The impact, frequency and care of foot problems in people with rheumatoid arthritis

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A thesis submitted in partial fulfilment of the requirements of the University of the West of England, Bristol for the degree of Doctor of Philosophy

Faculty of Health and Applied Sciences University of the West of England

January 2016

Word count: 87678

Volume 1

Abstract

Although foot problems are common in rheumatoid arthritis (RA) their prevalence and importance to patients, the barriers patients face accessing foot care, and the types of care received have not been adequately established. Previous studies were hospital based and/or sampled selected groups of patients and did not adequately capture the patient perspective regarding foot problems and the benefits of foot care. Further, the accuracy of the patient self-report, the basis of previous studies, is not known.

To overcome these limitations and address the question of how to improve access to foot care a mixed methods approach employed three interlinked studies: a qualitative analysis of interviews with patients to identify relevant outcome measures; a population survey using these measures to establish prevalence and impact of foot problems and factors influencing access to foot care; and a clinical assessment of the accuracy of self-report which also provided a detailed description of current foot problems.

Semi-structured interviews with patients with RA confirmed that foot problems are common and revealed how they impact on many aspects of patients' lives such as ability to work. Patients adopt a variety of self-management strategies to manage foot problems and can recognise common foot pathologies. Patients' decisions to access foot care or not were complex. Some considered access to foot care unnecessary but for others limited awareness of treatment options, lack of knowledge of how to access care and feet being ignored in rheumatology clinical practice emerged as barriers to accessing foot care. Patients who had accessed foot care prioritised their foot problems as an important health care need and provided a broad description of foot care interventions received. Positive experience of foot care received encouraged continued utilisation of foot care services, while negative experiences contributed to patients' decisions to discontinue interacting with foot care services. Important outcomes and issues raised by patients have not been previously investigated or quantified and therefore informed the content of the subsequent survey.

The survey in a random population sample of RA patients demonstrated that foot problems were prevalent and caused substantial impact. Many reported that their foot problems were severe, important and that they were not coping well with them. However, patients reported examination of their feet to be inconsistent and discussions during clinical consultations in relation to foot problems were often initiated by patients rather than the doctor or nurse. Although the literature suggests health resources are poorly accessed by men and people from socially deprived areas, in this survey two thirds of respondents had accessed foot care (often outside the NHS), including over half of the men and many from deprived areas. The survey also provides a description of the general and RA characteristics, prevalence of additional health problems in a large sample of the RA population.

Clinical assessment of a selected sub-sample of responders to the survey provided a detailed description of the nature and type of current foot problems. Additionally, the study demonstrates that self-report of most common foot problems is reliable and can be utilised with a high degree of confidence. However, there is a clear indication that a direct examination of patients' feet is required to detect numbness, pes planus and joint swelling. The number of patients with foot care needs was high and nearly half required immediate clinical intervention. Patient satisfaction and perceived benefits differed between foot care services.

Foot problems are common, important issues for patients with RA. Access to foot care was more prevalent than anticipated but many patients had serious current problems, questioning the appropriateness and effectiveness of current foot care which is provided by non-specialist clinicians. Further work should investigate how specialist foot care services could support non-specialist clinicians and improve outcomes.

Acknowledgements

Thank you to all the patients who participated in this research. I very much appreciate you giving your valuable time attending the interviews, completing the questionnaires and attending the clinical assessments. You are truly the unsung heroes of clinical research; as without patient's participation we are unable to improve clinical care. Many thanks to my patient research partners, Enid Quest and Caroline Swales, for all your invaluable contributions, comments and support throughout this research.

I am extremely grateful to the National Institute for Health Research for awarding me a personal fellowship award providing not only financial support but the opportunity to undertake this PhD. A note of thanks to my substantive employer Bristol Community Health (BCH); for granting me a career break to embark on the research and to Mrs Sam Draper, for providing access to BCH clinical rooms to conduct data collection. Thank you to Wendy Briggs for conducting the clinical assessments and data collection. You are not only a true professional but a wonderful friend.

Huge thanks to my supervisory team. Professor John Kirwan, my "day to day" boss who has encouraged, supported and guided me throughout this PhD. Enormous thanks for your thoughts, ideas, knowledge and patience with my initial phobia of statistics and for your detailed marking of every draft. Professor Sarah Hewlett has been a fantastic director of studies, not only encouraging my academic development but supporting me through times of great personal challenges and tragedy. I am eternally grateful for the emotional support and kind words you gave when my mother sadly died suddenly. Your door was always open when needed and you helped me through a really tough time. Sincere gratitude to both Dr Jon Pollock and Professor James Woodburn who kindly: disseminated their knowledge and guidance regarding the overall approach, statistical analyses and interpretation of the findings.

To the fantastic team UWE: Tessa Sanderson, Celia Almedia, Emma Dures and Zoe Plummer, many thanks for all your advice and technical IT support. A special thank you to my fellow PhD students Julie Taylor, Caroline Flurey, Tori Salmon and Serena Halls who have been with me every step of this very long quest! A big mention for all the clinical and academic staff in the rheumatology unit for supporting me throughout and

were always available to answer clinical queries. Dr Paul Creamer and Wendy Wilmott, thank you for assisting with identifying the patient population.

My wonderful husband Neil and amazing children Ed and India, you have all been so patient with me and not complained about my long hours or being an absent mother! Neil, I could not have done this without your love and support. You happily stepped up to the “plate” and looked after us all despite having a demanding job yourself. You also developed some amazing new culinary skills. Thank you for being you.

To my wonderful parents the late Dr Ronnie Houston and late Mrs Frances Houston. It is thanks to you I am the person that I am. My fantastic father whose tragic death at such a young age was a tremendous shock and he has sadly missed so many millstones and achievements in my life. My amazing mother Frances, the strongest, brightest and funniest woman I have ever known. Thank you for installing in me some priceless values such as the importance of a work ethic and the need to be tenacious when life becomes tough. My only regret is that you did not see me reaching the end. It took me a while but I got there eventually! I therefore dedicate this thesis to both of you with all my love and I hope that I have made you both proud.

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List of abbreviations

ACR	American College of Rheumatology
AFC	Accessed foot care
AHP	Allied health professional
BCH	Bristol Community Health
CI	Confidence interval
CPD	Continuing professional development
CRF	Case record form
DAS	Disease activity score
DMARD	Disease-modifying anti-rheumatic drug
EULAR	European League Against Rheumatism
FIS	Foot Impact Scale
GALS	Gait Arms Legs Spine Screen
GC	Glucocorticoids
GP	General practitioner
HAQ	Health Assessment Questionnaire
HCPC	Health and Care Professions Council
ICP	Integrated care pathway
IMD	Index of Multiple Deprivation
IPJ	Interphalangeal joint
IQR	Interquartile range
ITA	Inductive Thematic Analysis
LSOA	Lower Layer Super Output Area
MDT	Mutli-disciplinary team
MTP	Metarsophalangeal joint
NAFC	Not accessed foot care
NBT	North Bristol NHS Trust
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRS	Numerical rating scale
NSAID	Non-Steriodal Anit-Inflammatory Drug
OR	Odds ratio
PIS	Patient information sheet
PROMs	Patient reported outcome measures
PRP	Patient research partner
ROM	Range of motion
RCT	Randomised controlled trial
SD	Standard deviation
UHB	University Hospitals Bristol NHS Foundation Trust
UK	United Kingdom
UWE	University of the West of England
VAS	Visual analogue scale

Chapter 1: Introduction

This thesis investigates the prevalence, impact and care of foot problems in patients with rheumatoid arthritis (RA). Chapter 1 provides an overall description of the clinical features and management of RA and introduces foot involvement, describing features and symptoms that can develop as a consequence of RA. It goes on to describe the setting in which the research was conducted and the organisation that funded the research. Chapter 2 provides a detailed review of foot problems in RA, and Chapter 3 a detailed review of the organisation of relevant health services and access to health care. Chapters 4, 5 and 6 each present and discuss one of three interlinked studies designed to explore the patient experience, prevalence and nature of foot problems and finally to examine the accuracy of the self-report of foot problems. Chapter 7 draws together the findings from all three studies, the conclusions that follow, and the implications for future research and service delivery.

1.0 Rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic autoimmune condition causing symmetrical inflammatory poly-arthritis, sometimes with additional systemic features, and for which there is currently no cure. The aim of current clinical management of RA is therefore to achieve the lowest possible disease activity, ideally remission (Smolen *et al,* 2010). The lifetime prevalence of RA is estimated as 0.5% to 1.5% of populations in developed countries, with a peak onset of 40-60 years of age. It is three times more common in women (Hochberb and Spector, 1989; Crowson *et al*, 2011). Epidemiology data suggest that the prevalence of RA is reducing in women but not men (Symmons *et al,* 2002). The aetiology (cause) of RA has not been fully determined. However, genetic predisposition and gender, infection, stress or trauma, environmental factors and more recently health behaviours such as smoking have been proposed as possible triggers (Silman, Newman and Macgregor, 1996).

The initial clinical presentation of RA is most often symmetrical pain, swelling and stiffness of the joints, usually including the hands and feet (e.g. Grondal *et al,* 2008). Accompanying symptoms can also include flu-like symptoms, general malaise and fatigue. As the condition (disease) progresses, larger joints (knees, hips, elbows shoulders, knees and neck) and the spine can become involved. Patients with RA have potentially reduced life expectancy (Gabriel *et al,* 2003) with mortality being associated with the systemic features, such as cardiovascular involvement (Wolfe *et al,* 1994). Additionally it is widely recognised additional morbidity (other health conditions) is common in patients with RA (e.g. Gabriel, Crowson and O'Fallon, 1999). There is also evidence demonstrating that the number of additional health conditions is associated with higher levels of disability (Verburgge, Gates and Ike, 1991). The course of RA is highly variable between patients. The clinical features for the majority of patients follow a fluctuating pattern with episodes of flares (inflammatory process become more active and symptoms are more severe) followed by periods of remission (symptoms reduced or absent) resulting in increased disability over time (Hill, 2006).

The American College of Rheumatology (ARC) criteria for classification of RA (Arnett *et al,* 1988) are used as a standardised method of identifying patients. The criteria are:

1. Morning stiffness lasting at least one hour
2. Inflammatory arthritis of involving three or more joints
3. Inflammatory arthritis of hand or wrist joints
4. Symmetrical joint involvement
5. Presence of rheumatoid nodules
6. Serology - rheumatoid factor positive
7. Radiographic evidence of erosions and/or osteopenia of the hand and/or wrist

A standardised 'diagnosis' of RA requires the presence of 4 or more criteria, inclusion criteria 1 to 4 must be present for a minimum of 6 weeks. The classification of RA has since been revised following a joint initiative between ACR and the European League Against Rheumatism (EULAR) (Aletaha *et al,* 2010). The revised criteria were developed to be sensitive to patients with very early RA, who could be identified as being at risk of developing more severe and erosive disease; as well as supporting the initiation of disease modifying pharmacological therapy, and also be applicable to patients with established RA. The revised criteria for a classification of "definite RA" are:

1. Presence of synovitis in at least 1 joint and number of joints involved (score range 0-5)
2. Abnormal serology (presence of Rheumatoid factor (RF) or anti-citrullinated protein antibody (ACPA) (score range 0-3)
3. Elevated acute response (C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) (score range 0-1)
4. Duration of symptoms (score range 0-1)

A total score including the four domains greater than 6 (out of possible a 10) is required for a diagnosis of RA. The revised criteria for diagnosis of RA can only be applied to patients diagnosed with very early RA after 2010. The 1987 criteria will be used to investigate the prevalence, impact and care of foot problems of patients with RA in this thesis, as most patients were diagnosed before 2010.

1.1.1 Synovitis, extra-articular and systemic features

The pathology of RA involves inflammation of joint synovium (thin membrane lining the joint capsule), a process referred to as synovitis. The synovial membrane and underlying connective tissue become infiltrated with inflammatory cells (T- and B-lymphocytes, macrophages and neutrophils), which merge with overgrown synovial cells (pannus). Pannus then spreads over the articular cartilage, leading to the destruction of cartilage and the underlying bone becomes eroded (Firestein, 2003). Swelling within the joint develops due to accumulation of the by-products of the inflammatory process. The joint capsule becomes distended; supporting soft tissues (tendons and ligaments) become stretched and atrophied, eventually leading to wasting of adjacent muscle. The clinical symptoms of synovitis are joint pain, joint tenderness on direct palpation, joint swelling, warmth and joint stiffness (Grassi *et al,* 1998). Although the synovial blood supply is increased and it becomes hyperaemic (localised accumulation / congestion of blood), superficial joint erythema (redness) is not a common feature in RA, unlike in other inflammatory conditions such as gout or soft tissue infection. As the inflammatory process continues the joint space can become narrowed or lost and bone destruction accumulates, resulting in reduction of joint function (Shrader, 1999).

The clinical features of RA can also involve other tissues, non-articular structures of the musculoskeletal system (extra-articular features) and other organs (systemic features). The prevalence of extra-articular features is reported to be up to 40% of patients (Cimmino *et al,* 2000). Extra-articular features of the skin occur due to the presence of rheumatoid nodules and small vessel vasculitis (inflammation of the blood vessels). Small vessel involvement can present as splinter haemorrhages, (periungual infarcts). These infarcts can lead to tissue necrosis and potentially digital gangrene (Cojocaru *et al,* 2010). Neuropathies can also be a feature of RA such as diffuse peripheral sensory neuropathy, entrapment neuropathies (tarsal tunnel and carpal tunnel) and mononeuritis and mononeuritis multiplex (Agarwal *et al,* 2008). Patients with RA also have an increased risk of developing cardiovascular disease, compared with the general population (Soloman *et al,* 2003). Haematological involvement is also a clinical feature, with anaemia being the most common manifestation (Bowman, 2002). Pulmonary, oral and ocular involvement can also occur (e.g. Chanin *et al,* 2001).

1.1.2 Consequences and impact of RA

RA can have consequences and subsequently impact on many aspects of patients' everyday lives such as: 1) activities of daily living (ADL) (walking, ability to perform personal hygiene, general everyday tasks); 2) participation in valued activities (leisure activities, social interaction); 3) perceived loss of role and identity; 4) psychological well-being (depression, anxiety and body image); 5) ultimately quality of life (Katz, Morris and Yelin, 2006, Katz and Yelin, 2001; Pollard, Choy and Scott, 2005; Ryan, 1999; Whalley *et al,* 1997). RA can also have long- term economic consequences for individual patients. For example patients' ability to continue with current employment can be threatened. Work disability and subsequent loss of reduced income has been well documented in patients with RA (e.g. Albers *et al,* 1999). There is a general consensus that patients with RA have greater work related disability compared with the general population (working age). The risk of work disability (in RA) is reported to increase with disease duration (Verstappen *et al,* 2004), age, disease severity and the nature of job related tasks (Albers *et al,* 1999; Reisine, Mcquillain and Fifiled, 1995; Yelin, Henke and Epstein, 1987). The long-term economic consequences in terms of direct costs are also considerable for health care providers (cost of service provision, pharmacology therapy). In 2009 the annual economic cost of RA to the National Health

Service (NHS) in the UK was estimated at £560 million and additional sick leave and work related disability was £1.8 billion (National Audit Office, 2009).

1.1 Management of rheumatoid arthritis

The current aims of the management in RA are to reduce inflammation, control symptoms, improve physical function, promote self-management, improve psychosocial well-being and function, monitor for drug toxicity and screen for co-morbidity (Luqmani *et al,* 2006, Luqmani *et al*,2009). RA is a complex condition and is widely accepted to require multidisciplinary approaches to care which are tailored to the individual needs of patients (van de Hout *et al,* 2003, Hennell and Luqmani, 2008). The management of RA is primarily divided into pharmacological and non-pharmacological interventions.

1.2.1 Pharmacological management of RA

Pharmacological treatments (arthritis medications) used to manage RA aim to reduce the inflammatory process and to reduce symptoms (e.g. pain). Choices of treatments prescribed are dependent on individual patients' symptoms, severity of disease features and duration of disease (Smolen *et al,* 2010).The classification of drugs prescribed in RA consists of four categories: 1) analgesics; 2) non-steroidal anti-inflammatory drugs (NSAIDs); 3) disease modifying anti-rheumatic drugs (DMARDs) including biologic therapies; 4) glucocorticoids (steroids). Analgesics (non-opioid, compound analgesics and opioid analgesics) can be prescribed to provide pain relief. NSAIDs have a combination of both an analgesic and anti-inflammatory affect. DMARD medications can affect the immune response and suppress the progression of the inflammatory process, therefore inhibiting or preventing further joint damage. The more recent biologic therapies are also included in the DMARDs drug category. Biologic therapies suppress the immune system by targeting specific molecules on the cells of the immune system and bi-products of the inflammatory process secreted from joints, systemic and non-articular involvement. There are several different biologics now available, which vary in target action. Glucocorticoids are synthetic versions of the naturally occurring hormone cortisol. The clinical action of glucorticoids is reduction of the autoimmune response to inflammation. Mode of delivery can be to an individual joint or soft tissue (intra articular), orally or by intravenous infusion. There is substantial evidence demonstrating the clinical efficacy of these medications in the management of RA (e.g.

Kirwan, 1995) and usage in clinical practice is recommended in national guidelines (NICE GC79, 2009). Pharmacological management can be described as being monotherapy (one classification of drug prescribed) or more commonly as combination therapy (more than one classification of drug and/or one or more DMARDs prescribed).

1.2.2 Non-pharmacological management of RA

The non-pharmacological management of RA refers to all the other treatment (management) interventions (e.g. foot orthoses). Rheumatologists are considered to be the specialists who provide and coordinate the care for patients with RA. However, the disease features of RA are complex and require a multifaceted approach to management and to the provision of and access to care. It is widely accepted as best practice that a multidisciplinary team (MDT) approach to care is required (Luqmani *et al,* 2009; NICE CG7, 2009). The professional remit of members of the MDT ranges from managing general disease symptoms (rheumatologist) to regional anatomical focus (e.g. podiatrists). The professionals constituting the MDT can vary between different health care systems. Health professionals who can be involved in the management of patients with RA (Kennedy *et al,* 2005; Luqmani *et al,* 2006) in the UK are:

1. Rheumatology nurse specialist
   Provide advice and education regarding information about the general nature of RA, medication counselling, monitoring disease activity, screening and assessment, address issues of difficulty of activities of daily living (ADL) and self-management (pacing and planning, rest, relaxation, goal setting).
2. Occupational therapist
   Support patients with regards to issues with ADL by providing devices and support for continued participation in valued life roles (working, relationships, and leisure activities) through self-management. Joint protection (especially of the hand and wrist) is addressed with advice on the performance of particular tasks, splinting and exercise.
3. Physiotherapist
   Promote the maintenance of mobility, physical function and independence though therapeutic exercise (muscle strengthening, mobilisation and gait rehabilitation) and thermal therapies (heat, cold, hydrotherapy).
4. Orthopaedic surgeon

Orthopaedic intervention is considered when irreversible joint damage has occurred or pathologies involving soft tissues become severe (e.g. tendinopathies). The overall aim of orthopaedic surgery is to reduce pain and improve function.

5. Podiatrist

   Assess, provide treatment for and rehabilitate conditions of the foot and lower limb by assessment of biomechanical function, neurological and vascular status. Treatment is also provided for skin lesions (corn, callus and ulceration), nail pathologies, foot injuries and infections. Patient education regarding self-care, footwear and general foot health are also within the remit of podiatric practice. The aims of podiatric care is also to relieve pain, maintain function and improve mobility while protecting the foot from further problems (e.g. development of cutaneous lesions).

6. Orthotist

   Examine, assess and treat physical and functional limitations in patients with long term conditions such as RA. Treatment is provided in the form of devices which support, correct and/or accommodate deformities (braces, foot orthoses and hospital issued prescribed footwear). The orthotist prescribes, fits, monitors and educates patients regarding the use of device / devices issued.

7. GPs and practice nurse

   The majority of patients with RA are managed in secondary care (hospital outpatient departments). Patients with RA require continual monitoring of disease activity in particular for adverse side effects of pharmacological interventions. Regular blood tests are a component of monitoring, often conducted by primary care (community) based clinicians such as GP and practice nurses.

8. Pharmacist

   Patients with RA are usually prescribed some form of pharmacological therapy. Pharmacists ensure the quality and suitability of pharmacological interventions prescribed. Advice can also be provided to the individual patient regarding how to take their medication and possible side effects or adverse reactions they may experience.

9. Health psychologist

Psychological support for patients with RA is often considered part of the role of the rheumatology nurse specialist and occupational therapist. However, more recently the inclusion of the clinical psychologist as a member of the MDT has received attention for inclusion.

1.2.3 Patient education, self-management and self-care

Patients with RA have to live with and manage their condition on a day to day basis. In order for this to be achieved, patients need to be informed about the nature of the condition, their clinical management, when and how to access care, and what actions they can take to reduce the consequences and impact of living with RA. Patient education is widely viewed as an essential component to management of long term conditions. Hill (2006) defines patient education (in rheumatic diseases) as "any set of planned educational activities designed to improve patients' health behaviours and through this their health status and ultimately their long term outcome".

Self-management is viewed as complementing traditional patient education by the use of problem solving skills in which the patients can identify and self-manage their own individual problems and needs (Bodeheimer *et al*, 2002b). Personalised strategies and techniques can then be derived and supported by health professionals to assist patients manage their condition. A central element of self-management is the confidence of the individual in their ability to carry out a behaviour or action, referred to as self-efficacy (Bandura, 1977). Newman*,* Steed and Mulligan (2004), propose self-management of long term condition as a continuum of actions which vary in different health states. For example the authors propose the object of self-management of asthma and diabetes is to achieve disease / condition control and stability of symptoms primarily through pharmacological management. In contrast the authors consider the management of the complex clinical features of RA such as pain and subsequent disability to be additional challenges to disease control. Additionally the management of RA requires active patient participation and concordance with treatment regimens. Additionally patients with RA need to develop new coping strategies to optimise clinical and personal outcomes. Newman, Steed and Mulligan therefore infer the management of RA requires a combination of pharmacological management and active participation in self-management.

Structured self-management programmes such as the Arthritis Self-Management Programme (ASMP) have been applied in rheumatology practice. The programmes involve group sessions for patients led by health professions and lay educators (patients trained in facilitating education sessions). The benefit of the ASMP have been shown to include improved patient knowledge, engagement of self-management behaviours and reduction in pain (Lorig *et al,* 1985), and have additional reduction of health care costs in terms of health care usage (Lorig *et al,* 1993).

Discordance in the understanding of the meaning and interpretation of self-management can vary between health professionals. For example podiatrists generally consider self-management as a component of self-care, in which a patient participates (themselves or with non-professional support) in physical tasks to manage their foot health care needs (cutting their toe nails, apply emollients and using a foot file). Therefore the patient self-manages their general foot health. Conversely, the nurses' perspective is of a more global view, in which self-management involves supporting strategies, skills and beliefs to manage their RA in general terms, in order to self-care (Hill, 2006). A result of inconsistencies in the literature with regard to definitions of self-care and self-management, the terms will be used together in this thesis in order to encompass the global nature of how patients care and manage their foot problems.

