced fatigue were recruited from a specialist rheumatology department. The intervention consisted of 7 group sessions delivered by a physiotherapist and an assistant over 12 weeks. Each session consisted of a one hour education and discussion session followed by a 30 to 40 minute practical PA session. The intervention was evaluated using a questionnaire designed for the study. Data were analysed using descriptive statistics and qualitative content analysis.

Results

9 RA patients (8 female) were recruited (age range: 38 to 75 years (mean: 58.3); disease duration: 4 months to 12 years (mean: 4.9 years); Bristol Rheumatoid Arthritis Fatigue Numeric Rating Scale for severity: 6 to 9 (mean: 7.2)). 8 patients completed the intervention (mean attendance: 6.5 sessions). Overall feedback was positive. Likert scales (0-10, higher scores represent greater acceptability) were used to rate intervention components (overall satisfaction, usefulness of education/discussion and practical sessions, helpfulness of handouts, recommendation to other patients). Mean scores across all categories were between 8.9 and 10.

Qualitative feedback from open-ended responses on the questionnaire suggested that the group format and peer support were invaluable for improving motivation and self-management skills. All discussion topics, including pacing, goal setting and managing setbacks were helpful; practical sessions boosted confidence in selecting and undertaking PA, and provided ideas for home exercise. Support materials such as activity diaries and pedometers were considered useful for self-monitoring and motivation, and handouts were valuable for future reference.

Suggested improvements to the programme included a longer course, a 6 month follow-up session to review progress and ongoing support. It was not specified if this meant peer or professional support or both.

Conclusions

The format and content of this PA and education intervention and its associated support materials were acceptable to group participants. This justifies consideration for further evaluation in a pilot study prior to full scale testing in a randomised controlled trial.

References

1. Michie, S., van Stralen, M.M. and West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* 6:42

Appendix X: Presentations and awards

ACHEIVEMENTS AND AWARDS

April 2015	EULAR Annual European Congress of Rheumatology EULAR travel bursary
January 2015	British Health Professionals in Rheumatology educational bursary (£470)
July 2014	Santander Travel Bursary (£500)
June 2014	Best poster, UWE Postgraduate Research student conference (£50)
January 2013	British Society of Rheumatology Allied Health Professionals Bursary (£500)

POSITIONS OF RESPONSIBILITY

2012-2014	Postgraduate research student representative, UWE
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PRESENTATIONS AT NATIONAL AND INTERNATIONAL CONFERENCES

June 2015	<i>Annual European Congress of Rheumatology EULAR 2015 (accepted poster presentation – abstract in appendix W4)</i>
April 2015	Rheumatology 2015 (two poster presentations (abstract appendix W2&3, one on poster tour - appendix W2)
April 2014	Rheumatology 2014 (abstract, appendix W1, poster presentation and inclusion on poster tour)

PRESENTATIONS AT LOCAL CONFERENCES AND EVENTS

June 2015	<i>UWE PGR conference (accepted oral presentation, abstract in appendix W4)</i>
June 2014	UWE PGR conference (poster and oral presentation) Poster presentation: “Managing fatigue in rheumatoid arthritis with physical activity: lessons from other long term conditions” Oral presentation: “Patients’ views regarding the use of physical activity for managing fatigue in rheumatoid arthritis”
June 2014	UWE Public Engagement event Invited speaker: “Physical activity, fatigue and rheumatoid arthritis: Patient involvement in research”
May 2014	UH Bristol NHS Foundation Trust Research in Practice symposium Poster presentation: “Managing fatigue in rheumatoid arthritis using physical activity: lessons from other long term conditions”
March 2014	UH Bristol NHS Foundation Trust Research and Innovation symposium Invited talk: “Physical activity, fatigue and rheumatoid arthritis. How patients can shape research”
June 2013	UWE Postgraduate Research conference Oral presentation: “Interventions to promote physical activity in rheumatoid arthritis: a systematic review of the literature”