1.2.4 Complementary therapies

Patient with long term conditions have been reported to develop their own informal methods of self-care and self-management strategies with the use of complementary and alternative medicines (CAMs) in addition to advice and care they receive in the "traditional" health care setting (Herman *et al,* 2004, Quandt *et al,* 2005). The use of CAMs is popular in patients with RA, with an estimated usage of between 20% - 90% of patients and more commonly used by women compared to men, but usage is not associated with ethnicity (Efthimiou and Kukar, 2010; Tamahne *et al,* 2014). Patients' reasons for deciding to use CAMs have been proposed to be influenced by negative side effects of pharmacological therapies and or personal beliefs and values. Patients using CAMS to manage their foot problems particularly in RA, is not fully understood.

1.3 Foot problems in RA

Speigel and Speigel (1982) consider the development of foot problems in RA is a result of a combination of inflammatory disease and altered mechanics. The additional mechanical stresses of walking in a weakened musculoskeletal environment can lead to pain, deformity, secondary skin pathologies and further deterioration in walking distance, activity levels and general wellbeing (Turner *et al,* 2008; Grondal *et al,* 2008; Wickerman *et al,* 2004). The presence of deformity also raises issues regarding the ability to obtain accommodative footwear. Foot involvement in RA is a complex issue, and requires further investigation. It would be beneficial to establish the experience of foot problems in RA from the patient perspective, the type and prevalence of these problems, and the extent to which foot care services (podiatry, orthotics and orthopaedic surgery) are provided and used. National guidelines (Luqmani *et al,* 2006) call for an annual review of the feet of patients with RA, indicating recognition of the problem in broad terms. Additionally there is emerging evidence indicating some foot care interventions such as foot orthoses and prescribed footwear are effective (e.g. Woodburn Helliwell and Barker, 2002; Magãlhaes *et al,* 2006). However, the precise extent to which foot problems contribute to overall levels of pain and disability and the extent to which foot care services may contribute to improved care have not been determined. Furthermore, the current provision of foot care services dedicated to rheumatology varies widely across the UK (Redmond, Waxman and Helliwell, 2006). In addition, their ability to detect and diagnose rheumatological foot problems, the extent to which they are accessed by patients and the factors which determine access are not known. One exploration suggested that access to foot care in general was unrelated to care needs (Harvey *et al,* 1997), raising the possibility that social and societal barriers prevent appropriate foot care. Furthermore, an accurate assessment of the clinical features and consequences of foot problems in RA has potentially been hampered by a lack of standardisation of clinical assessments and failure to develop adequately valid foot assessment tools that can be used on a population basis. This has been addressed by the development of the Foot Impact Scale (FIS) (Helliwell *et al,* 2005), a validated self-report questionnaire for patients with RA. The FIS assesses the impact of foot problems, which can be applied to the general RA patient population to facilitate quantitative measurement of the impact of RA foot pathology with confidence. Best practice guidelines and care pathways for foot involvement in RA have been published

(Podiatry Rheumatology Care Association, 2008). However, evidence and expert opinion suggests that foot care standards are not being met (e.g. Williams *et al,* 2013). Foot care services, in particular NHS podiatry provision, have been identified as underused and under-resourced services (National Audit Report, 2009; Rheumatology Futures Group, 2009).

A pilot investigation conducted by the researcher (Wilson, 1999) showed that of a convenience sample of 75 patients attending for medical follow-up and not specifically referred for podiatry review, more than 60% were assessed as requiring foot care (e.g. foot orthoses). Of these, only 32% were receiving foot care. The complexity of foot problems can justify the need for assessment in a specialist clinic (Helliwell, 2003). Martin and Griffith (2006) found that podiatry was the highest reported additional service need requested by RA patients (46%). However, a contemporary review of service provision undertaken at a community podiatry clinic to inform this thesis found only 2% of the caseload had RA. This result is compatible with a primary care review of RA patients in Bristol which concluded access to care packages was highly variable (Memel and Kirwan, 1999). This apparent disparity between the extent of foot involvement in RA as described in the literature and low utilisation of foot care service provision requires further investigation. We do not currently know the barriers to accessing and subsequent utilisation of foot care services. It is possible access to foot care may be influenced by patients' beliefs regarding efficacy of foot care or to patients' lack of knowledge of treatment options. Barriers might also arise because of rheumatology clinicians' approach to the role of foot care services, or because of low levels of current service provision, or because of a combination of some or all of these reasons. It may be that foot care services concentrate provision and delivery of care to foot problems associated with other conditions. For example a large proportion of the local NHS podiatry service in Bristol focuses on foot care for problems associated with diabetes. Barriers of access to and utilisation of health care services can be multi-factorial (Gulliford *et al,* 2002). Therefore, it would be advantageous to identify level of foot involvement in RA, the proportion of patients who have accessed foot care and the types of care received. Additionally, capturing the impact of foot problems would provide valuable insight into the consequences of foot problems from the patient perspective. These considerations led to the overall research questions for this thesis: "What is the impact of foot involvement in RA and what determines if patients with RA receive foot care?” The literature relating to this research question will be reviewed in depth in Chapters 2 and 3

1.4 Research setting

These overall research questions will be addressed through a series of interlinking studies which were conducted in Bristol, UK.

1.4.1 General population characteristics

Bristol has an estimated population of 432,500 and is the eighth largest city in England. The median age of residents is younger than the national average for England and Wales, 33.7 years and 39.9 years respectively with 19% under the age of 15 years and 13% over the age of 65 years. Bristol has a slightly higher proportion of working age people (16-64 years) compared with the national average, 68% versus 63%. The city is ethnically diverse with approximately 22% of the population being classified as “non-white British” (Bristol Research Network, 2012). Deprivation levels in Bristol are mixed and general unemployment rates for Bristol are better than the national average (7.0% and 7.6%; respectively). However, academic attainment is lower than the national average for England. The average life expectancy for females and males in Bristol is estimated at 81.9 years and 77.2 years compared with national the average of 82.3 years and 78.2 years. Premature deaths due to cancer and cardiovascular disease have fallen in Bristol are over the last 10 years but are still reported to be higher than the national average (South West Observatory, 2012).

1.4.2. Clinical setting

The Rheumatology Departments at South Bristol (Rheumatology Centre, Bristol Royal Infirmary, University Hospitals Bristol NHS Foundation Trust (UHB)) and North Bristol (Rheumatology Department, Southmead Hospital, North Bristol NHS Trust (NBT)) provide all the hospital based rheumatology services to the City of Bristol. The departments also provide care to patients residing outside the Bristol area. Based on epidemiology data reported in a longitudinal observational study of adults over the age of 18 years (Doran *et al,* 2002), the estimated number of adults with RA in Bristol is approximately 1480. This estimation is based on falling prevalence of RA (Alamanos, Voulgari and Drosos, 2006) and therefore reflects 80% of the Doran *et al,* data (1955 to 1995).

The NHS community health services for Bristol are supplied by Bristol Community Health Social Enterprise (BCH) within which there is a single NHS community podiatry service. Access criteria to community NHS podiatry services is for patients registered with a general practitioner (GP) within the BCH boundaries rather than individual patients' location of residence. The BCH boundaries reflect the Bristol Local Authority and Bristol Clinical Commissioning Group (CCG) boundaries and include 56 GP practices. Some wards in North and North East Bristol are within the South Gloucestershire Local Authority and South Gloucestershire (CCG). Thus if a patient resides in South Gloucestershire CCG area but is registered with a GP within the BHC boundary, they would be eligible for an assessment with the BCH podiatry service. Orthopaedics and orthotics services are provided by both hospital sites to both the local and regional patient populations. The Podiatry service provision for both UHB and NBT is provided by BCH community services on a service level agreement. Over 90% of the hospital podiatry provision is dedicated to foot care for patients with diabetic foot diseases (e.g. foot ulceration) at both hospital sites, 8% of service provision for patients with renal disease at one site (NBT) and 2% allocated to rheumatology provision at one site (UHB). Secondary care rheumatology podiatry provision is accessed by referrals from members of the rheumatology multidisciplinary team (UHB) and NHS community podiatry service. The BCH community podiatry service currently operates an open access referral system. Referrals to the services are accepted from health professionals in both primary and secondary care in as well as self-referral by patients. In contrast access to orthopaedics is restricted to hospital based clinicians and general practitioners (GPs). Orthotic services at both sites accept referrals from hospital based clinicians and more recently from the BCH community musculoskeletal triage services (MATS). The community podiatry service does not have direct access to either hospital based services with the exception of secondary care based podiatry.

It is possible that some patients with foot problems may self-refer for foot care in the private sector, particularly in relation to podiatry and orthotics. Patients may also opt to have orthopaedic intervention in the private sector, although it is unlikely that the same access route applies i.e. self-referral. The researcher's personal knowledge of independent orthopaedic service provision, suggests the majority of patients who access independent care are referred by their GP.

Foot care services within Bristol therefore vary in terms of provision lead location (community or hospital based) and access. The target patient sample for the research studies in this thesis will sample patients with RA from both UHB and NBT rheumatology departments. However, the studies will also be community based to reflect the provision of the local primary care based podiatry services. Therefore, by taking only those patients registered with GPs within the BCH area, a direct comparison will be possible between the two hospital sites, as they will cover the same geographical area for primary and secondary provision. The rheumatology service provision in Bristol is similar to other centres in the UK in terms of multidisciplinary nature of care and long term RA follow-up patients (Kirwan *et al,* 2003). The findings may therefore reflect circumstances in other urban areas, although a more up to date survey of rheumatology and foot care services nationally may be warranted as a separate activity at a later date.

1.5 Funding of the research

The National Institute for Health Research (NIHR) funded the research in this thesis. The researcher was awarded a personal clinical doctoral research fellowship under the Clinical Academic Training Scheme for nurse, midwives and allied health professionals. The NIHR had no influence on the analyses, interpretation of research findings or publication.

1.6 Thesis structure

This thesis has been divided into seven chapters (including the current chapter). This introductory chapter is followed by two background literature review chapters. The background literature review chapters describe, critically appraise and discuss foot problems in general populations and in patients with RA, and empirical evidence and clinical reviews reporting non-pharmacological care of foot problems. The background chapters will also review the literature in relation to access and utilisation of health care in general terms and to foot care services in particular. The three interlinked studies of the thesis are presented as three separate chapters. The aims, methods, results and discussion for each study will be described in the relevant chapters. The thesis concludes with an overall discussion chapter which draws together the findings and conclusions of all three studies. Additionally the final chapter will describe this thesis contribution to knowledge, implications to clinical practice, organisation and delivery of foot care for patients with RA.

Chapter 2: The foot in rheumatoid arthritis

This chapter first explores foot structure, foot function and the prevalence of foot problems in general populations then goes on to review the literature relating to the prevalence, nature, consequences and impact of foot problems in rheumatoid arthritis (RA). It concludes with a review of empirical evidence and clinical opinions concerning the non-pharmacological management of the foot in RA.

2.0 Background

As the interface between the body and the ground, the foot has a significant role in human bipedal locomotion and is an essential component of the kinetic chain required for gait. Abnormalities involving any component of the kinetic chain can have consequences such as pain, altered function and subsequent deformities. In relation to the foot, gait abnormalities can cause “abnormal” stresses on the foot leading to development of foot deformity (e.g. Leardini *et al,* 2006). There is a substantial body of literature describing the influence of “abnormal” foot mechanics and development of foot problems in both general populations and people with specific health conditions (e.g. Cavanagh *et al,* 1997). Abnormal foot mechanics can have particularly significant clinical outcomes in patients with long term conditions. For example gylcosylation (adherence of glucose to collagen proteins) of the soft tissues in the diabetic foot can result in reduced skin and tendon elasticity. These features result in a limitation in the range of motion of the joints, abnormal loading on weight bearing, increased plantar pressures and subsequent callus formation, which individually and/or in combination can lead to ulceration (Shaw and Boulton, 1997). These clinical features, combined with “diabetic foot disease” (neuropathy, peripheral vascular disease and deformity) can have serious clinical significance and consequences (NICE NG19, 2015). However, the precise pathophysiology for development of foot problems in patients with diabetes is not fully understood (Allan, Munroe and Figgins, 2015). Nonetheless foot ulceration in patients with diabetes is widely recognised as the most common contributory factor for non-traumatic lower limb amputations (Reiber, Lipsky and Gibbons, 1998). However, global incidence of lower limb amputations is reported to be variable amongst developed and developing countries (Margolis and Jeffocate, 2013). In contrast the common clinical features of rheumatoid arthritis (RA) are joint pain, joint swelling and joint stiffness as a consequence of the inflammatory process (synovitis and joint effusion), which can lead to the destruction of articular structures (Firestein, 2003; Smolen *et al,* 2007). The inflammatory process can then lead to stretching and distension of joints (capsular distension) and supporting soft tissues (e.g. tendons and ligaments). This loss of stability increases susceptibility to deformity (Jaakkola and Mann, 2004).

However, the development of foot problems is not only limited to abnormal foot mechanics and function. It is widely accepted that such abnormalities increase pressure on soft tissues and can lead on to the formation of cutaneous lesions such as corns and calluses (e.g. Freeman 2002). Additionally, wearing restrictive footwear (e.g. shoes with a shallow or narrow toe box) can also be a contributory factor, particularly in the forefoot (Menz and Morris, 2005). Toe nails are a common site for pathology to develop due to trauma and infection (Cohen and Scher, 1992; Flint and Cain, 2014). Foot problems also include conditions affecting the soft tissues such as tendinopathies, plantar fasciitis, bursitis and Morton’s neuroma (benign fibrous lesions) (Ayub, Yale and Bibbo, 2005). Pathological involvement of the peripheral neurovascular system adds to the complexity and nature of problems that can develop in the foot.

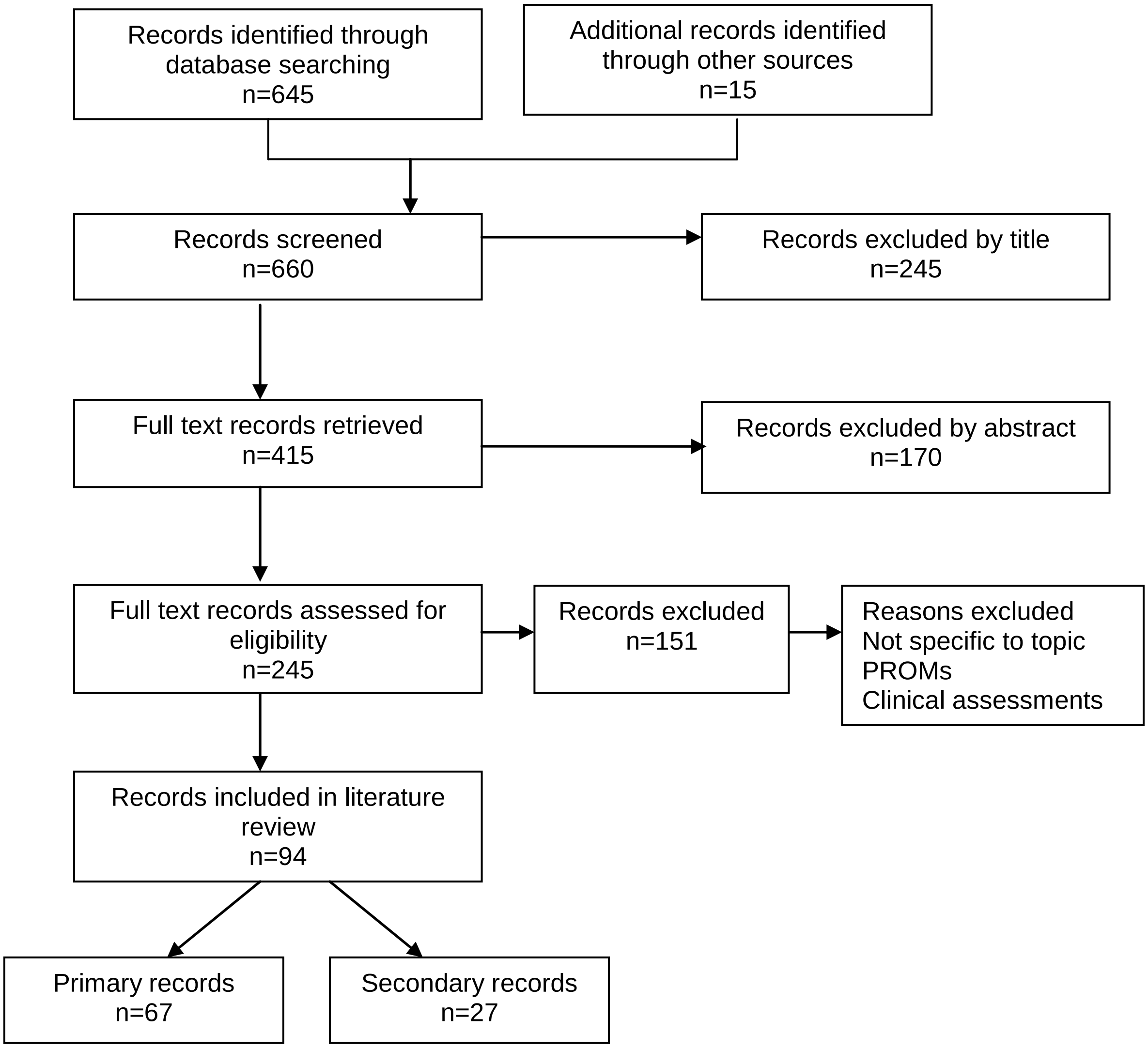
Quantifying the presence of a disease (health condition) in a population is of great value in the planning, organisation and delivery of health care. Measuring frequency of a condition can elucidate how common the condition of interest is in a population or the rate at which it is occurring (Feigin *et al,* 2014). It can also be used to plan and evaluate strategies for prevention and to assist the clinical management of patients who have already developed a health condition. In epidemiology terms “frequency” of a condition can be measured by prevalence (the proportion of the population with a condition at a defined point in time or over a specific interval), incidence (rate at which new cases of a condition occur in a population during a specific period of time) and mortality (death as a result of a health condition). All three are statistical terms for describing disease occurrence in a population (Coggon, Barker, and Rose, 2009). Information about the prevalence of a condition or event can be obtained from administrative data (e.g. amputation rates), clinical audits (e.g. number of patients with diabetes presenting with ulceration), clinical assessment (e.g. microbiology positive screening for hospital acquired infections) and self-report by patients (e.g. questionnaires).

One aim of this thesis is to investigate the prevalence and impact of foot problems in patients with RA. For the purposes of this thesis, the prevalence of foot problems is regarded as the development of a foot problem at any time since being diagnosed with RA. What is already known about foot problems in RA and gaps in our knowledge will now be assessed by a review of the literature.

Literature reviews may be narrative, systematic or quantitative systematic reviews (meta-analyses). The latter two are useful for establishing the level of evidence for the effectiveness of clinical interventions such as pharmacological interventions. Evidence generated from single studies can be limited due to small sample size. Combining the data from multiple studies investigating the same topic of interest and systematically identified to avoid omissions can therefore strengthen the evidence for the use (or non use) of an intervention. Additionally systematic reviews are valuable to investigate the evidence for a focused research or clinical question (Garg, Hackam and Tonelli, 2008). Although systematic reviews are generally considered providing the highest quality evidence they do have limitations. These include sampling and selection of studies (selective publication bias) and issues of heterogeneity (Eyseneck, 1994; Gopalakrishnan and Ganeshkumar, 2013). A narrative literature review includes a range of publications such as editorials (where the author synthesises information on a narrowly focused area of a small number of papers), commentaries (where the author presents their opinion), narrative overviews by acknowledged experts and studies using a range of methodologies investigating a topic of interest (Green, Johnson and Adams, 2006).

The areas of interest for this thesis (prevalence, impact and care of foot problems in RA) are broad and do not form a focused clinical question (e.g. “Are foot orthoses effective for reducing metatarsal pain in patients with RA?”). A pragmatic approach to reviewing the literature was therefore undertaken using a narrative literature review. A preliminary search identified literature reporting foot problems in both general and RA populations. To identify publications of interest the following search terms were used: foot, foot symptoms, foot pain, foot involvement, foot problems, rheumatoid arthritis, disability and impact. Databases searched for papers published in English were: CINHAL, MEDLINE, EMBASE and Cochrane Library. These databases were searched up until November 2015. Abstracts, full text articles, editorials, narrative overviews and commentaries of interest were retrieved for review. Those most relevant to the area of interest were initially retrieved for review. These included articles reporting foot problems in general and RA populations or where the focus was clearly on the prevalence and/or nature of foot problems. A subsequent “snowballing” approach was then utilised to identify further studies and clinical reviews from the reference lists of those already obtained (Greenhalgh and Peacock, 2005). Figure 2.1 presents the narrative literature reviewed undertaken.

Figure 2.1 Narrative literature review foot problems



2.1. Foot problems in general populations

To set foot problems in patients with RA in context, foot problems in general populations are first considered. The prevalence of foot problems (e.g. deformity, cutaneous lesions) and associated symptoms (e.g. pain) in the general population has been reported to increase with age, be more common in women, vary due to ethnicity and associated with prior use of particular footwear (Bevenuti *et al,* 1995; Dunn *et al,* 2004; Golightly *et al,* 2012; Dufour *et al,* 2009). Foot and lower limb problems resulting in decreased function, which can subsequently have a negative effect on quality of life and wellbeing, have also been described (Chen *et al*, 2003; Barr *et al,* 2005; Gorter, Kuyvenhoven, and de Melker, 2000).

Badlissi *et al* (2005) conducted a community based cross-sectional study of a random sample of older people (> 65 years). The aim of the study was to investigate association of foot problems (hallux valgus, toe deformities, pes cavus, pes planus, plantar fasciitis) and foot pain (self-report) with functional limitations (e.g. walking speed) using the self-reported Foot Health Status Questionnaire (FHSQ) (Bennett *et al,* 1998). The FHSQ has been shown to have good content validity (extent the questionnaire accurately captures information regarding foot health status), construct validity (extent the questionnaire measures foot health and correlates or not with other questionnaires quantifying foot health) and high retest reliability (level of agreement between results obtained by the questionnaire at different time points in stable populations) (Riskowski, Hagedorn and Hannan, 2011a). However, the content validity of the FSHQ has been questioned as items for inclusion were developed from focus groups with clinicians rather than patients (Walmsley *et al,* 2010). Data collected by clinical assessment showed over half of the sample had one or more deformities in the toes, and hallux valgus was observed in a third of the participants. Hallux valgus, toe deformities and foot pain were not however associated with slower walking time. The authors reported the odds ratio for foot pain in participants with plantar fasciitis was 14.4 (though with wide confidence limits of 4.2 to 50.6, indicating limited precision) and called for further work to investigate the risk factors and therapeutic interventions for the management of plantar fasciitis. However, the proportion of participants who had plantar fasciitis was small (6.9%). This study had a large sample size (n=713) and participants were a randomly selected community based population, and provides evidence that structural foot deformities are common in older people.

A survey of 156 randomly selected adults (women 90, men 66) conducted by Nancarrow (1999) investigated general health status, prevalence of self-reported foot pathologies and availability of health services in a rural geographical area. Data are presented on the report of foot arthritis, deformity (toe deformities, hallux valgus, pes planus), cutaneous lesions (corn or callus, toe nail problems), foot injuries and infection. Women reported higher prevalence than men of foot arthritis (30.8% versus 19.1%), toe deformities (15.1% versus 8.7%), fallen arches (14.9% versus 5.1%) and secondary skin lesions (corn and callus) (17.8% versus 14.5%). Infections and injuries were more common in men (10.2% versus 6.5%, 20.7% versus 8.7% respectively). Nancarrow presents data about a wider description of foot problems compared to Badlissi *et al* but the information was collected by self-report and was not confirmed with clinical assessment or review of clinical records. The results therefore depend upon the accurate recognition and appropriate reporting by respondents.

A multicentre case control study (cases 2452, controls 1913) investigated foot problems as risk factors for fractures in adults over the age of 45 years (Keegan *et al,* 2002). Cases are defined radiological confirmed fracture of proximal humerus, tibia or fibula and pelvis. Controls (no fracture at defined anatomical sites) were randomly sampled from the same hospital centres matched for age and gender. Data were collected by a standardised questionnaire (self-report). Categories of foot problems reported by the authors included toe deformities, bunions, corns, calluses, flat feet, high arches, ingrown toe nails and arthritis. Of the control group, 82.1% reported to have one or more foot problems. A range of categories of foot problems were reported. For example a third reported presence of calluses and corns (34.1% and 27.3%, respectively), 22.7% toe nail problems (ingrown toe nails and painful toe nails) and 19.4% reported to have bunions. Although the primary aim of the study was to investigate if foot problems were risk factors for fractures, the study provides further evidence that foot problems are common in general populations. However, prevalence data alone do not give an indication of clinical severity of foot problems or the clinical need for intervention.

A population based survey of 70,497 patients from 16 European countries undertaken to measure the prevalence of foot problems and comprised of two phases (Burzykowski *et al,* 2003). Phase 1 used “convenience” sampling of patients attending for GP and dermatology clinical consultations (irrespective of reasons for consulting) within the participating countries. The study inclusion criterion was consenting to clinical examination of their feet. Of the participating countries, 15 recruited patients to Phase1. Recruitment for Phase 2 also utilised “convenience sampling” of patients presenting for dermatology clinical consultations (irrespective of reasons for consultation or initial diagnosis), and patients consented to both a clinical and mycological examination of their feet. The authors use the term “foot diseases” capturing a range of foot problems categories. Categories of foot diseases included presence of fungal foot disease (tinea pedis), orthopaedic foot problems (toe deformities, pes cavus), metatarsal corns, viral infections (warts), skin diseases (eczema) and vascular disease (presence of ulceration, tissue necrosis). Additional categories of foot problems collected in Phase 2 included bacterial infections, connective tissue diseases (e.g. scleroderma) and toe nail pathologies. Women made up 57% of the sample and the most common “foot diseases” were: one or more orthopaedic condition (pes planus, pes cavus and toe deformities) which occurred in 20.4% (Phase 1) and 24.8% (Phase 2) and plantar metatarsal corns which occurred in 11.6% (Phase 1) and 9.6% (Phase 2). The frequencies of non-fungal foot diseases were broadly similar for both genders in each phase of the study (e.g. men 58.1%, women 56.2% in Phase 2). The study involved a large number of participants who had foot examinations from 16 European countries and supports the impression that foot problems are common in patients attending dermatology and GP consultations. The classification and categories of foot problems observed were similar for both Phase 1 and Phase 2. However, the study does have limitations. Firstly; the recruitment strategy was not a random sample. It is possible that patients attending dermatology clinics may be considered more likely to present with skin conditions (e.g. psoriasis). Data were collected using a standard questionnaire. However, data were collected by a number of assessors (physicians). A description of the training assessors received on the conduct of foot examinations, completing data collection forms or how the assessors were recruited is not given in the paper. Additionally, provision and access to health care varies across Europe. For example in the UK the health care system is publicly funded and mostly free to all at point of entry. In contrast France access requires initial self-funding which is later reimbursed from public funds. Although this study has a very large sample size, recruiting patients from particular clinical settings in multiple countries with variable health care systems raise issues of generalisability. Finally, although the study reports high prevalence of foot problems no measure of severity, impact and/or clinical significance of pathologies requiring further treatment are reported.

The reports briefly reviewed above suggest foot problems are common, vary between genders but do not necessarily increase with age. However, these conclusions cannot be definitive because of the methodological approaches of being hospital based studies, or community surveys of populations lacking heterogeneity, and/or age restricted.

Mølgaard, Lundbye-Christens and Simonsen (2010) conducted a community cross sectional study of randomly selected adults aged 18–80 years (864 women and 807 men). The purpose was to investigate the prevalence of foot problems, pain in the foot, leg and/or lower leg by self-report. Classification of foot problems included the self-report of general foot structure: pes panus (flat foot), neutral (neither flat foot nor high arched) or pes cavus (high arch) and regional pain with in the foot (toes, forefoot, midfoot, and rearfoot) and/or Achilles tendon. Foot pain in the last month was reported by 30.4%, of these 19.9% described consequences of limitations in activities of daily living. However, the prevalence of different symptoms was different in different age groups. The highest prevalence of toe and ankle pain was reported by older participants 60-80 years (10.5%, 14.1%) compared with 40-59 years (9.4%, 10.7%) and 18-39 years (5.6%, 5.6%). Forefoot, midfoot and rearfoot pain were more common in middle years 40-59 years (16.1%, 9.5%, and 6.7%) versus 60-80 years (11.2%, 5.6%, and 3.5%) and 18-39 years (10%, 9.0%, and 35%). The highest frequency of Achilles tendon pain was described by younger participants (18-39 years). Women reported more general foot pain overall (34.4%) compared to men (26.3%) in all foot pain regions with the exception of Achilles pain (women 4.8%, versus men 4.6%). Although this report is a more credible assessment of foot problems than the other more limited reports described above, the presence of foot pain is presented as a binary variable (yes / no) so an indication of severity is not apparent. The authors did report that foot pain limited activities of daily living (ADL) but did not use a validated scale to measure ADL, therefore limiting comparisons of the study findings to other populations.

Additional data relating to history of foot trauma, surgical intervention and/or co-morbidities in which foot pain is a feature (inflammatory arthritis, painful peripheral neuropathy and peripheral vascular disease) were not collected. The potential confounding effects of co-morbidities are therefore a limitation. Nevertheless, significant associations were found between foot pain and pain in the leg and/or lower back, and also with foot deformities. The study therefore demonstrates that foot pain is highly prevalent in a random sample of adults.

Hill *et al* (2008) conducted a two stage study of a community based cohort aimed at identifying the prevalence of health conditions to inform health policy and planning for a regional area of Australia. A total of 4,060 randomly selected individuals participated in the first phase (telephone interview). The second phase included attendance for a clinical assessment which included a self-completed questionnaire relating to demographics (age, gender), medical conditions (e.g. cardiovascular disease) musculoskeletal conditions (e.g. report of foot pain), physical activity levels (e.g. walking), and health related quality of life (Medical Outcomes Study Short Form 36 (SF-36)). Clinical assessments were conducted to calculate Body Mass Indices (BMI). Of the original cohort, 3,206 attended for a clinical assessment. Of these, 17.4 % reported foot pain in the last month. Women were 40% more likely to report foot pain. Factors associated with foot pain were increasing age and obesity. Additionally participants reporting foot pain had higher scores in each domain of the SF-36 compared with participants reporting no foot pain. Overall the study demonstrates that foot pain is common and is linked to quality of life, but the SF-36 is not a specific measure of the impact of foot health status and reported presence of foot problems does not give an indication of severity and/or clinical need for intervention. The total number of individuals invited to participate in Phase 1 is not reported, nor are demographic data of non-responders (decliners). Participation bias is therefore a consideration. This could be further exacerbated by not having similar information for the 25% who did not attend for clinical assessment.

An investigation about the impact of foot pain in relation to disability was conducted in a random sample of patients (18-80 years) from two general practices in the north of England (Garrow, Silman and Macfarlane, 2004). The study included self-report of foot problems (nail problems, callosities, corns, athletes' foot, verrucae, bunions / hallux valgus), location of musculoskeletal pain (self-reported on outline manikins of feet and lower leg) and foot related disability. Disability as a consequence of foot pain was measured using the Manchester Foot Pain and Disability Index (MFPDI (Garrow *et al,* 2000)). The MFPDI is a validated scale to measure general foot pain which is not condition / disease specific and includes items (questions) covering three domains: functional limitations, pain intensity and concerns about foot appearance. Of the 4,780 questionnaires posted 3,417 were returned. All patients reporting foot pain on the day the questionnaire was completed were invited for a clinical assessment including a foot examination. A random sample of 50 patients not reporting foot pain was also invited for a clinical assessment. Of the responders to the survey, 56% were female. Overall 10% of responders reported disabling foot pain at the time of completing the questionnaire. The portions of men and women reporting foot pain in the last month were similar (20% versus 24%). The most common sites of foot pain were plantar aspect of the heel, mid foot, 1st MTP joint and 1st toe. One or more foot problems were reported by two thirds of responders. Overall more women reported presence of corn / calluses, swollen feet and bunion compared to men (39% versus 20%, 16% versus, 6%, bunions 12% versus 3%; respectively). In contrast the proportion of men reporting athletes' foot infections (23%) was higher than women (11%). The frequency of toe nail problems reported was similar for both genders (24% versus 24%). However, the presence of all categories of foot problems diagnosed by a clinician (podiatrist) was greater than the self-report. Sensitivity for all categories of foot problems was <58% indicating a lack of agreement between the self-report of foot problems and those observed by clinical assessment.

This study presents the most comprehensive data regarding the prevalence and type of foot problems (deformities, skin conditions, infections injuries and previous surgery) of studies discussed so far. It confirms that foot pain is common in the general population. A further strength is the conduct of a foot examination in a selected sub-sample of patients. However, analyses demonstrate that patients may not recognise and therefore fail to report some foot problems for example “flat feet”. Thus data reported in the questionnaire may potentially be an under estimation of the prevalence of foot problems. Although the study target population was ‘randomly selected’ the authors do not report whether sampling included all the patients registered as the total number of patients each practice served. Generalisability of the study findings may be limited as gender and age are the only demographic variables presented. Nevertheless the study is strengthened by the methodological approach (community based random sample), the use of a validated questionnaire (MFPDI), large sample size, very high response rate (84%) and investigated levels of agreement between the self-report of foot problem with foot problems assessed by a clinician. This was a novel approach to investigating prevalence of foot problems.

2.1.1 Summary of foot problems in general populations

Foot problems cover a wide range of pathologies such as cutaneous lesions (corn, callus, toe nail pathologies), deformity (hallux valgus, pes planus, pes cavus), soft tissue pathologies (e.g. Achilles tendinopathy), which can individually and/or in combination lead to foot pain. Despite methodological weaknesses in some studies, the literature indicates foot problems are common in the general population. However, the majority of the literature report foot prevalence data by self-report. As discussed in Chapter 1 foot problems can be important additional features of RA. A review of the literature reporting foot problems in RA was therefore undertaken.

2.2. Foot problems in rheumatoid arthritis

Vainio (1956) conducted a review of 1000 hospital-based patients with rheumatoid arthritis (RA) and in 16% the initial symptoms of RA involved the foot and ankle. The prevalence of foot problems and ankle problems was similar for women and men (91% versus 85%). Michelson *et al* (1994) conducted an observational study of a convenience sample of 99 patients with RA involving a clinical assessment including information relating to general joint involvement and functional capacity (Steinbrocker, Traeger and Atterman, 1949) and presence of foot pathology (foot and ankle symptoms and foot deformity). Of the 99 study participants, 93 are reported to have experienced foot and/or ankle problems at some time since being diagnosed with RA. These studies were both hospital based, used “convenience” sampling, were conducted a long time ago and are therefore not likely to reflect the current RA patient population. The pharmacological management of RA has undergone substantial development in the time since both studies were conducted and reported. While both studies raise the possibility of foot problems being common clinical features of RA, neither provides a detailed clinical description of the nature and/or severity of foot problems in RA.

Speigel and Speigel (1982) considers the main complications of RA in the foot are a result of a combination of inflammatory disease and altered foot mechanics with weight bearing and its consequent mechanical loads contributing to further joint damage. The mechanics of the foot and ankle in RA may also be influenced by a combination of foot joint misalignment and lower limb tendon pathologies (Dubbeldam *et al,* 2013). The additional mechanical stresses of walking in a weakened musculoskeletal environment can lead to pain, deformity, secondary skin pathologies, deterioration in walking and activity levels and reduction in general wellbeing (Turner *et al,* 2008; Wickerman *et al,* 2004). The variable and unpredictable progression of RA coupled with complex anatomy, mechanics and synovitis are a challenge to the protection of foot joints from further damage (Smyth and Janson, 1997; Woodburn and Helliwell, 1997). There is a significant body of literature devoted to investigating the association between pathomechanics (abnormal mechanics) and foot problems in RA. A detailed review and critical appraisal of this highly specialist and technical topic is beyond the scope of this thesis. A review of the literature describing the specific clinical features of foot involvement in RA is presented and discussed next.

2.2.1 Forefoot involvement

Jaakkola and Mann (2004) consider forefoot pathology to initially develop as a result of synovitis involving the MTPs. Inflammation of the synovium leads to stretching of the joint capsule and supporting structures (ligaments and tendons). The loss of stability and the influence of weight on unstable joints further increases susceptibility to deformity. Smyth and Janson (1997) and Stainsby (1997) describe how instability of MTP joints can lead to displacement of the transverse metatarsal arch leading to “splaying” of the forefoot and eventual subluxation of the metatarsals. Additional features of forefoot involvement can also include fibro fat pad atrophy and displacement. Toe deformities can also occur as a result of contraction of the extensor tendons compensating for instability of the MTPs. The forefoot position is further influenced by abnormal ground reaction forces at the 1st MTP leading to the development of hallux valgus deformity. Deviation of the hallux then forces the lesser toes laterally. In an attempt to compensate for the abnormal forefoot mechanics, the lower limb and foot extensor tendons and soft tissues contract, contributing to deformities in the lesser toes (Saltzman and Vogelgesang, 1997). A review of a convenience hospital based sample of 200 patients with RA (194 feet) reports 59% of patients were observed to have hallux valgus (bilateral or unilateral) and 28% hallux rigidus (bilateral or unilateral) (Kirkup, Vidigal and Jacoby, 1977)

2.2.2 Midfoot and rearfoot involvement

Description of midfoot involvement as a clinical feature of RA is predominately reported in clinical observation studies utilising highly complex imaging techniques and biomechanical assessments (e.g. Woodburn, Barker and Helliwell, 2002). Synovitis of the joints of the mid foot is considered by some authors to be less common compared with MTP involvement (Smyth and Janson, 1997). Bouysset *et al* (1987) report talo-navicular involvement in 32% of patients with RA. Speigel and Speigel (1982) observed patients with shorter disease duration (<5 years) had fewer changes (deformity) involving the rearfoot compared with patients with longer disease duration (> 5years) (8% versus 25%). Pes planus (reduction in the medial longitudinal arch) and pes planovalgus (reduction in the medial longitudinal arch and valgus deformity of the calcaneus) are also considered to be additional features of rearfoot involvement in the foot (e.g. Turner *et al*, 2003). Additionally tibialis posterior tendon is considered to be an important extra-articular feature of rearfoot pathology in RA. The tendon can be a site of pain, tenderness and also dysfunction can result in reduction in hind foot function. The association of tibialis posterior dysfunction and development of pes planovalgus has received attention (Bouysset *et al,* 2003). However, the prevalence of pes planus in patients with RA has not been fully established. Involvement of the midfoot and /or rearfoot can result in alterations in foot function and subsequently result in abnormal gait (Turner *et al,* 2008)

2.2.3 Extra-articular features

Clinical features of RA are not only confined to articular joints (joint pain, joint stiffness and joint swelling), and associated clinical features (tendonitis, tendinopathies). Manifestations can also occur in the soft tissues such as: rheumatoid nodules (lesions comprising of granulation tissue, inflammatory cells and central fibrous tissue), adventitious bursa, neuritis (inflammation of the nerves) and vasculitis (inflammation of blood vessels) (O'Brien, Hart and Gould, 1997). Boutry *et al* (2003) evaluated the feet and hands of 30 patients with RA using magnetic resonance imaging (MRI). Over half of the study sample was found to have bursae present between or inferior to one or more MTP joints. Entrapment neuropathies and mild peripheral neuropathy also occur in the feet of patients with RA. For example presence of tarsal tunnel syndrome and sensory peripheral neuropathy has been observed in 13% and 7% of a group of patients with RA (McGuigan, Burke, and Fleming, 1983). Wilson and Kirwan (2006) reported reduced protective sensation in the feet in 58% of patients with RA. The different results in these two studies may be accounted for by different methods of assessments (electro diagnostic versus clinical screening tool).

2.2.4 Cutaneous lesions

Corns and calluses can develop due to mechanical stress (e.g. narrow footwear), abnormal mechanics (e.g. deformity) and increased stress (e.g. prolonged activity) Freeman (2002) proposes that the formation of corns and calluses is “a normal physiologic response of the skin to chronic excessive pressure or friction”. Deformity and abnormal mechanics can be clinical features of foot problems in RA. It is therefore possible to postulate that patients with RA with these features may be more likely to develop corns and calluses. Patients with severe deformity involving weight bearing joints with secondary callus formation may be at risk of developing foot ulceration (Vogelgesang, Shurr and Saltzman, 1999). Work conducted by Firth *et al* (2008) investigating the prevalence of foot ulceration in RA supports Vogelgesang’s, Shurr’s and Saltzman’s clinical opinions that patients with RA can develop foot ulceration. The prevalence of toe nail pathologies in RA is not fully known as the topic has received little attention.

2.2.5 Overview of clinical presentation of foot problems

This review of the literature indicates that foot problems in RA can be complex and multifactorial in presentation. Publications supporting this impression thus far are clinical reviews supported by some empirical evidence. The empirical evidence has methodological weaknesses (e.g. sampling small numbers) and was generally collected prior to the introduction of modern treatment paradigms for RA (e.g. biologics). However, both clinical research and clinical reviews have value in terms of a descriptive overview of foot problems in RA. The use of clinical outcome measures including patient reported outcome measures are considered to be essential to monitor disease progression and evaluation of treatment interventions (e.g. van Riel and van Gestel, 2000). The studies reviewed thus far have largely neglected the severity, consequences and impact of foot problems in RA. Studies reporting foot problems in more recent patient samples and/or inclusion of outcome measures will be reviewed next, focussing on observational studies presenting data using clinical assessments (imaging techniques and clinical examination) and self-report by patients.

2.3 Observational studies reporting foot problems in RA

Rojas-Villarraga *et al* (2009) conducted a hospital based cross sectional study investigating foot related disability in 95 patients with RA. Data were collected from foot examinations, measures of disease severity (Disease Activity Score (DAS), Prevoo *et al,* 1995) and general disability (Health Assessment Questionnaire (HAQ)). The foot examination was conducted by two examiners. Overall foot deformities were observed in the majority of patients (82%). Presence of hallux valgus (65%), lesser toe deformities (75%), reduced medial longitudinal arch and transverse arch (42%) were common. Dorsal and/or plantar calluses were observed in 73 patients. On assessment of the MTPs, 46% of patients were metatarsal squeeze test positive. Similar observations for one or more current foot problems and hallux valgus are reported by Göksel Karatepe *et al* (2010). In regression analysis conducted after adjustment for age, gender and disease duration, forefoot pain was associated with disease activity (DAS (adjusted odds ratio / AOR = 14.4; 95% CI, 1.6 -133.2: P<0.0001)) and disability (HAQ (AOR= 16.6; 95% CI, 4-69.3: P < 0.0001)). However, the wide confidence intervals indicate lack of precision of association. Further, the authors do not provide a detailed account of the examiners in relation to data collection. For example, were all participants were examined concurrently or simultaneously by both examiners? Levels of interrater agreement are therefore not known. The study was hospital based and used “convenience” sampling. The study sample may therefore be criticised for lacking representation and generalisability. However, demographic (age, gender) and clinical characteristics (e.g. disease activity and disability) are provided. Participation bias is also a consideration, in that is patients experiencing foot problems may have been more likely to consent to take part in the study. Nonetheless data reported indicates deformity, presence of calluses and clinical indications of inflammatory disease were common in the study sample.

Borman *et al* (2012) conducted an observational study of foot involvement in a randomly selected sample of 100 patients with RA. Method of randomisation is not available in the report. Of the sample, 89% of patients reported current or past foot involvement at some time. On examination, the most frequent site of pain was the ankle (30%), followed by forefoot, hindfoot and midfoot (30%, 17% and 7%; respectively). Other clinical features classified as “non-pain complaints” observed were: swelling (68%), numbness (51%), toe nail pathologies (37%), corns (24%), bunions (14%) and flat foot (11%). No significant correlation was observed between current foot pain and age or gender. The lack of association with gender could potentially be accounted for by the high number of female participants (male to female ratio 1:9). However, foot pain was found to be weakly associated with higher BMI, longer disease duration and glucocorticoid therapy (r=0.24, r=0.23, r=0.24 all p=0.01). As with Rojas-Villarraga (2009) *et al* study inter-observer reliability and therefore inference of the study findings is a consideration (data collected by more than one assessor). Data reported by Borman *et al* (2012) provide a broad description of current foot problems in a randomly selected patient group. Additionally the association of disease duration with the report of foot pain is of interest, raising the possibility that disease duration may be an important determinant of the development of foot problems in RA. Disease duration, foot pain and swelling of the ankle have been reported to be significant predictors of disability (Health Assessment Questionnaire scores) in patients with RA (Baan *et al*, 2011), further supporting the association of disease duration as a factor related to the report of foot pain.

A prospective longitudinal study of patients reports the prevalence and course of forefoot impairments and walking disability in a cohort of patients with early RA (n=848) followed up over an eight year period (van der Leeden *et al,* 2008). Data presented are sub-analyses of a cohort of patients participating in the Early Arthritis Study (Jansen *et al,* 2000). Measures of foot involvement were captured by clinical examination of MTP joints (reported pain and clinical indication of swelling in MTP joints), radiological examination of joint changes (erosions, joint space narrowing) and impairment of foot problems (lower limb domains of HAQ). At baseline, pain and swelling in one or more MTPs was noted on examination in 70% of patients, reducing to 40%–50% after two years. One or more forefoot erosions were recorded in 19% of the study sample at base line increasing to 60% after 8 years. Mild walking disability was observed in 57% at baseline, stabilising to 40% after one year. The study has particular strengths in relation to sample size. However, the attrition rate was high as only a third (n=239) of the original cohort attended for the study exit review. Attrition is a challenge for all longitudinal studies. Additionally the study assessed patients with early disease, focused on forefoot joint involvement and self-reported walking disability. However, the authors demonstrate the prevalence and severity of forefoot joint involvement increasing over the follow up period. The study raises an important clinical issue regarding the deteriorating progression of forefoot involvement in RA.

A longitudinal prospective cohort study of patients with RA (n=149) conducted by Hooper *et al* (2012) aimed to determine the prognostic factors associated with forefoot related disability using the Foot Impact Scale - FIS (Helliwell *et al,* 2005). The main clinical variables of interest were: the presence of forefoot bursae, metatarsophalangeal joint hypertrophy, metatarsal head erosions (determined by ultrasound imaging), and disease activity (van der Heijde *et al,* 1993). Disease duration and presence of forefoot bursae were significant determinants of foot impairment (r = 0.70, p = 0.009 and r = 0.16, p = 0.012, respectively). Disease duration, forefoot bursae and metatarsal head erosion were statistically significant factors associated with limitation in activity (r = 0.36, p = 0.002; r = 1.47, p = 0.006 and r= 1.14, p = 0.019, respectively). The limitations of the study relate to sampling strategy (hospital based, “convenience” sampling) and participation attrition (loss to follow up was 60%). However, the results support other studies reporting foot problems in RA that disease duration may be an important determinant of foot problems and foot related disability.

A clinical audit conducted in New Zealand by Rome *et al* (2009) observed foot problems (skin and nail pathologies, tissue viability,) foot function and structure (Structural Index Score (Platto *et al,* 1991)), footwear suitability (Menz and Sherrigton, 2000) and self-reported foot impairment (FIS). A convenience sample of 100 patients with RA attending for rheumatology medical review participated in the audit. The median disease duration was 15 years and female to male ratio was 4:1. Hallux valgus, lesser toe deformities and forefoot calluses were observed in 64%, 86%, and 63% respectively. Of the 100 patients who participated in the audit, 65% were classified as wearing inappropriate footwear. Moderate to high levels of foot impairment are reported. No analyses were conducted for correlation between foot pathologies and impact as quantified by the FIS or patient characteristics such as age, gender, and disease duration and/or disease severity. The primary aims of the work were to investigate the nature of foot problems and the impact of foot problems to support the review of foot care provision for patients with RA. Identifying factors associated with or predictors of developing foot problems were not aims of the audit.

Williams and Bowden (2004) conducted an audit of foot problems in patients with rheumatic diseases. The audit was not specific to RA but supports the findings of Rome *et al* that foot problems are common in patients with RA. The findings of clinical audits can be criticised for lacking methodological research. Additionally clinical audits can be considered to only be of value in relation to planning and evaluation of health care provision at a local level. However, the data reported in both audits are supported by the empirical evidence that foot problems are common, complex and can have functional impairment to patients with RA.

2.3.1 Overview of observational studies reporting foot problems in RA

In summary observational studies are beneficial in relation to providing an indication of the classification and categories of foot problems in RA. The studies discussed support the general clinical impression that foot problems can involve articular features (joint deformity), extra-articular features (bursae), cutaneous lesions (calluses) and structural deformity (hallux valgus).

Additionally observational studies provide an indication of how frequent (common) foot problems are in RA. However, they do not give an indication of prevalence in the general RA population. Further, the classification and categories of foot problems reported varies. Data regarding foot problems in RA can be obtained by clinical assessment and self-report by patients. Self-completed questionnaires provide the opportunity to sample a large number of patients simultaneously (e.g. postal surveys). Results of questionnaires can be used to estimate prevalence of a condition (disease) within a defined population. In order to identify the prevalence of foot problems in RA, a review of the literature reporting population surveys is required.

2.4 Studies reporting prevalence of foot problems in RA by self-report

Grondal *et al* (2008) conducted a survey of 1000 patients with RA using a convenience sample. Data were collected by self-completed questionnaires by patients. Items included in the questionnaire related to joint involvement (initial clinical presentation of RA and current joint involvement), foot problems and subjective walking difficulty. Patients were approached to participate in the study by direct contact with a member of the clinical team immediately prior to a clinical consultation. Almost all of the study participants were taking arthritis medications and a third were taking biologic therapies. Of the biologic group, the proportion reporting current foot joint involvement was 82%. The portion of patients in the non-biologics group was similar (79%). Of the whole study cohort, 71% described walking difficulty and the majority reported current foot problems (94%). Of these, 86% related to the forefoot, 52% rearfoot and 45% both rearfoot / ankle and forefoot joint involvement. The aim of the study was not to estimate the prevalence of foot problems in RA. Nonetheless the results of the survey indicate high levels of self-reported foot involvement in a large number of patients with RA.

Otter *et al* (2010) conducted a postal survey to measure the prevalence of foot symptoms (foot pain, numbness, swelling and stiffness), frequency of foot assessments and access to foot care services (podiatry, receipt of insoles, prescribed footwear and foot surgery) in patients with RA. To inform the content of the survey items were derived from focus groups of patients with RA and health care professional (podiatrists and rheumatologists). The study target sample consisted of two groups: 650 members of a national patient support group (National Rheumatoid Arthritis Society (NRAS)) and all patients attending for rheumatology clinical review at one NHS hospital site during one month (n=390). Of the 585 patients who returned questionnaires, 68.2% reported moderate to severe current foot pain. The most frequently reported sites of foot pain were the forefoot (40.3%) and ankle (25.5%). Women reported higher levels of foot pain compared to men. The proportions of responders reporting stiffness, swelling and numbness were 31%, 23, and 11%; respectively. In univariate analyses, current foot pain was significantly associated with BMI, disease duration, stiffness, swelling and numbness ($p = 0.001$, $p = 0.009$, $p = <0.001$, $p = <0.001$, $p =<0.001$). These variables were then used to investigate statistical relationships between the dependent variable of interest, foot pain and potential independent predictive variables. In a multivariate analysis only stiffness and swelling were significantly associated with current foot pain (OR 5.31, 95% CI 1.93 – 14.98 and OR 2.67, 95% CI 1.29 – 5.50, respectively). While supporting the growing body of literature showing foot involvement is common in patients with RA this study had the additional benefit of incorporating the patient perspective through items included in the questionnaire. However, the study does have some limitations. Firstly, the sampling of members of a national patients support group (NRAS) may be prone to membership bias particularly in relation to gender. Dures *et al* (2014) conducted a postal survey of patients with RA from 6 hospital sites and one national patient support group. Of the responders from the patient support group, 85% were female. In contrast of the responders to the survey from the combined hospital sites, 65% were female. Secondly, sampling patients attending for outpatient hospital appointments may have influenced patients' decisions to participate. The study may therefore be subject to participation bias. Furthermore, patients attending outpatients might be more likely to represent those with more severe disease and not be representative of the whole patient population. Thirdly, though a higher BMI was identified as a factor associated with current foot pain, the reliability and accuracy of self-report of body weight has been questioned (Kemp *et al,* 2000) and so caution is required in the interpretation of BMI derived from self-reported weight. Nevertheless the study provides useful data in relation to the prevalence of foot pain in a large sample of patients with RA.

The prevalence of foot ulceration in RA was investigated by Firth *et al* (2008). Data were initially collected through a postal survey. The accuracy of the self-report (foot ulceration) was investigated though review of clinical records and/or clinical assessment. All patients with a consultant diagnosis of RA within a fixed geographical boundary (n=1130) were sent a questionnaire by post. A response rate of 78% was achieved. Following validation the overall prevalence of foot ulceration was 9.7% and 12.3% reported current and/or previous ulceration. Validation review was possible for the majority of patients reporting foot ulceration. Of these 9.7%, 33% reported more than one area of ulceration. The anatomical locations of ulceration were: toes 51%, other forefoot locations 57% and rearfoot 15%. The validation of the self-report adds strength to estimating the prevalence of foot ulceration in RA. However, it is not clear whether all the patients included had similar opportunities to access foot care services.

2.4.1 Overview of the self-report of foot problems in RA.

The categories and classification of foot problems reported differs in these three studies but taken together they support the conclusion from observational studies and clinical reviews that foot problems are variable in presentation and some features are more prevalent than others, for example foot pain. Foot ulceration appears to be less prevalent. However, foot ulceration is an important clinical feature which has implications for patient care as these patients are at risk of developing soft tissue infection.

The large sample sizes of all three studies are strengths. Additionally the study by Firth *et al* indicates the self-report of at least some foot problems can be utilised with a high degree of clinical confidence. However, levels of agreement between self-report of other foot problems by patients with clinical assessment by health professionals, requires further attention. Furthermore prevalence of foot problems does not necessarily provide an indication of clinical severity and/or need for care and none of these studies take account of the availability of foot care services in different locations.

2.5 Management of foot problems in RA

The non-pharmacological management of foot problems in RA can involve multiple interventions such as treatment of cutaneous lesions, provision of foot orthoses, prescribed footwear and orthopaedic surgery. Helliwell (2003) advocates a multidisciplinary approach to the management of foot problems in RA is required to achieve improved clinical outcomes for patients.

2.5.1 Podiatry

Podiatrists are allied health professionals who specialise in the assessment and management of conditions affecting the foot and lower limb and recognised as members of the multidisciplinary rheumatology team (NICE GC79, 2009). Korda and Baliant (2004) endorse the role of podiatry in rheumatic diseases: “Podiatrists are experts on foot disorders: both patients and rheumatologists can profit from the involvement of the podiatrist”. Best practice professional guidelines and care pathways for the podiatric management of foot problems in RA have been published (Podiatry Rheumatology Care Association, 2008; Williams *et al,* 2011). However, a UK based survey of rheumatology services reported that the availability of dedicated specialist podiatry for rheumatic diseases services is variable (Redmond, Waxman and Helliwell, 2006). Recent expert opinion has called for podiatry interventions to be targeted early in the disease course and for regular monitoring to achieve "tight control" of rheumatological foot problems to optimise outcomes (Woodburn *et al,* 2010).

Treatments for reduction of cutaneous lesions (e.g. corns and calluses) and nail pathologies (ingrown toe nails) are routine interventions in podiatry practice. The MTPs are reported to be commonly affected joints (e.g. Grondal *et al,* 2008). Persistence of the inflammatory process, weight bearing on unstable joints and stresses experienced in gait can lead to increased focal pressure at the MTP joints with the formation of calluses (Sing, Bentley, and Trevino, 1996). Painful MTP calluses are recognised clinical features of foot involvement in RA (Woodburn and Helliwell, 1996), which require appropriate clinical management (Woodburn, Stableford and Helliwell*,* 2000; Davys *et al,* 2005). Siddle *et al* (2013) conducted a randomised controlled trial (RCT) of the therapeutic benefits of sharp callus debridement (reduction of callus using a scalpel blade) in 65 patients with RA with painful plantar calluses. The inclusion criteria were presence of reported painful plantar calluses and no previous exposure to sharp debridement. A "therapeutic approach" was adopted, including for each patient (if considered appropriate by the clinician): foot health education, self-management, casted foot orthoses, footwear advice, referral to physiotherapy and intra-articular glucocorticoid injection. In addition, the intervention group received sharp scalpel debridement at each of eight follow up reviews, if determined necessary by the observing clinician. Overall there were statistically significant differences between the groups in relation to measures of foot pain (Revised Foot Function Index, Budiman-Mak *et al,* 2006) impact of foot problem (FIS) and general disability (HAQ) at study exit (18 months). Although RCTs generally provide reliable evidence for the clinical effectiveness of interventions, the findings of this study may require careful consideration before implementation in general and rheumatology podiatric practice. Firstly, the study involved a relatively small number of patients. Secondly, the confounding and possibly interacting influence of the multiple interventions in the "therapeutic approach" is not considered or controlled for in the analyses. However, study participants were recruited from both specialist (hospital based) podiatry clinics and community foot clinics reflecting the provision of NHS podiatric services.

2.5.2 Patient education, self-care and self-management of foot problems in RA

The benefits and importance of patient education to support self-care and self-management of foot pathologies, particularly concerning diabetic foot ulceration, is well described in the literature and widely implemented in clinical practice (Jeffcoate and Harding, 2003; Boulton *et al,* 2005; Singh, Armstrong and Lipsky*,* 2005). In diabetes Rönnemaa *et al* (1997) conducted an evaluation of the influence of a podiatry education programme. Participants were randomised in to two groups; a podiatry group (treatment and education, n= 267) and a control group (written instructions only, n= 263). Patients in the podiatry group had greater improvement in knowledge scores relating to diabetic foot care and self-care (p = 0.004, p < 0.001). An RCT investigated the effectiveness of a foot self-management education programme for self-referring patients (over 60 years of age) compared with usual care (NHS community podiatry only (FOOTSTEPS, Waxman *et al,* 2003). Patients in the self-management group at study exit (6 months) had reduced disability scores (measured by Manchester Foot Pain Disability Index, Garrow *et al,* 2000) and had less treatment interventions during the study period compared with the usual care group (39 and 92 treatments respectively).

Waxman *et al* (2003) study provides useful information about the benefits of a self-management programme for foot problems in a general patient group. The self-management programme was subsequently evaluated in a consecutive sample (n=30) of patients with RA (Semple *et al,* 2009). However, over half of the study participants (57%) were unable to participate in self-care and self-management of their foot health needs (e.g. cut toe nails) due to functional impairment in the hands and elsewhere caused by their RA. Thus there is a paucity of evidence about the effectiveness of patient education and self-management programmes for foot involvement in RA (Graham, Hammond and Williams, 2011). Indeed, which strategies patients actually adopt for self-care and self-management of their foot health is not known.

2.5.3 Foot orthoses (Insoles / orthotics)

Published evidence and expert clinical opinion have promoted foot orthoses as interventions for foot involvement in RA (Gossec *et al,* 2006, Liqumani *et al,* 2006, NICE CG79, 2009). The use of foot orthoses as a treatment intervention for patients with RA is also supported by systematic reviews (Farrow, Kingsley and Scott, 2005; Hawke *et* *al*, 2008; Loveday, Jackson and Geary, 2012). The rationale for the use of foot orthoses for foot problems in RA are to: stabilise joint function, correct non-fixed anatomical mal-alignment, reduce pain, prevent deformity, support soft tissues, and improve or maintain function and range of movement (Helliwell *et al,* 2007). A large body of literature describes the evidence of the use of foot orthoses in an attempt to achieve some of these aims. However, a critical review conducted by Clark *et al* (2006) concludes that inconsistencies in the evidence from clinical trials are hindering the development of appropriate best practice guidelines for the use of foot orthoses in patients with RA. A more recent quantitative systematic review (meta-analyses) considered the evidence from 17 studies investigating the effectiveness of foot orthoses for foot and ankle problems in RA (Hennessy, Woodburn and Steultjens, 2012). Of the studies reviewed, the strength of internal and external validity was variable and the evidence that foot orthoses improve foot function and walking speed was inconclusive.

The use of foot orthoses in clinical practice is confounded by variation in the assessment and prescribing of foot orthoses. Types of devices available for clinicians to prescribe are also dependent on local service provision. Additionally patients can be provided with foot orthoses by a variety of health professionals (podiatrists, orthotists, physiotherapists, occupational therapist) in both the public and independent health care (non-publically funded) and commercial sectors such as pharmacies and sports retailers. These self-sourced foot orthoses may or may not be appropriate for individual patient's foot health care needs. In early disease the aims of foot orthoses are to prevent deformity, improve function and reduce pain (Forestier *et al,* 2009). In contrast in established disease, when deformity may have occurred or surgical intervention has been performed, the ethos of clinical care focuses on palliation, redistribution of pressure to prevent overloading and prevention of secondary skin lesion such as corns, calluses and ulceration (Hodge, Bach and Carter, 1999). However, the evidence for the longitudinal benefits foot orthoses in relation to preventing secondary skin pathologies in RA is currently limited in comparison to research conducted in diabetes.

In order for the therapeutic benefits of foot orthoses to be achieved, patients have to use the devices issued. A major consideration in choice of foot orthoses prescription and selection of construction materials is the accommodation of the devices in a patient's personal footwear. In some circumstances this will require patients to alter their choice of footwear. In routine clinical practice patients can experience difficulties in accommodating foot orthoses in footwear which is both cosmetically acceptable and commercially available. These issues can be limiting factors in patients' active participation and concordance with foot orthoses therapy.

2.5.4 Prescribed footwear

Difficulties relating to footwear are commonly reported by patients in clinical practice. Accommodation of deformities, foot orthoses (see 2.5.3) and fluctuating symptoms such as swelling and pain can be challenging for both patients and clinicians. Additional demands faced by patients are sourcing footwear that is comfortable, affordable and aesthetically acceptable (Goodacre and Candy, 2011; Naidoo *et al,* 2011). The use of prescribed footwear is commonly considered as a treatment option for general foot problems (e.g. congenital deformities) and those associated with RA. The therapeutic benefits of the use of prescribed footwear are further advocated by national, professional and clinical guidelines which recommend the provision of specialist prescribed footwear for patients with RA when required (Luqmani *et al,* 2006; NICE CG79; 2009; Podiatry Rheumatology Care Association, 2008).

Fransen and Edmonds (1997) conducted an RCT of patients with RA and self-reported foot pain (n=30) to evaluate the effectiveness of "off the shelf" specialist footwear. In comparisons between base line and post-footwear issue assessments, statistically significant improvements in scores of disability, walking pain and walking speed were noted. An observational cross over design study conducted by Chalmers *et al* (2000) compared semi-rigid foot orthoses, soft foot orthoses and supportive footwear (n=24). The findings support the combination of foot orthoses with prescribed footwear as interventions for painful forefoot involvement in RA. Hennessy *et al* (2007) compared the benefits of running shoes, "off the shelf" orthopaedic footwear and control footwear in patients with RA and chronic self-reported forefoot pain (n=20). The study was a randomised single blind, cross over trial. The aim was to quantify the benefits of the three different types of footwear in reduction of in-shoe peak plantar pressures. Mean forefoot peak plantar pressures were significantly reduced by 36% in the running shoe and 20% in the orthopaedic footwear compared with the control shoe. Cham *et al* (2013) report prescribed extra-depth footwear with rocker sole additions are beneficial in reducing foot pain, disability and function measured by the Foot Function Index (FFI

(Budiman-Mak, Conrad and Roach, 1991)). Female patients with self-reported foot and ankle pain, duration of RA > one year and disease activity score (DAS >1 <2.4) were recruited to the trial (n=17). At study exit (30 days) significant reductions in pain, disability and activity limitation were reported.

The emerging evidence indicates the use of foot orthoses, prescribed footwear and specific categories of footwear (trainers) may be beneficial interventions for foot involvement in RA. However, “good data are sparse” (Riskowski, Dufour and Hannan, 2011b). One reason for a dearth of research on footwear could be the resistance of patients to wearing prescribed footwear (Williams and Meacher, 2001; de Boer *et al,* 2009) therefore reducing participation in clinical trials. Comparisons between patients who have individual foot problems requiring a more bespoke (individualised) prescription for footwear is a further challenge to both study design and recruitment of patients.

2.5.5 Surgery

Orthopaedic surgery provides additional non-pharmacological interventions for the management of foot problems in RA. The overall aims of surgical intervention are to reduce pain, correct deformities and improve function. Numerous operative procedures have been developed for the surgical management of the RA foot. Procedures selected are often influenced by an individual surgeon’s personal preference and experience. Further, the use of non-surgical interventions such as foot orthoses and prescribed footwear are encouraged prior to and in conjunction with orthopaedic surgery (Trieb, 2005). As with all surgical interventions post operative complications are considerations. Patients with RA may be at risk of post operative complications as they have advanced deformities requiring complex surgical interventions (Nassar and Cracchiolo, 2001). da Silva *et al* (2003) conducted a retrospective review of orthopaedic interventions in a US based cohort of 609 patients with RA. They reported that 40% had under gone at least one orthopaedic procedure. Overall having RA related surgery was associated with younger age at diagnosis, rheumatoid factor positivity and subcutaneous nodules. Women had significantly more surgeries overall compared with men (8.6/100 per person per year, 4.0/100 per person per year). However, pharmacological interventions in management RA and the risk of post-operative issues (e.g. infection) are factors requiring consideration prior to performing orthopaedic surgery (den Broeder *et al,* 2007).

There appears to be a general reducing trend in the number of orthopaedic interventions performed in patients with RA. This may be related to advances in medical and pharmacological management. A retrospective review of medical records of patients with RA (n=813) conducted by Shourt *et al* (2012), reports 23% of the cohort having one or more orthopaedic surgeries over a 27 year period. The cumulative incidence of surgery reduced between the 1980-1994 cohort (27.3%) compared with the 1995-2007 cohort (19.5%). However, the trend was not statistically significant (p=0.08). No statistically significant difference was reported in the cumulative incidence of foot surgeries performed between the two groups (5.6% versus 5.3% p=0.99). In contrast a cross sectional multicentre study (Matricali *et al,* 2006) reports foot surgery to be common in patients with RA (n=285), with an increased trend of intervention observed in patients earlier in disease. Female gender and younger age are reported to be factors associated with foot surgery (Backhouse *et al,* 2011). This more recent study reports longitudinal data of a large sample of patients with early RA. The study is strengthened by the large sample size (n=1237). However data were collected between 1986 and 1998, potentially restricting the generalisability of findings to the current RA patient population. Nonetheless, there appears to be an overall reduction in the frequencies of orthopaedic procedures generally for patients with RA. However, despite the developments in the management of RA, foot problems are still common (see 2.3 and 2.4).

A multidisciplinary approach to foot care clinics has been advocated (Helliwell *et al,* 2003). And the researcher has herself taken part in such clinics for many years. These clinics employ a podiatrist, a rheumatologist and orthotist, and readily available access to other members of the clinical team (e.g. physiotherapist). Siddle *et al* (2011) report an evaluation of a combined orthopaedic and podiatry clinic (n=41). Base line and follow up (two-year) measures of impact (FIS) and pain measured on a 100mm visual analogue scale (VAS) were recorded. Of the 22 patients who had undergone surgical intervention significant reductions were reported for measures of impact (activity) and foot pain compared with patients who had not under gone foot surgery (p=0.051, p=0.002). Further evaluation of multidisciplinary approaches would provide valuable information about the best way to provide collaborative care for patients with RA and foot involvement.

2.5.6 Summary of care of foot problems in RA

Despite advances in the pharmacological management of RA to reduce disease activity and improve clinical outcomes, foot problems remain common. However, the prevalence of foot problems in the RA patient population overall has not been established fully. This has been hampered by limited categories and classifications of foot problems reported, failure to collect evidence about the severity and/or clinical need, and the use of patient populations that may be inherently biased towards greater severity of disease because they are attending specific hospital clinics and the use of self-report measures without validation against clinical observation. There is emerging evidence to support the use of non-pharmacological management of foot problems in RA. However, the evidence tends to focus on the clinical benefits of interventions as interpreted by health professionals (such as the ‘success’ of an operation). The patient perspective regarding their experience of foot problems and their beliefs of the perceived benefits and efficacy of foot care received has not been adequately explored Patients’ reasons for deciding whether or not to access foot care will also be important, therefore the next chapter considers access and utilisation of health care in general, and reviews the literature regarding access to and use of foot care services by patients with RA.

Chapter 3: Organisation of health care, access to services, barriers to foot access and the rationale for the three-phase research project

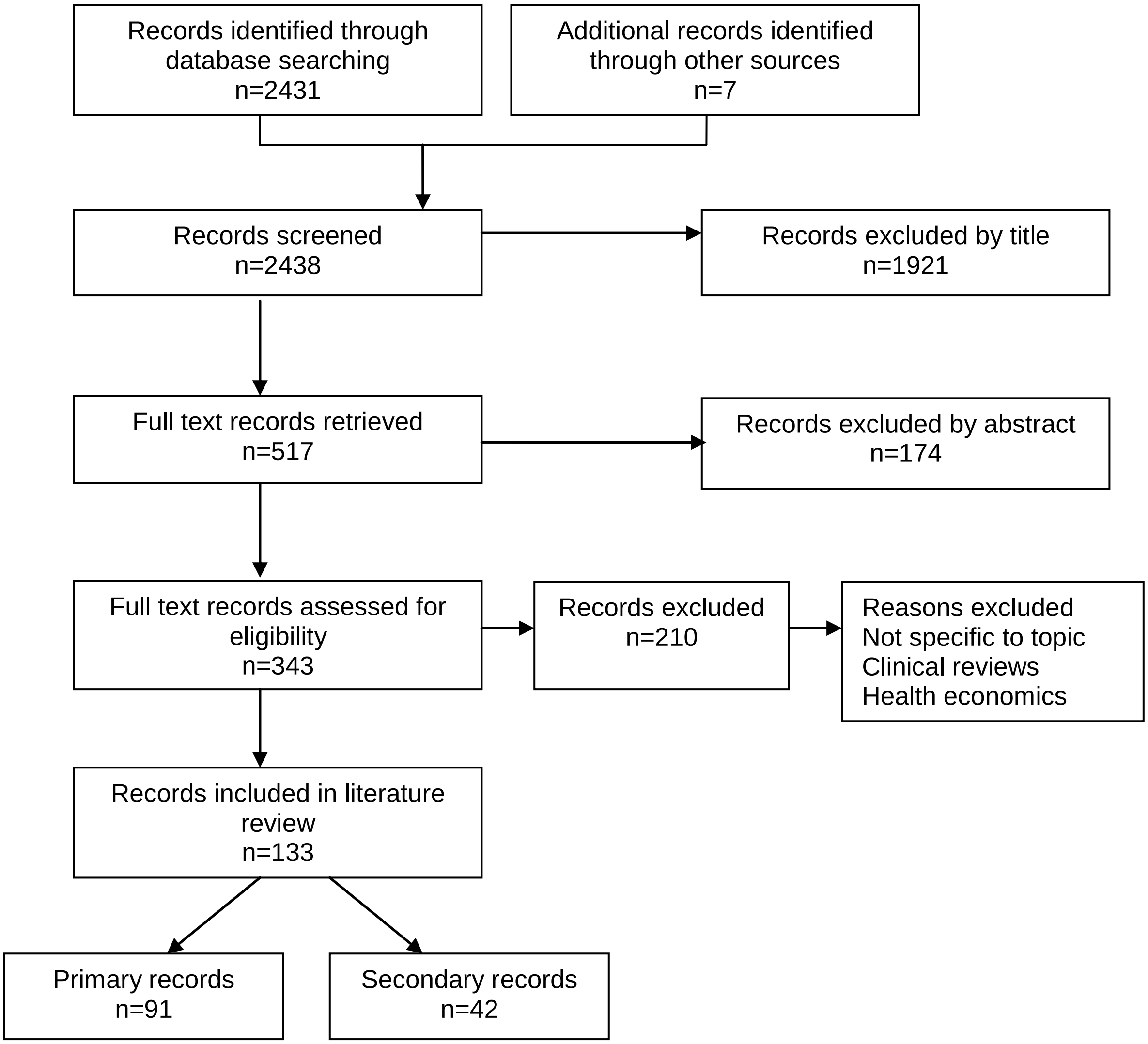
Whether or not patients receive adequate foot care for their RA depends not only upon the effects of their condition in general and on their feet in particular, but also in what way foot care services are provided and whether patients can gain access to them. This chapter considers access to and utilisation of health care in general, and reviews the literature regarding access to and use of foot care services by patients with RA. Models and theories of access to and utilisation of health care services are reviewed and determinants of access and utilisation of health care in general and specific populations considered. The rationale for the three-phase research project presented in this thesis is then developed from the information reviewed in Chapters 1, 2 and 3.

3.0 Introduction

Concepts of "health" are considered from different perspectives by two separate but interlinking disciplines, clinical practice and public health. Clinical practice tends to focus on the health of an individual (physical, mental and functional ability). In contrast the remit of public health is to maintain health in populations. An additional function of public health is health promotion (e.g. physical activity, smoking cessation, healthy nutrition) to prevent ill health and premature death (Mann *et al,* 1994). Public health considers access to and provision of health care as components that facilitate health in populations. Access and utilisation of healthcare are widely accepted as important determinants of health in individuals (Field and Briggs, 2001). In order to access health care there is a requirement for health services to be available (Gulliford *et al,* 2002). Organisation and delivery of health care varies considerably amongst developed and developing countries. Universal eligibility for free health care was amongst the founding principles of the National Health Service (NHS) in the UK. The majority of health care provided by the NHS is free at point of access, though there has been the emergence of some financial costs to service users which vary regionally (e.g. cost of prescriptions). Provision of publicly funded services incurs significant financial support for the system not only to function but to be maintained. Thus measurements of access and utilisation to health care are essential for both planning and delivery of services.

A preliminary review of the literature indicated that access to and use of health care in general terms is multi-factorial and complex. Factors acting as determinants of access are described and discussed extensively in the literature. Access to and use of health care is influenced by a number of predisposing factors (e.g. provision of services) and personal perceived need, the individuals perceiving / recognising the need to interact with health care. In relation to accessing foot care for disease specific conditions (e.g. RA), determinants of access to care appear to have received limited attention. A further narrative review of the literature was therefore undertaken. Databases searched in the narrative literature review were CINHAL, MEDLINE and EMBASE. These were searched up until November 2015. Search terms used were: access to health care, barriers to health care, determinants of access, health care use, health care utilisation / usage, fee, foot care, long term conditions and rheumatoid arthritis. Full text articles of interest were retrieved for review. A subsequent “snowballing” approach to identify further studies was then undertaken. Conducting literature reviews of complex issues can require a flexible and practical approach (Greenhalgh and Peacock, 2005). The narrative review, presented below, supported the initial impression that access to and use of health care in general is complex, that the evidence in relation to determinants of access to foot care is limited (particularly in RA) and that patients’ reasons for accessing foot care and their decisions to do so (or not) are poorly understood. Figure 3.1 presents the narrative literature reviewed undertaken.

Figure 3.1 Narrative literature review access to health care



3.1 Access to and utilisation of health care services

There are variations of the definition of the term “access” described in the literature. Some authors consider access as the reference to point of entry to health care whilst others regard access in terms of factors influencing entry or use. Additionally access may also be considered in relation to when care has been received (Campbell, Roland and Buetow, 2000) thus encompassing utilisation as a component of access to health care. In contrast Frenk (1992) considers access to health care to be influenced by an individual’s ability to request and obtain care as access is initiated by an individual’s perceived need to enter into the health care system. Levesque, Harris and Russell (2013) define access to health care as “access to a service provider or institution”. Penchansky and Thomas (1981) propose access to health care as a general concept comprising of specific dimensions (availability, accessibility, accommodation, affordability and acceptability). Additionally the authors consider access to health care not only relates to an individual’s ability to access care but also their readiness to enter and engage with the health system. Aday and Andersen (1974) consider access in terms of “having access” (ability to utilise a health service if required) and “gaining access” (initial introduction to the commencement of utilising a service). For the purpose of this thesis, access to health care is considered to comprise the point of entry to and use of health care.

The provision of health care services does not necessarily mean that individuals who require care will access those services. Thus there is a requirement to consider barriers to accessing health care. On the whole, NHS health care in the UK does not incur any financial implications to service users (patients). Nevertheless there is some regional variation in financial costs to patients such as prescription charges. However, provision of publicly funded health care is not universal internationally. For example, lack of health insurance in the United States is widely considered to be the most common barrier to health care (e.g. Ahmed *et al,* 2001; DeVoe *et al,* 2007). Gulliford *et al* (2002) suggest barriers to access from service users perspective should include personal barriers, financial barriers and organisational barriers. Personal barriers relates to the individual’s recognition of the presence of a health condition, acceptance of their need to interact (access / utilise) health care and consent to receive care. If an individual does not recognise, accept or interact with the health system, these authors consider barriers to care are due to individual choice rather than lack of provision. Financial barriers do not only encompass financial implication of funding care but also include the need for patients attending for clinical appointments to fund travel costs or take absence from paid employment. Additionally organisational barriers such as long waiting lists may result in a delay in patients accessing and receiving care. Goddard and Smith (2001) suggest barriers to health care may be influenced by service providers (supply side). The authors point to variation in the availability of health care and the quality of care provided, and these not being equitable to all groups or populations. Further, service users (patients) need to be informed of the availability of services and how to access care when needed. However, personal and organisational barriers are not the only issues to be considered. Carrieri and Bilger (2013) suggest the influence of clinicians (failing to advise), geographical location (residing in rural areas), organisational barriers (long waiting lists) and health beliefs (personal knowledge) are factors associated with underuse of health services.

In order for patients to access health care the services need to be available, relevant, effective and equitably distributed (Gulliford *et al,* 2002). Further, for optimal access to be achieved, Rogers, Flowers and Pencheon (1999) consider the organisation of health care to be an additional important factor “providing the right service at the right time in the right place”. In contrast, variations in the equity of access to health care in terms of supply and standard of care received is well described (e.g. Goddard and Smith, 2001). Access to and utilisation of health care is therefore complex and further exemplified by both variations in definition and interpretation of access presented in the literature.

3.1.1 Health care access and utilisation models.

Theories, models and theoretical frameworks have received attention as approaches to understanding the process of access to and utilisation of health care. Theories provide a description of the points where decisions are made to access or the process of accessing health care. In contrast models are regarded as visual representations of a set of interlinking variables (determinants) to present or test a theory. Proposed theories and models of health care access and utilisation are addressed in the sociology literature and the psychological literature. The terms “help seeking”, “health care seeking” and “access and utilisation of health care” are often used interchangeably within the literature. The term help seeking tends to be applied in the health psychology literature whereas health care seeking tends to be employed in organisation of health care publications, epidemiology and clinical literature. All three terms can be interpreted as relating to factors which may influence consulting behaviour (reasons for interacting with the health system). A number of theories and models as descriptors of access to and utilisation of health care are available in both the sociology and psychology literature.

In one example Parsons (1951) developed the sick role theory which evolved from role theory. The theory proposes that when an individual becomes unwell they adopt a role of being ill and therefore are unable to undertake certain tasks such as stay in employment. Society (other individuals) accepts that the individual is unable to perform certain activities as a consequence of being ill and recognises that experiencing illness is a negative experience or event. The theory also proposes the individual is required to access medical care and “comply” with treatment in order to achieve improved health and / or recovery. Suchman’s stage of illness and medical care (1965) proposes a five step linear approach to access to health care when an individual experiences ill health: 1) symptom experience; 2) assumption of sick role; 3) medical care contact; 4) dependant patient role; 5) recovery from illness. The pattern of illness (disease), medical treatments and provision of health care has changed dramatically since Parsons’ and Suchman’s work and therefore may not be applicable to current access to and use of health care. For example historically healthcare systems were organised to respond to acute illnesses and injury. The changing nature of health such as the emergence of long term conditions has required the organisation and delivery of health care to be reconsidered (Wagner *et al,* 2001). Additionally Parsons’ and Suchman’s work do not consider a number of further components such as health care access in long term conditions, or account for general characteristics as determinants of access (age, gender, and social deprivation), or service user satisfaction and/or personal priorities.

The Health Belief Model (HBM) is based on aspects of health behaviour in relation to perceived threats and perceived barriers and benefits. It was initially developed by Rosenstock (1966) in response to failure of use and lack of effectiveness of a public health screening program for tuberculosis conducted in the United States. The model was subsequently further reviewed and refined (Rosenstock, Stretcher and Becker, 1988). The HBM focuses on perceived susceptibility (the individual's beliefs about developing the health condition of interest), perceived severity (beliefs about how serious the condition is and what its consequences), perceived benefits (does the benefit of a health behaviour outweigh the cost), perceived barriers (beliefs about obstacles to performing the health action), cues for action (symptoms, education) and self-efficacy (an individual's confidence in their ability to perform the behaviour). The HBM has been applied to several aspects of health relating to screening programmes, participation in positive health behaviours (smoking cessation, physical activity, reduction in alcohol consumption) and long term conditions (hypertension, diabetes and cardiovascular disease) (e.g. Cerkoney and Hart, 1980). In relation to RA the HBM has been used when investigating medication adherence. DiMatteo, Haskard and Williams (2007) conducted a meta-analysis of the relationship between treatment adherence and patients' beliefs of disease threat, self-rated health status and objective disease severity. The authors concluded that severity of disease and personal awareness of disease severity was associated with greater patient adherence to medical care. However, patients with poor health (as defined by Illness Rating Scale (Roesnberg, Hayes and Perterson, 1988) as a consequence of a "serious" health condition (e.g. heart disease) were less likely to adhere to medical care. Patients' health beliefs and adherence to pharmacological therapies in RA has received attention (Goodacre and Goodacre, 2004; Neame and Hammond, 2005) but has not been applied to investigate predicting behaviour in relation to access to health care.

There are several other health behavioural theories and models in the psychology literature such as: Theory of Reasoned Action (Ajzen and Fishbein, 1980, Theory of Planned Behaviour (Ajzen and Madden, 1986), Social Cognitive Theory (Bandura, 1986) and Transtheorectical Model of Health Behaviour Change (Prochaska and DiClemente, 1997). Indeed a substantial body of literature is devoted to understanding and explaining health behaviour and determinants of behaviour. Probably the most used model in the literature is the Health Belief Model (HBM) discussed above. Detailed consideration of the advantages and disadvantages of the theories and models of health behaviour as determinants of access to and use of health care is beyond the scope of this thesis. Additionally although health behavioural theory is widely used and referred to in the literature, there is a paucity of empirical evidence investigating the comparability and predictability of the various theories and models as predictors of health care use. Health behavioural theories and models do have limitations. For example they assume that all individuals have equal access to the same information, do not account for the influence of social desirability, individuals' attitudes towards health behaviours and/or the combined influence issues towards health behaviour and behaviour change (Noar and Zimmerman, 2005).

Work conducted during the 1960s and 1970s led to the development of a model of health care utilisation (Andersen, 1995). The framework aimed to address some of the limitations of previous theoretical perspectives of health care usage. The model proposes that access to health care is dependent on three interlinking factors: predisposing characteristics (age, gender and marital status), enabling factors (income, access to health insurance, cost of access) and need factors (perceived health status, evaluated health status and customer satisfaction). Jacobi *et al* (2001) conducted a postal survey to measure health care use (accessed GP care, specialist care, allied health professional care, community social care) of patients with RA (n=757) and to estimate the relative contributions of gender, age, disease duration and co-morbidity to receiving appropriate and timely care. The authors utilised the model of health care utilisation as a frame work to investigate access and utilisation of health care services. Multivariate analyses demonstrated that age (<70 years), female gender, disease duration, additional morbidity and poor functional status explained most of the utilisation of services. Some general characteristics were also related to service utilisation. However, Andersen's model was developed based on experiences and observations of the US health care system. The model may therefore not be applicable to other health care systems in terms of describing access and utilisation of health care in other countries.

Following a narrative review of the literature it is apparent that access to and use of health care is complex. Although theories and models of access and utilisation provide a basis for understanding the processes they do not provide a full explanation why patients do or do not access health care. Clearly, for health care to address the needs of individuals and /or populations it needs to be available in an appropriate, timely and effective manner. However, provision of health care alone is not enough to ensure patients access and interact with the health care system. Perceptions of health status, health care systems, and care preferences vary between individuals (Strauss *et al,* 1993). It is largely accepted that general characteristics (age, gender, deprivation) and clinical characteristics (acute illness, long term conditions), availability, geographical location of services, care provided by lay support or family members and frequent interaction with health system (e.g. additional morbidity) are additional factors associated with access to health care. Further, patient (service user) satisfaction is widely used as a measure to assess quality of services provided and a valuable predictor of health related behaviour (Pascoe, 1983). Identifying factors related to and determinants of access to care is essential to planning, organising and delivery of services. Current evidence about specific characteristics as determinants of access to health care are considered and discussed next.

3.1.2 Influence of gender on health care access and utilisation

The literature and observations in clinical practice suggest women generally use more health care services than men (Hulka and Wheat, 1985; Bertakis *et al,* 2000; Courtenay, 2000). Malmusi *et al* (2012) report data from a national survey of self-rated health in which women reported significantly poorer health, reduced activity levels and higher prevalence of long term conditions (e.g. arthritis). Bertakis *et al* (2000) found women utilise primary care and diagnostic services more frequently than men. Hunt *et al* (1999) reports women to have higher consultation rates. However, the authors challenge the general assumption that consultation rates vary according to gender because when symptoms were experienced in long term conditions, men and women were equally likely to consult with a health care professional. The traditional assumption that women are more likely to access health care has been further challenged. A UK based survey conducted by Adamson *et al* (2003) reports the chance of men consulting for chest pain or self-detection of a lump in the axilla was similar compared with women.

The incidence and prevalence of health conditions can vary between genders due to genetic, hormonal and metabolic differences. However, Denton, Prus and Walters (2004) argue gender differences in health are more complex than these biological differences alone. The authors propose that gender differences in health are influenced by a combination of psychosocial variables (stress and life events), the influence of local environment (e.g. area in which an individual resides) and health behaviours such as smoking. If the notion that “health” varies between genders it is possible that access and utilisation of health care will also vary between men and women. This proposition is supported by Doyal (2001) who suggests access to health care in relation to gender is complex and not solely influenced by biological differences alone. Rather social, economic and cultural differences between men and women require consideration. Redondo-Sedino *et al* (2006) investigated health care usage in a Spanish population over the age of 60 years. A higher proportion of consultations with GPs were by women but no gender differences were observed for hospital admissions. The authors also suggest that being female, having more than one health condition and poorer health related quality of life are likely determinants of health care usage. Influences on health behaviours and access to health care are reported to vary between genders in patients with diabetic foot ulceration. For example there appears to be a tendency for women to be more likely to actively participate in self-care strategies. Conversely men are more likely to access care for acute problems (e.g. soft tissue infection). However, men are reported to have a more “laissez faire” / passive approach to self-care and rely on health professionals and family members to provide care (Hjelm, Nyberg and Apelqvist, 2002). In spite of the reservations of some authors, it remains accepted that in general women tend to use health care more than men. However, this may not be the case for specific conditions or long term conditions such as RA.

Gender as a determinant of access to health care for patients with arthritis has not been fully explored (Bradley, 2001). The frequency of joint replacement surgery for patients with inflammatory arthritis has been reported to be higher in women (e.g. da Silva *et al,* 2003). However, there appears to be a tendency that women undergo orthopaedic procedures when they have more severe arthritis and arthritis symptoms than their male counter parts (Katz *et al,* 1994; Hawker *et al,* 2000; Shourt *et al,* 2012). Backhouse *et al* (2011) report data of a longitudinal cohort study of patients with newly diagnosed RA. Female gender was independently associated with increased chance of undergoing orthopaedic interventions and with accessing podiatry services.

3.1.3 Influence of age on health care access and utilisation

The medical needs of older people can be both complex and substantial. For example the proportion of older people having more than one health condition has been estimated to be approximately 80% (Bates *et al,* 1995). The management of multi-morbidity in older people can also require complex medical and pharmacological treatment (Buurman et *al,* 2011). Some conditions are more prevalent in older people, for example osteoporosis (Ginalidi, Benedelto and Martinis, 2005) and so with advancing age, it is reasonable to postulate individuals are more likely to develop health conditions and functional impairments which in turn require access to health care.

Some foot problems (e.g. hallux valgus, corns, and calluses) are prevalent in both general and RA populations, as described in Chapter 2. However, the consequences of foot problems for disability and impact on activities of daily living (e.g. walking) are particularly relevant in the elderly (Benvenuiti *et al,* 1995; Griffith *et al*, 2010). Additionally older people are at high risk of developing other significant foot problems from non-arthritic causes (e.g. peripheral vascular disease) (Plummer and Albert, 1996). Older people are reported to recognise common foot problems and seek appropriate care for the foot health care needs (Gorter, Kuyvenhoven, and de Melker, 2000). Jacobi *et al* (2001) conducted a postal survey of 725 patients with RA to quantify access and use of additional health care services (non-rheumatology care). The authors conclude that overall most patients received appropriate additional care. However, younger patients (<70 years) were more likely to receive allied health care (e.g. podiatry) than older patients (>70 years). As RA is a long term condition it is reasonable to envisage that longer disease duration and older age may increase the chance of developing foot problems. Additionally these factors may also influence access to foot care simply through increased experience of living with the condition. To what extent age is a determinant of access to foot care for patients with RA therefore requires further investigation.

3.1.4 Influence of social deprivation on health care access and utilisation

The link between social deprivation, ill health and associated health outcomes is well established. Social deprivation can be measured at the individual level (e.g. personal income, education attainment) or area level (e.g. proportions of persons unemployed, social class). Alder and Newman (2002) propose social deprivation as a major determinant for the need of health care (e.g. limited ability to source and fund health care), environmental exposure to potential pathogens (e.g. industrial waste) and health behaviour (e.g. smoking). Further, social deprivation has been shown to be associated with increased hospital admissions (Zhao *et al*, 2011) and subsequent mortality (Conway *et al,* 2012). Comparing the findings of studies relating to access and utilisation of health care the role of social deprivation is not clear, in particular in relation to the heterogeneity of health care systems and variations in measurement of social deprivation (Hussey *et al,* 2009). For example despite the provision of a universal publicly funded health service, social deprivation continues to influence health outcomes in the UK (Smith, Bartley and Blane, 1990; Knowles *et al,* 2006). Indeed, measures of social deprivation are widely considered in the planning, organisation, delivery and subsequent funding of health care services and capturing health inequalities not only in the UK but internationally.

Measures of social deprivation have been applied in studies of patients with RA in relation to aetiological risk factors, assessment of health outcomes and health care utilisation. For example Pedersen *et al* (2006) investigated association of individual level indicators of social deprivation (education and economic status in childhood and adulthood) as associated risk factors of developing RA. The authors concluded that shorter duration of formal education was a risk factor for developing rheumatoid factor positive (RF positive) RA. This supports previous work by Bengtsson *et al* (2005). Area level social deprivation (Townsend Index score, Townsend, Phillimore and Beattie 1988) has also been reported to be related to developing RF positive RA (Mackie *et al*, 2012). Additionally, a relationship between higher levels of social deprivation and poorer health outcomes in patients with RA has been reported in terms of higher disease activity, poorer physical function and emotional aspects of mental health (Harrison *et al,* 2005; Margaretten *et al,* 2011).

Utilisation of health care services by patients with RA has been shown to be associated with disease related features (e.g. measures of disease activity) and social deprivation in relation to formal education (Jacobi *et al,* 2001). Patients with RA who completed university level education were found to be statistically more likely to access allied health professional (AHP) services compared to patients with shorter time spent in formal education. Jacobi *et al* define access to an AHP as having accessed physiotherapy, occupational therapy and / or podiatry. However, it is not possible from the data presented to assess the influence of social deprivation as a determinant of access to foot care. Social deprivation may increase use of health services because of more severe disease, or may decrease use of health services because patients are less likely to make use of them.

3.1.5 Influence of additional morbidity on health care access and utilisation

The number of people diagnosed and living with more than one health condition (co-morbidity / multiple-morbidity / additional morbidity) is increasing (e.g. van der Akken *et al,* 1998; Vogeli *et al,* 2007). Multiple-morbidity would seem to be more common in older age (Wolff, Starfield and Anderson, 2002; Marengoni *et al,* 2011). However, a UK study of a national primary care data base conducted by Barnett *et al* (2012) reports the prevalence of multi-morbidity to be similar in primary care patients under 65 years compared with older patients. Morbidity and multiple-morbidity are reported to be more prevalent in deprived areas compared to more affluent areas (Eachus *et al,* 1996; Barnett *et al,* 2012). Individuals with multiple health conditions are considered to have poorer health outcomes (e.g. higher mortality rates) and to be more likely to access primary care (France *et al,* 2012) and secondary care (Glynn *et al,* 2011; Payne *et al,* 2013). Salisbury *et al* (2011) conducted a retrospective cohort study investigating the relationship between multiple-morbidity, primary care consultation rates and continuity of care. While multiple-morbidity was frequent in the general population, it accounted for over half of all primary care clinical consultations. Similar conclusions regarding the association of multi-morbidity and health care utilisation are described by Westert *et al* (2001). Of interest, Westert *et al* report the presence of musculoskeletal diseases (back problems osteoarthritis, rheumatoid arthritis and/or other rheumatological problems) in conjunction with other long term conditions as related to increased health service utilisation.

The presence of additional morbidity in RA is common (Mikuls, 2003; Michaud and Wolfe, 2007; Gullick and Scott, 2011). Nevertheless, the influence of additional morbidity as a determinant of health care utilisation has not been fully explored. Patients with RA often require regular interaction with the health care system, for example for monitoring of pharmacological therapy (e.g. haematological testing) and patients with co-morbidity may require greater contact with health care. Consequently co-morbidity in RA may be an additional determinant of health care use.

3.1.6 Influence of service user satisfaction on health care access and utilisation

A patient's experience of and satisfaction with care received is now considered an important outcome in measuring the quality of health care (e.g. Llanwarne *et al,* 2013). It is reasonable to postulate that patients who are satisfied with the care they receive may be more likely to continue to use services. One component of satisfaction is the relationship between patients and clinicians. Positive relationships between health service users and health care providers have been identified as a factor associated with further access to and utilisation of health care (Thiede, 2005). Yuen (2012) reported that patients with diabetes are more likely to access additional preventative care and screening if directly advised to do so by a clinician. However, poor communication between health professionals and patients can result in patients not acting on self-care and self-management advice (e.g. self-checking feet) (Gale *et al,* 2008). Patients' perceptions of communication with clinicians may vary with age. Devoe, Wallace and Fryer (2009) propose younger patients have higher expectations of the health encounter in terms of appropriateness and personal control of their care. In contrast older patients prefer continuity of care and perceive the clinician (health professional) to be responsible for their health care. Additionally Campbell, Ramsay and Green (2001) conclude older patients more positively evaluate their health care needs being met during clinical consultations compared to younger patients. The authors also propose that older people have higher clinical consultation rates due to multiple health conditions, therefore have more contact with and become more familiar with their primary care clinicians. Patients' perceived appraisal and satisfaction of clinical encounters is also reported to have an impact on concordance with medication and subsequent re-engagement with health care (Snelgrove, 2006).

3.1.7 Summary of health care access and utilisation

From this narrative review it is evident that access to and utilisation of health care in general terms is complex. A number of predisposing factors such as general characteristics (age, gender, social deprivation), clinical characteristics (nature of illness acute or long term, additional morbidity), experience and satisfaction of care received appear to influence individuals in their decision to access the health care system or not. It is acknowledged there are additional characteristics influencing access to health care in society at large, such as ethnicity, marginalised populations (vulnerable groups) and personality type. However, these additional characteristics as determinants of access or barriers to health care are beyond the scope of this thesis. How access specifically to foot care services is influenced by the characteristics considered above in general and in RA patient populations are considered next.

3.2. Foot problems and access to health care

3.2.1 Foot problems in General Practice consultations

In the UK general practitioners (GPs) act as gatekeepers to additional health care services. GP consultation rates for clinical review of foot and lower limb problems can therefore be seen as indicating a combination of prevalence and patient-perceived severity, in that patients consider their foot problems to be sufficiently significant to seek medical care. Consultations rates may reflect patients' beliefs regarding the effectiveness of treatment. A study of GP consultations reported that 8% of all consultations were for foot and ankle problems (Menz *et al,* 2010). Jordan *et al* (2010) investigated musculoskeletal consultation rates recorded by 12 UK general practices over a 12 month period. The most common musculoskeletal consultation overall was about back problems (591 consultations per 100,000 registered patients). Although foot problems were the most frequent consultation category for children (14% of all consultations for children < 15 years), for adults the consultation rates for foot problems increased with age and were similar for both men and women. An earlier Dutch survey of GP consultation rates conducted by van der Waal *et al* (2006) reported 142 consultations for lower limb problems per 1000 registered patients. Of these, the highest frequency was for knee complaints (14.2 per 1000) followed by foot and toe complaints (13.7 per 1000). Consultation rates for foot and toe problems were similar for both genders in children (0-18 years) and for the elderly (>80 years). Statistically significant differences are reported for consultation rates for foot / toe problems in middle age (> 30 years < 80 years) with women consulting more frequently than men. These studies indicate that foot problems are common but do not provide information about specific health conditions such as diabetes or RA, nor do they provide a description of the nature and severity of foot problems or the need for specialist foot care (e.g. podiatry or orthopaedics).

3.2.2 Foot problems and podiatry consultations

Farndon *et al* (2009) conducted a service evaluation of podiatry in rural, semi rural and urban populations using the Podiatry Health questionnaire (PHQ) (Macran *et al,* 2003). The PHQ was developed by NHS regional podiatry managers and academics to measure clinical outcome but has not been validated. Questionnaire items relate to limitation in walking, foot hygiene, nail care, foot pain, impact on quality of life and clinician global measurement of severity of current foot problems. Data were collected immediately prior to the podiatry appointment from 1,047 patients (64% female). Most (81%) were classified as having mild or moderate foot problems. While most patients (75%) reported that their foot health and pain had improved or was stable after treatment, 25% reported an exacerbation of foot symptoms following treatment. Whether these results, from a non-random sample of patients who had already accessed podiatry, can be generalised to other NHS podiatry departments is debatable, but the result clearly gives cause for concern. For example a quarter of responders reported an exacerbation in symptoms following treatment. Further, the PHQ was developed by service managers with a direct interest in the provision of the service and without reference to clinician or patient involvement, and has not been validated. It may therefore omit important clinical and patient oriented outcomes.

3.2.3 RA foot problems and access to foot care

In a retrospective secondary analysis of data collected from a multicentre UK-based inception cohort following the first 9 years of RA, 30% accessed podiatry care, 16% were reviewed by an orthotist and 4% had undergone foot surgery (Backhouse *et al,* 2011). Increasing age and being female were associated with accessing podiatry. In contrast younger females were more likely to have undergone foot surgery. Data relating to range of joint motion and the presence of extra-articular features (nodules) are presented, but other clinical features such as classification of deformity, presence of cutaneous lesions, reasons for access to podiatry, orthotics and orthopaedics, and care received are not described. Although the study is strengthened by the length of follow-up and large sample size, patients were recruited from 1986 to 1998, before the introduction of modern pharmacological paradigms (e.g. biologics). Access to foot care of patients with early RA before modern treatment approaches were adopted may not reflect the current general RA population.

Marsman *et al* (2013), in a Dutch based longitudinal study of patients with RA with short disease duration, subsequently followed up over 15 years, found accessing podiatry to be more common earlier in disease (33% in first year) but the number of patients reviewed by orthopaedics (5%) or a multidisciplinary foot clinic (8%) was small. This study reported only foot care accessed in secondary care where the rheumatologist acts as the gate keeper, and did not record other routes of access. Access to and the provision of foot care, and the professional remits of service providers, varies in different health care systems. Additionally foot care services can also be provided in the independent (self-funding) sector.

The work conducted by Backhouse *et al* and Marsden *et al* demonstrates the common occurrence of foot involvement in RA and shows that access is variable and potentially inadequate. However, both studies recruited patients early in disease and so the study findings may therefore not reflect the current general RA population. This has been addressed in part by Juarez *et al* (2010) who conducted a postal survey of a randomly selected sample of 1200 with inflammatory arthritis registered for medical care at one hospital site. Response rate to the survey was 37.7%.Of the respondents, 83% reported a diagnosis of RA, 14% psoriatic arthritis (PsA) and 3% ankylosing spondylitis (AS). The survey included an adaptation of the Arthritis and Musculoskeletal Alliance (ARMA) audit tool (Podiatry Rheumatology Care Association (PRCA) Standards Project, 2008) relating to access to foot care services, patient education on self-care of foot problems and overall satisfaction rates of rheumatology service provision. Of the total sample 68% reported current foot problems, 24% had undergone a foot examination within 3 months of diagnosis and 31% reported they had access to foot care specialists. However, categories and classifications of foot problems are not defined; therefore a detailed description of the nature and severity of foot problems is not known from these data. Additionally foot care specialists are not defined nor are the location of foot care service provision (hospital based or community base). Nevertheless Juarez *et al* (2010) work supports the literature in that foot problems appear to be common in patients with RA.

In an observational hospital study of 100 patients with RA (Borman *et al*, 2012) the majority (89%) reported current foot problems. Ankle and/or forefoot pain was reported by one third of patients. Other foot problems observed and reported were: swelling in the foot (68%), numbness (51%), nail pathologies (37%) and corns (24%). Nearly half (49%) reported difficulty in being able to self-care and self-manage their foot symptoms. Of those who had accessed foot care, 39 had been issued with prescribed footwear and/or issued with insoles but 59% of these had stopped using their devices. Although the study has its limitations in terms of sampling (non random sample) and was hospital based, it supports clinical observations that foot problems in RA are multifactorial (e.g. joint pain, deformity and formation of secondary skin lesions) and gave clear indications that patients experience difficulty with self-managing their foot problems.

Otter *et al* (2010) conducted a postal survey of 990 patients with RA. The target sample for the study comprised of 650 members of a national patient support group and 340 patients attending an outpatient rheumatology appointment during a one month period. A total of 585 returned completed questionnaires. Almost all of the respondents reported foot pain at some time since being diagnosed with RA and the majority (68%) reported daily moderate to severe foot pain. Of the 585 respondents, 64% had seen a podiatrist and 30% an orthopaedic surgeon. Over half (54%) had been prescribed foot orthoses and a fifth (21%) had been issued with prescribed footwear, though only 56% of these were still using the devices issued. A major strength of the study is the large sample size, although the nature of the sample selection process may have been biased towards those with more severe disease and greater problems with their feet. No information is reported in relation to non-responders clinical demographics (e.g. disease duration), therefore the influence of bias cannot be confirmed or refuted. Data were not collected investigating patients' reasons for accessing foot care or referral routes of access (self-referral or clinician initiated). Previous authors have shown that the provision of dedicated foot care services is variable (Redmond, Waxman and Helliwell, 2006), and limitation in service provision may be a barrier to access. The relatively high access to podiatry reported by Otter *et al* may be due to good local provision of NHS specialist podiatry provision (personal communication with the author) and this, together with the potential response bias in the sample selection means the generalisability of the study findings to the wider patient population may be limited.

3.2.4 Foot problems and other care providers

The assessment and management of foot problems are not confined to the remit of GPs but can be provided by other clinicians such as podiatrists, orthotists, physiotherapists and medical specialists in both public funded and private health care systems (Gorter, Kuyvenhoven and de Melker*,* 2000). The professional remit of other health professionals providing treatment for common foot problems includes: nail care, corn and callus reduction, prescribing and issuing foot orthoses and wound care (Bálint *et al,* 2003; Apelqvist and Larsson*,* 2000). The GP is often considered the “gate keeper” of access to health care in general. However, access to additional health care provided by AHPs (podiatry and physiotherapy), particularly in the independent (private) health care sector is not reliant on GP initiated referral. A community based survey of older people conducted by Harvey *et al* (1997) concluded there was a high level of need for professional foot care which was not met by adequate service provision and as a result respondents’ foot health care needs were met by family members. The extent to which access to independent (self-funded) foot care for patients with RA or reliance on lay support (family members) to provide basic foot care is not known.

3.3 Barriers to accessing foot care

3.3.1 Barriers in relation to Podiatry

Best practice guidelines advocate the development and implementation of specialist podiatry services for managing foot problems in RA (Podiatry Rheumatology Care Association, 2008). However, Hendry *et al* (2013) propose there is a lack of podiatrists specialising in the management of inflammatory arthritis. Williams *et al* (2013) report the results of a survey conducted on a convenience sample of podiatrists (n=245). The majority of responders (93%) were classified as non-specialists clinicians (podiatrists not specialising in management of foot problems in rheumatic diseases) and almost all (97%) were unaware of the best practice guidelines. Lack of rheumatology specialist knowledge among non-specialist podiatrists might hinder the implementation of the guidelines. The reasons may be due to limited dissemination of the guidelines and each individual practitioner’s clinical interests (general podiatry, diabetes, sports medicine and non-inflammatory musculoskeletal conditions). Although continuing professional development (CPD) is not only essential to maintain and improve clinical standards and is also a statutory requirement for professional registration with the Health and Care

Professionals Council (HCPC). Nevertheless maintaining CPD can be a challenge for clinicians in terms of personal time and financial resources. Furthermore, as Hendry *et al* (2013) point out, non-specialist practitioners working in isolation may not have the required knowledge and skills to manage the complex clinical features of some foot problems in RA. Current professional expectations of the ability of non-specialists to manage foot problems in patients with RA may need reconsideration for best practice guidelines to be implemented.

Lack of knowledge of the scope of podiatry practice among other health professionals (particularly medical practitioners) may limit referrals and hence access to foot care. As Brodie (2001) comments (p.175) “Podiatrists may consider themselves to be experts, but how many medical students in training get to know who podiatrists are or what they can do. How many foot problems or potential foot problems are not passed onto the podiatrist for lack of knowledge about the profession and its role?” Additionally, the wider health community needs to be knowledgeable / informed about the provision of and access criteria for local podiatry services. One qualitative study suggests that low access to podiatry may be due to lack of focus on feet during rheumatology consultations (Williams and Graham, 2012). The continued use of the dual titles of podiatry (used by the majority of NHS departments) and chiropody (used by some HCPC registered clinicians working in the independent sector) is an additional complicating factor (Vernon *et al,* 2005).

Foot health education is a component of the podiatrists’ clinical remit (Williams *et al,* 2011). A qualitative study conducted by Graham *et al* (2012) explored podiatrists’ perspectives of the nature and content of foot health education for patients with RA and barriers to foot health education provision. Participants considered patient education a key component for podiatric management of foot problems in RA. However, a number of barriers were identified to providing it such as lack of time, lack of resources, inadequate training in consultation skills and motivational interviewing techniques. The study found the most common time for delivery of foot health education was during clinical consultations, which included verbal communication supported by written information. There were very few who used group education sessions or patient support websites.

Patients’ knowledge of the availability of podiatry services and their experiences and beliefs regarding the efficacy of treatment may influence their decisions to access professional foot care. In a qualitative study exploring RA patients’ perceptions of foot health services by Hendry *et al* (2013), those who had accessed podiatry services described variations in the benefits (effectiveness) of care received. Reasons for not accessing podiatry included limited awareness of service provision, not knowing the remit of podiatric practice and limited personal financial resources. However, the study was conducted in Australia where health service provision is not generically publicly funded for the whole population. Blake, Mandy and Stew (2013) conducted a qualitative study exploring factors influencing the decisions of patients with RA to access podiatry. Decisions for “seeking help” for foot problems varied between patients’ perceived “benefits” and “costs”. Patients considered accessing foot care after acquired self-management strategies failed. Thus access to podiatry care was a perceived “benefit” Whereas perceived “costs” were described in relation to patients considering inability to cope with foot problems that they accessed foot care. Inability to cope with their foot problems was perceived by some patients as a negative experience. Additionally perceived costs of accessing podiatry included time demands of attending for additional consultations and financial restrictions. As may be expected, patients considered that if their feet problems were not a primary concern, access to podiatry was not required.

Taken together these studies show there are many influences on patients’ decisions to access foot care but the studies have not provided a clear or quantitative assessment of which are the main contributory factors.

3.3.2 Barriers in relation to foot orthoses

In order for the therapeutic benefits of foot orthoses to be achieved (as discussed in Chapter 2), devices need to be available for clinicians to prescribe and patients need to be able to accommodate the devices in their shoes. Foot orthoses can be provided by a number of health professionals within different local organisational service provision. Additionally patients may self-source and self-fund foot orthoses independently without advice from health professionals. Commissioners of health care and service providers often adopt the “episodes of care” (assess, treat and discharge) model (Hussey *et al*, 2009). However, such an approach may not be appropriate for patients with RA who have fluctuations in symptoms, variable disease progression and remain in long term follow up in secondary care. Patients' foot orthoses prescriptions require timely review and replacement when worn out or no longer effective. Follow up care and advice on how to self-initiate is often needed to achieve this. As Helliwell (2003) comments: "To ensure the patient is satisfied with the result of the intervention (s), multiple visits may be necessary."

Economic pressures on publicly funded health care in the UK have also impacted on the issuing of foot orthoses. The trend has been to move towards cheaper, mass-produced, "off-the-shelf" orthoses rather than using "bespoke" (individualised) orthoses. Even so, the majority of podiatry services are primary care based with limited resources for even mass-produced orthoses. In some podiatry services the only access to foot orthoses is via secondary care orthotic services, often only accessible through referral from hospital based clinicians. In order to access orthotic services for patients not already under secondary care follow up, community based clinicians have to request a referral to secondary care from the patient's GP. The individual patient need and subsequent financial costs would then need to be evaluated by the referring GP. A further consideration is the evolvement of musculoskeletal triage assessment services (MATS) placed at the primary/secondary care interface. In some regions of the UK, access to secondary care services for non-urgent musculoskeletal conditions is regulated through triage and treatment by MATS, adding an extra layer of complexity.

3.3.3 Barriers in relation to prescribed footwear

There are clear clinical benefits from prescribed footwear for patients with RA who have foot involvement (Fransen and Edmonds, 1997). William, Rome and Nester (2007) suggest the therapeutic aims and benefits of prescribed footwear are "pain relief, ulcer prevention and improved mobility". In order for these aims to be achieved prescribed footwear must be worn and used by patients. However, some patients do not embrace the use of prescribed footwear as treatment interventions and decline or do not use them following issue (Herold, and Palmer, 1992; Williams and Meacher, 2001; Goodacre and Candy, 2011). Reasons for not using prescribed footwear are reported to be variable and include poor fit, general design and being cosmetically unacceptable (Williams, Rome and Nester, 2007). These findings raise issues relating both to missed therapeutic benefits to patients but also financial implications to an already economically challenged publicly funded health care system. However, previous studies on the use of prescribed footwear in patients with RA have tended to focus on the female experience. There is a paucity of information regarding the perceived benefits and usage of prescribed footwear from the male perspective. In contrast, a cross sectional study conducted by de Boer *et al* (2009) of 240 patients with RA (185 women) report on 91 patients issued with prescribed footwear and 80% of the study participants reported wearing the footwear daily. Taking these studies together there appears to be variation in the use of prescribed footwear in patients with RA. The proportion of patients with RA currently using prescribed footwear is not known.

3.3.4 Barriers in relation to surgery

Severe foot joint damage as a consequence of the disease process may require surgical intervention (Wolfe and Zwillich, 1998; Massardo *et al,* 2002). There are widely accepted benefits of orthopaedic interventions in terms of reduced pain and improved function but a general trend in the reduction of orthopaedic interventions for patients with RA has been described (Louie and Ward, 2010; Shourt *et al,* 2012). Weiss *et al* (2006) suggest the reduction of surgical intervention may be due to advancements in the clinical management of RA. However, this may not be the only factor. The general trend to provide health care in the outpatient rather than in-patient setting combined with the suggestion that foot joints are not routinely assessed in clinical practice (Bann *et al,* 2011) means opportunities for consideration of surgical intervention may be missed. Patients expect the clinician to raise the issues and organise intervention accordingly (Hudak *et al*, 2002). Also, the benefits of foot surgery often accrue several months after procedures have been performed and in the meantime during post surgical rehabilitation increased weight bearing will be required on the contra-lateral limb, in conjunction with the use of assisted devices such as crutches (Wilkinson, Stanely and Getty, 2004). For patients with RA who may have bilateral foot and upper limb joint involvement, the impact of post surgery rehabilitation may be considered untenable and the perceived increase in pain and disability post operatively has been reported to be a potential reason why patients decide not to proceed with surgery (Hudak *et al*, 2002). Qualitative data also raise the consideration of the patients' perceived outcomes of surgery which appear discordant with traditional clinical objectives and rationale for considering foot surgery. Backhouse *et al* (2012) describe functional ability, participation in valued activities and appearance to be more important post operative outcomes than reduction of pain, for patients who had undergone foot surgery. Thus explanations for the reduction in rates of surgery may not simply be related to improved medical management.

3.4 Rationale for the three-phase research project

3.4.1 Overview of the current evidence

Chapters 2 and 3 have reviewed and discussed the current evidence in the literature in relation to the pathological and clinical occurrence of foot problems in the general population and in patients with RA, the benefits of foot care interventions, and how often these are accessed, particularly by RA patients. It is clear from these reviews that foot problems in RA patients are common and complex. Foot pain frequently restricts activity levels and the presence of deformity raises issues regarding the ability to obtain accommodative footwear. Furthermore general disability and loss of hand function can have consequences in patients' ability to self-manage / self-care their basic foot care (Semple *et al,* 2009). A high level summary of the evidence about access to care in general and foot care in particular suggests that provision of foot care services is poor, and that access to foot care is subsequently likely to be relatively low and to occur more in affluent, older women with longer disease duration.

Beyond these broad generalisations, when it comes to an adequate quantitative evaluation, the evidence base is insecure. It rests on observational hospital based studies using convenience (and almost certainly non-representative) sampling strategies which cannot be extrapolated to the general RA population. Earlier population surveys examining access to foot care sampled self-selecting groups (e.g. members of a patient support group) and used restricted outcome measures. These issues almost certainly omit signs and symptoms which are relevant to clinicians and patients. Additionally some works report the findings of service evaluations (e.g. audits) which relate only to particular local service provision. Furthermore these studies stretch back over a long time period during which the availability of musculoskeletal services in the UK has been transformed. The available medical management strategies have evolved from the late use of pharmacological therapies to the early use of multidisciplinary team intervention and deployment of highly effective combination drug treatments. In addition, no studies have clearly documented the clinical features of foot problems in RA in detail, and no studies have addressed the full range of possible barriers to access to foot care.

In order to establish the prevalence of foot problems and access to foot care in RA patients as a whole, a survey is required including a large cohort of patients with RA randomly selected from a well defined population which has equitable access to primary and secondary foot care services (so that issues related differential local service provision are excluded). The survey will need to measure foot problems, symptoms and outcomes relevant to patients and clinicians, to ensure patient self-report is adequately verified and is reliable, and to include questions relating to all the issues which might affect access to care. The purpose of the work presented in the following Chapters is to undertake and analyse such a survey and interpret the results.

3.4.2 Aims of the thesis

1. Measure the prevalence of self-reported foot problems in RA by examining a large sample of patients in a postal survey.
2. Quantify the nature and types of foot problems experienced by patients.
3. Measure the impact of current foot problems.
4. Identify the proportion of patients who have accessed foot care services.
5. Discover patients’ reasons for accessing or not accessing foot care services.
6. Identify factors associated with accessing foot care.
7. Provide a description of the foot care patients have received.
8. Identify self-care and self-management strategies adopted by patients to manage foot problems.
9. Validate self-report of current foot problems (or lack of foot problems).

3.4.3 Methodological approach and conduct

To meet the aims of this thesis a series of interlinked studies were conducted. The main study - a postal survey of a large random sample of all patients with RA within a fixed geographical location – would be successful only if all the relevant questions were included in the survey. Therefore a preceding study (semi-structured one-to-one interviews with patients) was undertaken using qualitative techniques to ensure this would be the case. However, the survey would only be successful if the patient self-report of foot problems was accurate (or at least sufficiently accurate). The validation study conducted on a selected sub-sample of patients was designed to establish the extent of reliability (self-report), but also provided an opportunity to re-check some of the earlier findings. The conduct of three interlinking studies in this thesis is therefore a mixed method approach to addressing the aims of this thesis.

3.4.4 Ensuring coverage of all the issues

To ensure the inclusion of the patients' experiences and important issues from the patients' perspective, the use of appropriate phases and words to inform the content of the postal survey was the purpose of Study 1 of the research, which is presented in Chapter 4. This involved a detailed qualitative study using one-to-one interviews with patients and interacting with patients who became research partners in the implementation of the study, analysis of the results, and preparations for the main survey. The clinical content of the survey was determined by the construction of a recognised and defined list of foot pathologies with appropriate clinical and lay terminology from the qualitative data. A further aim of conducting Study 1 was to provide a rich description of the individual patient experience of foot problems, explore patients' beliefs regarding efficacy of foot care and their reasons for accessing foot care or not.

3.4.5 Establishing the population sampling frame

The population sample frame needs to have equitable access to primary and secondary foot care services. Access to foot care services is defined for this thesis as a patient having been seen by a podiatrist, orthotist and/or orthopaedic surgeon. In the UK orthotic and orthopaedic services tend to be located within secondary care (hospital based). In contrast NHS podiatry services traditionally have been viewed as providing general foot care in primary care to local populations. However, sometimes the provision of specialist podiatry services can also be located in secondary care. For example the role of the podiatrist as an essential member of the multidisciplinary team to manage diabetic foot disease is widely recognised (NICE NG19, 2015). NHS primary care organisations (GP, AHPs and nursing) provide health care for predefined populations within a fixed geographical location. In contrast secondary care services provide health care for geographically dispersed populations. Additionally in the UK patients are provided with the opportunity to select which secondary care facility they would like to receive care from. This has resulted in hospitals providing care to both local and regional populations (Jones and Mays, 2009).

In order to capture and quantify access to foot care for patients with RA, a sampling strategy therefore needs to be conducted within a defined geographical location that covers both primary and secondary foot care provision. This approach has not been previously utilised to estimate access to foot care for patients with RA. The city of Bristol offers an opportunity to implement this approach. The majority of patients with RA in the city will be treated at one of two hospital sites, North Bristol NHS Trust (NBT) and University Hospitals Bristol NHS Foundation Trust (UBH). Orthotic and orthopaedic services are provided at both hospital sites. NHS Podiatric services for Bristol are provided by Bristol Community Health Social Enterprise (BCH) which cares for patients whose GP is located within a fixed geographical area covering the city of Bristol. Therefore, patients with RA who are registered with either of the hospitals and who are registered with a GP within the podiatry service area form the sample frame for the survey. The survey undertaken in this group is Study 2 of the research and is presented in Chapter 5.

3.4.6 Ensuring reliability of self-report

Prevalence of foot problems can be obtained by clinical assessment by health professionals and self-report by patients. Levels of agreement between these two approaches have not been previously investigated in RA. The accuracy of the self-report data collected in Study 2 was investigated in by Study 3, in which a selected sub-sample of patients attended for a direct clinical assessment by an independent podiatrist and which is presented in Chapter 6.

3.4.7 Mixed methods

A paradigm has evolved for conducting research in which qualitative and quantitative methods are combined and is referred to as “mixed methods”. Tashakkori and Teddlie (1998) describe mixed methods research as “the use of qualitative and quantitative methods in a single study or multi-stage study”. Creswell (2009) suggests mixed methods can be applied to all or some stages of the research process including sampling strategies, data collection, analysis, integration of the findings and/or overall interpretation. Several reasons for the benefit of conducting mixed methods research have been proposed:

1. Answer different research questions - mixed methods can be applied to research questions that cannot be answered by qualitative or quantitative approaches alone (Cresswell and Plano Clark, 2007).
2. Confirmation (Triangulation) – findings of one method can validate or support the findings from another method (O'Cathain, Murphy and Nicholl*,* 2010).
3. Completeness – to provide more accurate understanding and interpretation of the research area to aid generalisability of study findings to a larger population (Bryman, 2006).
4. Offset weakness – a mixed methods approach can allow the limitations of qualitative and quantitative methods to be offset or neutralised therefore provide stronger and more accurate assumptions of the research topic findings and conclusions (Bryman, 2006).
5. Inform multi-stage study design – whereby a qualitative study can be conducted to develop hypotheses to be tested in a follow-up quantitative phase (Doyle*,* Brady and Byrne 2009).The findings of qualitative studies can also be beneficial to deign quantitative tools such as questionnaires which are sensitive and reflect individual experiences and beliefs (Coyle and Williams, 2000).

The use of mixed methods in health research has increased over recent years. A review conducted by O'Cathian, Murphy and Nicholl (2007) of research commissioned by the Health Research and Development Programme in the United Kingdom (UK) reported 17% of studies commissioned before 1995 used mixed method approaches compared with 30% funded between 2000 and 2004. The use of traditional research approaches (qualitative or quantitative methods) as individual enquiries may not address the composite nature of health, health care intervention and health care utilisation (O'Cathain, 2009). Additionally mixed methods can provide data to reflect the needs of patients at individual, local and national level (Doyle, Brady and Byrne*,* 2009; Coyle and Williams, 2000). Given the current state of knowledge, the aims of this thesis could be achieved only through adopting a mixed methods approach.

The design and conduct of mixed methods research is flexible to address individual research questions (Johnson and Onwuegbuzie, 2004). That is researchers can select the order of the conduct of research studies. For example if the topic of interest was to provide information regarding how many patients with RA had undergone foot surgery and what were the patients experience of care received. It would seem reasonable to collect the quantitative data first then explore the patients' experience of care using qualitative techniques. As the area of interest in this thesis is the prevalence, impact and care of foot problems in patients with RA, it was considered appropriate to commence with a qualitative phase to inform the content of a postal survey. The rationale for conducting a postal survey was to provide information regarding the prevalence of foot problems in patients with RA and identify the proportions of patients who had accessed foot care. Johnson and Onwuegbuze (2004) guidance of the conduct of mixed methods research was followed in approach and design. This thesis therefore used a sequential concurrent design in which the research commenced with a qualitative study (Study 1) followed by two concurrent quantitative studies (Study 2 and Study 3). Additionally equal weight and importance was given to each study in relation to research governance, data collection and analyses and interpretation of the findings.

3.4.8 Epistemological position - Pragmatism

The processes of conducting research are determined by views: on ontology, the assumptions of reality (how we know what is real); epistemology, the justification of reality (how do we know what we know); methodology (how to go about finding out) and methods (practical activities of finding out) to provide knowledge (Carter and Little, 2007). Historically the traditional paradigms of conducting health research have involved the application of qualitative approaches (text as data) or quantitative approaches (numbers as data). The qualitative paradigm is referred to as naturalist, constructivist, post-positive or interpretive in approach (Creswell, 2009). The aim of qualitative research is to have a deeper understanding of the phenomena of interest, by purposively sampling small numbers of respondents / cases. The main characteristics of utilising qualitative methods are: induction, discovery, exploration and theory or hypothesis generation. The researcher acknowledges to being an integral part of the research process in both data collection and analysis (Johnson and Onwuegbuzie, 2004). Qualitative researchers propose that there are "multiple realities" or "multiple truths" and different interpretations therefore acknowledge that the findings may not be generalisable to all cases in all situations. The quantitative paradigm which is referred to as the positive tradition seeks to identify causal relationships, generalise study findings based on statistical relationships, hypothesis testing and is deductive. Sample sizes tend to be larger and sampling strategies are applied to reduce potential sources of bias. The researcher is considered independent and objective as opposed to the qualitative researcher being subjective and immersed in the research process (Doyle, Brady and Byrne, 2009).

If positivism and interpretism were placed at either end of a hypothetical continuum pragmatism would be placed in between the two extremes assuming the "middle ground". Pragmatism is derived from the Greek word *pragma* from which practice and practical are derived. Pragmatism is not committed to one philosophical stand point of understanding reality (Dures *et al*, 2011) and can provide a basis for knowledge (Cresswell, 2009). Pragmatism is associated with mixed methods providing researchers with the freedom to select research methods which are the most appropriate to their research topic and understanding of the research questions or problems (Johnson and Onwuegbuzie, 2004). Following review of the literature, the researcher selected a pragmatic approach to this thesis.

3.4.9 Collaboration with patients and clinicians

The involvement of patients in health research is widely advocated. Patients have personal experience of their health conditions and treatments they receive to manage their conditions (Tallon, Chard, Dieppe, 2000a; Hewlett *et al,* 2006). These experiences can provide useful insights in relation to informing research study design and interpretation of findings. Further, patient involvement in clinical research can be beneficial to identify important issues for patients (Entwistle *et al,* 1998). Failure to consider the patient perspective in clinical research has been suggested as a potential source of bias (Tallon, Chard and Dieppe, 2000b). Additionally the agenda of the researcher can vary with that of the clinician. Non-clinical researchers' duties in health research tend to be focused on following study protocols and determined methods. In contrast clinical researchers also have these responsibilities but also duty of care to consider (Resnik, 2009). Further, patients and clinicians can have varying perspectives in relation to treatment outcomes and priorities (Hewlett, 2003). It was decided that the inclusion of patients', clinicians' and clinical researchers' perspectives would therefore be essential in the overall approach to the design and conduct of the 3 studies in this thesis. This was achieved through discussions with the researcher's supervisory team and the Research Advisory Group (RAG). The RAG included representation of patients with RA and clinicians from both hospital sites (NBT and UHB), clinical researchers, the researcher and a member of her supervisory team (JK). Discussions with the RAG commenced with the researcher providing a summary of the background to the proposed works and discussed gaps in the literature in relation to foot problems in RA. The researcher presented the research question "What determines whether a patient with RA accesses or does not access foot care services?", and the justification for the need of three interlinked studies being required to address the overall aims of the thesis. Members of the RAG provided valuable comments to the approach and conduct of all three studies. For example items for inclusion in the interview topic guide (Study 1). The clinicians proposed valuable suggestions in relation to identifying patients at both hospital sites. Patients raised topics for further investigation. These included importance of foot problems (e.g. "How important are your foot problems?"), impact of foot problems (e.g. impact of foot problems on clothing choice) and clinical practice (e.g. "Has anyone examined your feet since developing RA?"). Overall, meetings with the RAG provided valuable comments and suggestions to the researcher particularly regarding overall identification and sampling strategies, content and phraseology of questions in the interview topic guide for Study 1. Additionally these discussions provided an invaluable insight from both the patients' and clinicians' perspective that could not have been appreciated *a priori.*

3.4.10 Conclusion

A mixed methods approach using three interlinking studies have been designed to investigate the prevalence, impact, and care of foot problems in patients with RA. In summary, Study 1 will facilitate the understanding of the impact of foot problems in patients with RA in relation to their personal experiences and discover patients' reasons for accessing or not accessing foot care services. This information will be utilised to inform the content of a postal survey (Study 2). To measure the prevalence and impact of foot problems and identification of the proportions of patients who had accessed foot care. A detailed clinical description of current foot problems, patients reasons for accessing foot care or not, and patients' perceptions of the benefit of foot care received are investigated in Study 3. Additionally Study 3 provides investigation between levels of agreement between the self-report of foot problems (or absence of foot problems) with clinical assessment by a clinician. Chapters 4 to 6 present the results of each study, Chapter 7 will then discuss the results overall and their implications for contributions to knowledge (literature, clinical practice) and organisation and service provision for foot problems in patients with RA.

Chapter 4: Study 1 - Exploring the patient perspective of the impact and care of foot problems in RA.

This chapter presents the findings of the first of three interlinking studies to address the overall research questions for this thesis: “What is the impact of foot involvement in RA and what determines if patients with RA receive foot care?” Foot problems in patients with RA can be complex and multi-factorial in presentation as discussed in Chapter 2. However, previous work has not fully captured the consequences of foot problems in RA from the patient perspective. Additionally, patients’ reasons for accessing or not accessing foot care have not been fully explored. To investigate these issues further by means of a population survey a clear understanding of their scope and of the potential range of patient experiences is required to inform the survey. A qualitative approach was adopted to achieve this in Study 1.

4.1 Qualitative methods

The traditional paradigms of conducting health research involve the application of quantitative (numbers as data) or qualitative (text as data) approaches. The quantitative paradigm seeks to identify causal relationships, generalise study findings based on statistical relationships, hypothesis test and is deductive (Sale, Lohfeld and Brazil, 2002). Sample sizes tend to be larger and sampling strategies are applied to reduce potential sources of bias. The researcher is considered independent and objective as opposed to the qualitative researcher being subjective and immersed in the research process (Doyle, Brady and Byrne, 2009). The primary aim of qualitative research is to have a deeper understanding of the phenomena of interest, by purposively sampling small numbers of respondents or cases for detailed exploration (Cresswell, 2009). The main characteristics of utilising qualitative methods are induction, discovery, exploration and theory or hypothesis generation. The researcher acknowledges that they themselves are an integral part of the research process in both data collection and analysis (Johnson and Onwuegbuzie, 2004). Qualitative researchers consider that there are “multiple realities” or “multiple truths” and different interpretations of these (interpretism), and therefore acknowledge that the findings from a small number of individual experiences may not be generalisable to all cases in all situations. To explore in-depth, the personal account of the experience of foot problems in RA from the patients’ perspective, a qualitative approach was appropriate.

Semi-structured, one-to-one interviews were selected as the method for data collection. Focus groups were considered as an alternative approach as they can be a useful method in health research (Parker and Tritter, 2006). For example group work can be valuable as a ranking exercise to identify priorities, review service delivery or to seek a combined expert panel opinion. However, participants who disagree with the general group consensus may not feel able to voice their opinion. Additionally confidentiality cannot be maintained because of the presence of other participants (Kitzinger, 1995). As the aims of this study were to explore the in-depth individual patient experience, semi structured one-to-one interviews were therefore selected to avoid these issues.

4.2 Aims Study 1:

1. Understand the impact of foot problems in patients with RA in relation to their personal experiences.
2. Discover patients' reasons for accessing or not accessing foot care services.
3. Utilise this information to inform the content of a postal survey.

These address the thesis aims 3 and 5 described in Chapter 3 section 3.4.2 and also to inform the planned survey (Study 2).

4.3 Methods

Approval for the study was obtained from the South West 4 Medical Regional Ethics Committee (reference 10/H01021/46) and the University of the West of England Research Ethics Committee (reference HSC/10/07/54). Research and development approval was obtained from two hospital sites: North Bristol NHS Trust (NBT) and University Hospitals Bristol NHS Foundation Trust (UHB).

4.3.1 Identification and sampling

Patients with a consultant diagnosis of RA (Arnett *et al,* 1988) over the age of 18 years and who met the inclusion / exclusion criteria set out below were recruited from two hospital sites (NBT and UHB). Patients were approached, using the screening question "Do you have problems with your feet because of your RA?" and if they answered "Yes" were asked whether they had accessed foot care services (podiatry, orthotics and/or orthopaedics) since being diagnosed with RA. The rationale for the screening questions was to capture the patient experience of the topic of interest (experienced foot problems) and to provide the opportunity to discover patients' reasons for accessing foot care or not. Patients attending the UHB rheumatology department were approached by the researcher who has an honorary clinical contract with the department. Patients attending the NBT rheumatology department were approached by a member of the rheumatology direct care team. The study inclusion / exclusion criteria were:

Inclusion criteria:

1. Consultant diagnosis of RA.
2. Reported foot problems due to their RA.
3. Sufficient English to participate in one-to-one interviews.

Exclusion criteria:

1. Known diagnosis of additional morbidity in which foot problems can be a clinical feature (e.g. diabetes, multiple sclerosis, peripheral vascular disease and neuropathy).

For patients at UHB, the researcher continued the conversation and provided more information about the study. Patients expressing an interest to participate at NBT were introduced to the researcher by a member of the rheumatology direct care team for further information. All patients expressing an interest (in the study) were provided with patient information sheet with a reply slip (agreeing to be contacted by the researcher) and pre-paid envelope (See Appendix A1 and A2). All patients who returned the reply slip were considered for recruitment.

A purposive sampling strategy was applied (Marshall, 1996) using a sampling frame to capture a range of patient characteristics: age, gender, disease duration and whether or not they had accessed foot care services (podiatry, orthotics and/or orthopaedics). To understand patients' reasons for accessing or not accessing foot care it was necessary to sample patients who had and had not accessed care. Recruiting a diverse sample of patients with RA with experience of foot problems facilitated a range of individual experiences to be explored. Patients who filled an appropriate space in the sampling frame were contacted by the researcher to arrange a convenient time, date and location for the interview. Recruitment to the study continued until data saturation had been achieved, indicated by no new major issues emerging in three consecutive interviews (Guest, Bunce and Johnson, 2006).

4.3.2 Patient descriptors

In order to describe the participants (patients) in the study the following data were collected pre-interview: demographic data (hospital site, age, gender), clinical data (arthritis medications, disease duration, disability (Health Assessment Questionnaire, HAQ, Fries *et al,* 1980; Kirwan and Reeback, 1986) and the patient global measure from the Disease Activity Score (DAS, van der Heidje *et al,* 1993). These clinical descriptors of patients with RA are widely used in clinical trials. Health conditions affect both patients' physical function and health related quality of life, and impact on a patient's ability to lead a "normal" everyday life (Finlayson, Moyer and Sonnad, 2004). Sandersen *et al* (2011) proposed that the impact of RA may not be captured from clinical measures alone (e.g. disability or measures of disease activity). The authors formulated the "Impact Triad" whereby the impact of RA is a combination of the severity of RA, the patient's ability to cope with clinical symptoms and the personal importance of the aspects of daily living that are affected by their RA. It would be advantageous to measure all of these.

Patient reported outcome measures (PROMs) have been developed to evaluate foot health status (e.g. Budiman-Mak, Conrad and Roach, 1991; Bennett *et al,* 1998). These questionnaires have been validated and capture foot health status in relation to foot pain, foot function, disability and activity restriction. However, they do not provide an indication of severity of foot problems. The severity of skin disorders (e.g. psoriasis and pruritus) has received attention in the dermatology literature. The use of visual analogue scales (VAS) has been proposed as a method to capture severity of dermatological conditions (Flyström *et al,* 2012; Reich *et al,* 2012). One limitation of the use of VAS is they may not be suitable for patients with motor dysfunction (e.g. inability to hold a pen and/or mark the VAS line with a pen). Motor dysfunction involving the hands can be an issue for patients completing any PROMs not just VAS. Additionally, methods of reproducing VAS may lead to distortions in the scale and potentially lead to misinterpretation of results (Snow and Kirwan, 1988). An alternative approach is the use of 11, 21 or 101 numerical rating scales (NRS) in which the end points (anchors) are the extremes of the topic of interest (e.g. feet not a problem to feet severe problems). NRS have been shown to have high levels of agreement with validated questionnaires. Additionally patients are reported to prefer completing NRS rather than VAS, due to simplicity of completion (van Tubergen *et al,* 2002). In order to provide information about the global impact of foot problems in patients with RA, it was decided to include items capturing the severity and ability to cope with foot problems. Quantifying severity of foot problems and patients ability to cope with foot problems is novel but has not been validated using NRS. However, NRS have been validated to capture foot pain and foot related disability in patients with RA (Budiman-Mak, Conrad and Roach, 1991). Therefore for ease of administration and considering patients' (reported) preferences regarding completing rating scales, one 11 point numerical rating scale (NRS) was selected to measure the severity (magnitude) of foot problems ("Please circle the number which shows how much of a problem (on average) your feet have been in the last week"? range 0 no problem to 10 severe problem) and the global nature of their arthritis ("Considering all the ways your arthritis affects you, please circle the number which shows how well you are doing?" range 0 very well to 10 very badly). All study participants completed the both numerical rating scales prior to the commencement of the one-to-one interviews. A copy of the pre-interview data collection sheet is presented in Appendix D1.

4.3.3 Interview process

The one-to-one interviews were held in rooms at UHB or NBT rheumatology departments, whichever was most convenient for the participant. Informed written consent was obtained by the researcher from each participant prior to commencing the interview.

Interviews at UHB were conducted in non-clinical rooms within the rheumatology department, whilst at NBT they were conducted in consulting rooms due to lack of availability of non-clinical rooms. Consideration was given to conducting the interviews in a non-hospital environment rather than the hospital outpatient departments as it is possible that location may influence power relations between researcher and participant (Elwood and Martin, 2000). However, in a study conducted by Memel *et al* (2002) in which participants were offered a choice of location for attending an in-depth interview, the majority preferred to discuss their medical conditions and care in a clinical setting.

The researcher endeavoured to conduct the interviews in a quiet, relaxed and informal environment so the participants would feel at ease. Additionally the researcher was aware of the importance of being interactive and sensitive to the participants' disclosure of their personal experiences. The interviews lasted between 35 and 60 minutes. The interviews were audio recorded and transcribed verbatim. The researcher checked the transcripts for accuracy and anonymised names and identities. To maintain confidentiality all participants were allocated an identifier consisting of a code containing the hospital site, patient number and gender (e.g. BR 05 M).

The interviews commenced with an introductory question: "Can you tell me in a couple of sentences about your arthritis so I can understand a bit more?" This provided participants with the opportunity to disclose the nature and impact of their arthritis in general terms. A more detailed account of the experience of foot involvement and accounts of access to foot care services was then explored using the interview topic guide (see Table 4.1). The interview topic guide was developed by the researcher based on the review of the literature; discussions with a research advisory group (consisting of patients, clinicians, and academic supervisors) and a patient research partner (PRP) who became an integral part of the research team. The interview topic guide consisted of 7 neutral questions covering three main issues: 1) experience of foot involvement in RA; 2) its impact on the patient's life; 3) access to foot care services. The aims of the open-ended questions were to identify the extent of the overall topics of interest. The additional use of probes and prompts facilitated the opportunity for the participants and the researcher to discuss some topics in more detail. All the study participants were offered the opportunity to indicate if they would like to receive a summary of the study findings.

Table 4.1 Topic guide Study 1

Question
1: Tell me the story about your feet? • How important are your foot problems to you? • Have you discussed your foot problems with anyone?
2: What are your foot problems? • Have your feet changed since developing RA? • Has anyone examined your feet since developing RA?
3: How do you manage your foot problems? • Can you give an example?
4: Have you had any experience of foot care services? • If so, how did you access care?
5: How much do your foot problems affect your activity? • How do you feel about your foot problems affecting your activity levels? • Are you able to drive, work, and take part in leisure activities? • How do your foot problems affect the way you feel about things?
6: Do they have an impact on your choice of shoes, clothes etc? • How does this make you feel?
7: If we could make things better, do you have a wish list for foot care services?

4.3.4 Choice of analytical methods

Analyses of qualitative data can be inductive or deductive. Inductive analysis is described as data driven (bottom up) in approach whereby knowledge and ideas emerge directly from the data. Such analyses can be used to generate hypotheses. In contrast deductive analysis is described as top down. This approach to analysis commences with a predefined idea or hypothesis. Data are then analysed to confirm or refute the original idea or hypothesis (Thorne, 2000). Inductive analyses facilitate discovery while deductive approaches are more suited to testing of theory (Pope, Ziebland and Mays, 2000). As the aims of Study 1 were to understand (discover) the individual patient experience of foot problems and their reasons for accessing or not accessing foot care, an inductive approach to analysis of the data was selected.

Consideration was given to the application of Interpretative Phenomenological Analysis (IPA) (Sokolowski, 2000; Smith and Osborn, 2003) as a method of analysis for Study 1. The primary aim of IPA is to enquire about the individual’s lived experience while recognising a process of interpretation by the researcher. Participants are recruited because of their experience of an event or condition. In IPA only a small number of participants are included, as it is a very detailed analysis with a lot of researcher interpretation. Therefore IPA was not applicable here where the need was to capture a wide range of patient experiences.

Inductive thematic analysis (ITA) was used to identify codes and themes arising from the data. Boyatzis (1998) describes thematic analysis as a method for identifying and reporting patterns (referred to as themes) within qualitative data and facilitates further interpretation of the research topic. ITA ensures a systematic approach to identifying common themes within and across data sets. It is also a useful approach to summarising large data sets to identify similarities and differences between data (Hayes, 2000). ITA is flexible as there is no prerequisite to have a predefined theoretical or epistemological position but still provides an opportunity to gain a thick description when researching an under investigated topic area (Braun and Clarke, 2006).

4.3.5 Inductive Thematic Analysis process

There are different descriptions of how systematic ITA should be performed (Boyatzis, 1998; Attride-Sterling, 2001; Braun and Clark, 2006). Braun and Clarke (2006) recommend a six stage approach to conducting ITA:

<u>Stage 1:</u> Commences with familiarisation of the data by transcribing the data (if required) followed by reading and re-reading the data and recording initial thoughts or ideas.

<u>Stage 2:</u> Involves generating initial codes with codes being described as “interesting features” within and across the data set. Codes are then exemplified with extracts from the data.

<u>Stage 3:</u> Codes are then grouped to form themes and supported by all data which might be relevant to each theme.

<u>Stage 4:</u> Is the process of reviewing themes. At this stage some themes may not have sufficient data to be supported, may be very similar and therefore combined, or may contain a combination of themes and therefore need to be broken down and analysed as separate themes. This stage of the analysis can then be presented as creating a “thematic map” diagrammatically representing the links between codes and themes.

<u>Stage 5:</u> Refers to the process of defining and naming themes by generating clear definitions and names for each theme.

<u>Stage 6:</u> The final stage in the process is the presentation of the analysis in a concise logical approach with sufficient extracts of the data to support the findings.

Attride-Sterling (2001) describes thematic analysis as a method to unpick themes in textual data at different levels which can be supported by the use of “thematic networks” to diagrammatically represent the hierarchical order of themes. Thematic networks are tools to support the organising and presentation of the data and are constructed as web-like illustrations. The lowest order themes are referred to as “basic themes” which are derived from the textual data. Basic themes are then grouped in clusters into middle order “organising themes” which surmise conceptual assumptions of basic themes. The highest order or super-ordinate themes are “global themes” which summarise and interpret the clusters of lower order themes. Attride-Sterling (2001) proposes six steps for utilising thematic networks as a technique for conducting thematic analysis:

<u>Step 1:</u> The reduction of the textural data into small units of meaning (codes) using a coding framework.

<u>Step 2:</u> Identify abstract themes from the coded text and extract salient or common themes which are then refined to encompass the meaning of numerous segments of text.

<u>Step 3:</u> The construction of thematic networks by arranging interlinking basic themes, grouped in organising themes which support the development of global themes.

<u>Step 4:</u> Relates to the description and exploration of thematic networks. The networks are initially described with supporting textural data then reviewed to explore interwoven links between the themes. Networks then also become tools for the reader who is able to interpret the analysis using the networks as a summary guide to refer to the description and exploration of the analysis.

<u>Step 5:</u> Presents a summary of the main themes and patterns that have emerged in the data analyses.

<u>Step 6:</u> The final stage of the process draws together the overall findings of the concepts, patterns and interwoven links in the data with reference to established theories if indicated.

For the analysis presented here a coding strategy was employed combining the two sets of guidance. The coding process commenced with familiarisation of the data with the researcher checking the interview transcripts for accuracy with the audio recordings. The transcripts were then read and re-read to gain an understanding of and familiarisation with the data. Next, the data were systematically explored and small units of meaning identified and given descriptive labels (codes). The data handling package NVivo 8 (QSR International, Melbourne, Australia) was utilised. NVivo is a software tool which assists in organising data and therefore supports the analysing non numerical data. NVivo facilitates the coding process through a system of nodes. The codes were the lowest order themes extracted directly from the data. The codes were then grouped in similar meaning to form sub-themes, which in turn were clustered into organising themes, and finally organising were grouped to form global themes / underpinning themes to support the more abstract meaning of organising themes. Analysis was iterative and used constant comparison. The technique compared data sets, individually and across the whole data set, for emerging themes, and also sought links between codes and themes. In the iterative process the identification of new themes in early interviews could then be explored in subsequent interviews and also applied to earlier data sets.

The terms authenticity and trustworthiness are often applied in qualitative research. Authenticity refers to the findings of a study being represented accurately and trustworthiness to enable the reader to have confidence in the research and its findings (Lincoln and Guba, 1985). Authenticity and trustworthiness of the analysis was supported by the use of quotations to illustrate the evidence supporting the findings. This provided an in-depth appreciation of the individual experience in the participants' own language and words, rather than the researcher's interpretation of what was said. The terms reliability (findings constant over time and reproducible) and validity (measure / capture information of what was intended to be measured) are widely used in quantitative research to ensure replication and repeatability of findings. In contrast the term "rigour" is applied in the qualitative literature. Rigour is an umbrella term to assess quality, trustworthiness and credibility of findings of qualitative data (e.g. Golafshani, 2003). Rigour was addressed through independent analysis of the data sets (transcripts) and agreement of the emerging themes generated. The first 2-3 transcripts were analysed not only by the researcher, but independently (as advocated by Mays and Pope, 1995) by two other researchers (Professor Sarah Hewlett and Dr Emma Dures) and the PRP (Enid Quest). Agreement was achieved following discussions with the study analysis team on emerging codes and themes before the remaining transcripts were analysed by the researcher. The overall emergent themes were agreed by all the members of the study analysis team and academic supervisors. Table 4.2 presents the study team characteristics.

Table 4.2 Study team characteristics

Team	Gender	Position	Years of rheumatology experience
OW	Female	Researcher / PhD student	15 years
ED	Female	Rheumatology psychology researcher	5 years
EQ	Female	Patient research partner	RA diagnosed >20 years
JK	Male	Academic rheumatologist	>30years
SH	Female	Academic rheumatology nurse	>20 years

4.3.6 Ensuring the quality of research process

As the researcher had no previous experience of conducting qualitative research, training was addressed through successful completion of two level M modules in qualitative methods at the University of Oxford and the University of the West of England. Individual guidance on conducting thematic analysis was provided by an experienced qualitative researcher (Dr Marianne Morris) and the practicalities of conducting in-depth interviews was supported by the PRP and a postdoctoral researcher (Dr Tessa Sanderson).

Reflexivity is an important consideration of qualitative research as the person undertaking the research is an integral part of the research process (Pillow, 2003; Horsburgh, 2003). A professional background as a podiatrist may influence the approach, design and analysis of the study. In order to reduce this potential for bias the researcher used reflexivity and reflective practice. The content of the interview schedule (topic guide) was derived from discussions with the research advisory group (patients, clinicians, academic supervisor), and the researcher introduced herself to potential participants as a clinical doctoral research fellow rather than a podiatrist. This is because disclosure of professional background has been reported to influence participants' responses during qualitative interviews (Richards and Emslie, 2000). Revealing the researcher's professional background may prevent a participant from feeling at ease when describing their experiences, for example some participants may not freely discuss negative experiences of foot care with a podiatrist. To facilitate this, if a participant directly asked about the researcher's background (clinical or non-clinical), the researcher postponed disclosure of her background to the end of the one-to-one interview saying, "I am really interested to hear your experiences, we can talk about me at the end". During the study this occurred only once. As a member of the clinical team in one of the departments where patients were recruited there was the possibility that the researcher may have been involved in the clinical care of a participant. Richards and Schwartz (2002) suggests if the researcher is directly involved in the care of the participant, it is possible disclosure would change the nature of the interview and data obtained. This is a consideration for all clinicians conducting clinical research, but during Study 1 the researcher was not directly involved in the clinical care of any of the study participants. The researcher's reflexive thoughts of the research process were recorded in field notes.

Patient partner involvement also provided support to the research process. The patient research partner (PRP) participated in a semi-structured in-depth practice interview to provide some initial experience of conducting qualitative interviews prior to the study. The practice interview was observed by an experienced qualitative researcher (Dr Tessa Sanderson). The PRP and the qualitative researcher both provided valuable advice and comments to the researcher. The PRP also independently analysed 3 interview transcripts, participated in study team meetings to agree the emergent themes of the analyses, and contributed to the interpretation of the overall study findings. The PRP was also a member of the research advisory group.

4.4 Results

4.4.1 Participants

In total 27 patients with RA and self-reported foot problems (symptoms) were approached to participate in the study. Of these, 9 declined to participate - 2 indicated that they did not wish to attend for an additional hospital visit and 7 did not mention a reason. Of the 18 participants who expressed an interest in taking part in the study, 4 could not be contacted by telephone and did not respond to written invitations and 1 did not attend for the arranged one to one interview. The 13 participants were distributed across the sampling frame (Table 4.3).

Table 4.3 Sampling frame patient recruitment

	Age (years)				**Disease duration (years)**				**AFC**	
	< 35	35-50	51–64	>64	<5	5-10	11-20	>20	Yes	No
Female	1 (1)	3 (1)	7 (3)	6 (3)	2 (2)	2 (2)	3 (0)	6 (2)	7 (4)	7 (4)
Male	0 (0)	1 (1)	5 (3)	4 (1)	3 (3)	4 (0)	4 (2)	3 (2)	4 (4)	9 (1)

Key:
AFC = accessed foot care services Figures are: Number approached (Number participating)

Interviews with 13 participants were conducted. However, data were lost for one interview due to equipment failure. Participant characteristics are presented in Table 4.4. Most participants were British white Caucasian, apart from one Afro-Caribbean participant. Working and domestic living arrangements were mentioned by all participants during the interviews. Of the 5 men who participated in the study, only 1 was currently in full time employment. Of the 7 women, none were employed at the time of data collection. The youngest female participant disclosed her reason for not working was a personal choice so that she could care for a young child. Three participants lived alone. Participants' perception of disease activity and severity of foot problems covered a wide range from 0 to 9 (10 being worst disease activity or foot problem). Five participants were taking biologic therapy for their RA. Data saturation seemed close after nine interviews and was confirmed by conducting a further three interviews whereby no new themes emerged.

Table 4.4 Participant (patient) characteristics

ID	Gender	Age (Years)	Disease duration (Years)	Current medication	HAQ	Patient Global	Foot Global	Accessed Foot care
BR02	Male	61	3	Biologics, DMARDs, GC	2.875	6	6	Yes
BR03	Female	62	2	DMARDs, GC	0.375	2	3	No
BR04	Male	39	2	DMARDs, GC, NSAIDs	0	1	1	No
BR05	Male	55	27	Biologics, DMARDs, NSAIDs	2.75	8	9	Yes
BR06	Female	61	23	DMARDS, GC, NSAIDs	2.75	7	7	Yes
BR07	Male	54	2	Biologics, DMARDS, GC, NSAIDs	2	8	9	No
BR08	Female	71	11	Biologics	0.375	7	1	No
BR09	Male	72	20	DMARDs, NSAIDs	1.87	9	5	Yes
BR10	Female	46	24	Biologics, DMARDs, NSAIDs	2.375	6	8	Yes
NB01	Female	29	5	GC	0	0	0	No
NB02	Female	55	7	DMARDs, NSAIDs	1.87	5	7	Yes
NB03	Female	69	18	DMARDs	1.75	7	8	Yes
Mean		**56.2**	**12.0**		**1.56**	**5.5**	**5.3**	
Range		**(29 - 72)**	**(2 - 27)**		**(0 - 2.875)**	**(0 - 9)**	**(0 - 9)**	

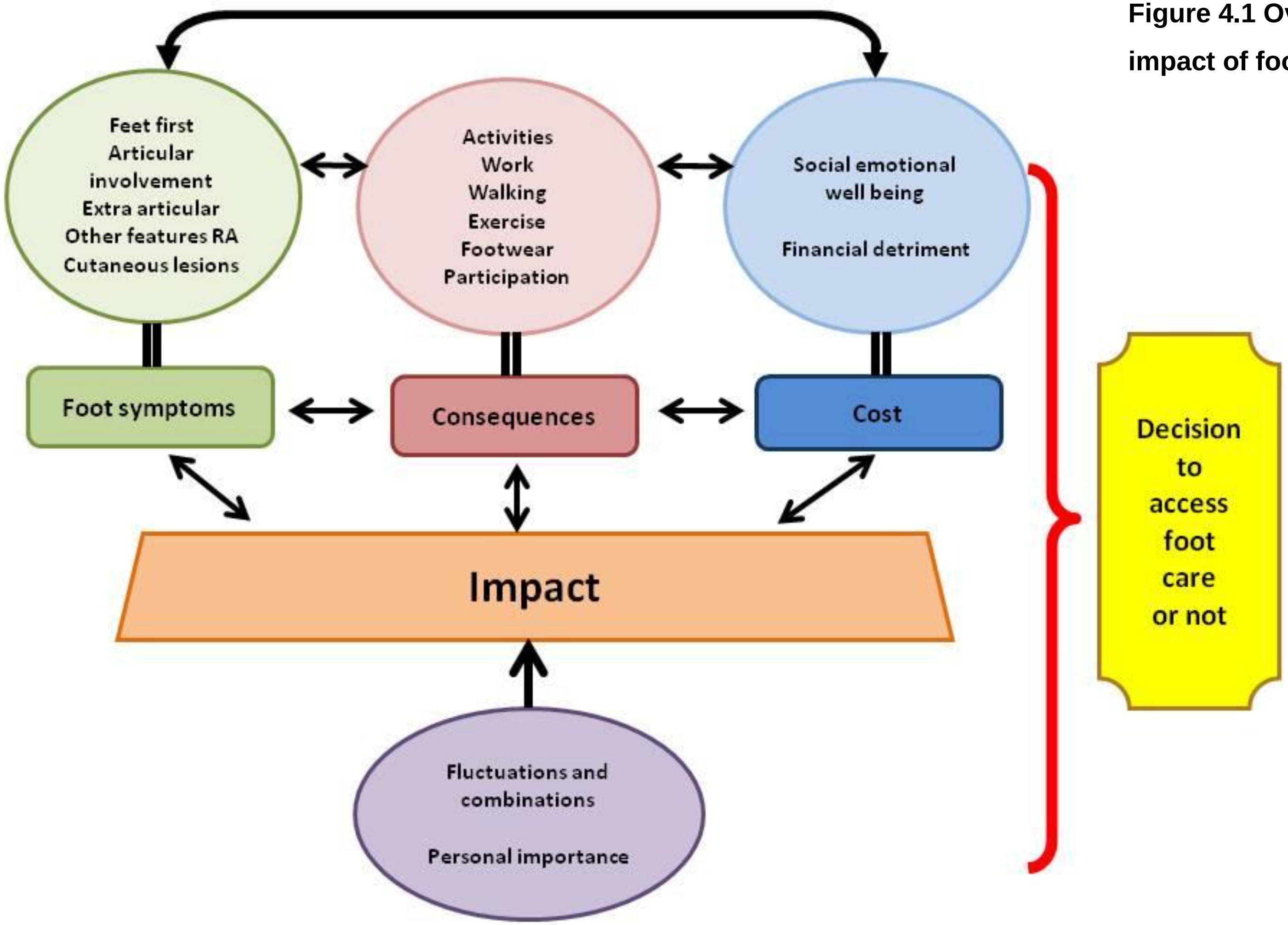
Key:
ID: BR = UHB patient, NB = NBT patient.
Foot Global = Numerical rating scale 0 (no problem) -10 (10 severe problem
NSAIDs = Non-steroidal anti-inflammatory drugs.
DMARDs = Disease-modifying anti-rheumatic drugs.
GC = Glucocorticoids.
Patient Global = Numerical rating scale 0 (very well) - 10 (10 very badly)
HAQ= Health Assessment Questionnaire score 0-3 (3 is most disabled)

Data were collected between October 2010 and April 2011. Each participant provided an individual account of their personal experience of the impact of foot symptoms (problems) in RA, and beliefs regarding access to and efficacy of foot care services. The findings include themes from within individual cases and across the whole data set on both common and individual experiences raised by the participants. In total, 159 codes were identified, and drawn together into 15 sub-themes, 3 organising themes, 1 underpinning theme and 1 global theme, which are described below. These all related to the decision to access foot care, which emerged as a global theme in itself and is discussed in section 4.4.3.The coding tree is presented in Appendix D3.

4.4.2 Impact of foot problems

Overall, three organising themes were identified: ‘Foot symptoms’, ‘Consequences’, and ‘Cost’ with an underpinning theme of ‘Impact’. Within each organising theme are related sub-themes that represent the diversity of individual experiences, beliefs and values, and are independent and interlinked but mutually influential (Figure 4.1). Exemplars from the data are presented at the sub-theme level and labelled by the patient identifier consisting of a code containing the hospital site, patient number and gender (e.g. BR 05 M).

Figure 4.1 Overview of experience and impact of foot problems in RA



4.4.2.1 Foot symptoms

The organising theme ‘Foot symptoms’ demonstrates that clinical features of foot problems are multi-factorial: these can be an early symptom of RA (‘Feet first ’), with joint and other system involvement (‘Articular involvement’, ‘Extra articular features’ and ‘Other features of RA’) and also include skin and nail pathologies (‘Cutaneous lesions’).

4.4.2.1.1 Feet first: “The arthritis started in my feet”

Participants described a range of experiences in relation to foot symptoms (problems) with some recalling that the first symptoms of RA were in their feet. Other participants described the evolvement of foot symptoms as a more gradual insidious clinical feature that varied in severity, consequences and impact:

> *“The arthritis started in my feet. I thought I'd stood on a little stone. It started off like if you stand on a little stone on the ball of your foot it feels like a bruise, they call them stone bruises. It wasn't going away. It's like if you put a marble in your sock and then try walking on them, that kind of feeling.” (NB02F)*
>
> *“The first sign something was going on was my feet. The balls of the foot were really uncomfortable when I walked. It seemed to come from nowhere. Couldn’t understand why they [referring to feet] were playing up. The next thing I knew my hands were playing up as well.” (BR04M)*
>
> *“Then eventually it [RA] showed up in a blood test. Um … well by that time I was starting to get it in other places, especially in the feet, um … prevented me from walking [referring to foot pain] when I put my foot down.” (BR05M)*
>
> *“But the feet came last. But when they came you know it's over … obviously over a period of time but they did get very bad.” (NB03F)*

4.4.2.1.2 Articular involvement: “Really out of shape”

The participants described a number of foot symptoms that are general clinical features of RA such as pain, swelling, stiffness and joint deformity. One patient reported general morning stiffness which included his feet.

> *“Can I describe the pain? It's more stabbing if I move the ankle. It's more a kind of stabbing pain and I can feel it in the actual joint.” (BR09M)*

> “*They get quite hot and swollen. My ankles swell up as well; get a lot of fluid on the ankle around here.” (BR10F)*

> *“But the worst thing is in the morning getting out of bed. Because [BR05 small laugh] it takes me a long time to get out of bed. Mainly with the back. I mean I'm still stiff in the morning, like knee joints and like in the feet.” (BR05M)*

These participants tended to be older and have longer disease duration. Foot deformity was linked with the sub-theme of ‘Footwear’ (4.4.2.2.5) in the use of self-care and self-management strategies whereby some participants were aware of having to be selective with their footwear to prevent secondary skin lesions. The practical elements of self-care and self-management adopted, relate to participants’ ability to conduct practical tasks such as cutting toe nails. In contrast the more global aspects of self-care and self-management relate to strategies, skills and beliefs participants adopt in order to manage their RA on a daily basis (e.g. pacing and planning).

> *“Some of the toes have sort of clawed up a little bit ur and when I’ve got certain shoes on the knuckle, the first knuckle becomes quite sore if I got certain types of shoes and I might have a blister.” (BR06F)*

> *“If I’m going somewhere special I’ll take a second pair of shoes in my bag. When I’m sitting down nobody can see my frumpy shoes under the table” (NB03F)*

The evolving nature of foot deformity was associated with the sub-theme of ‘Personal importance’ (4.4.2.4.1). Although joint deformity had occurred, one patient did not consider it to be an important feature of their RA, while for others the consequences of joint deformity in terms of pain, impairment and having difficulty sourcing comfortable footwear resulted in the need for surgical intervention.

> *“The toe is out of … you know is at an angle. The big toe. It's gradually got worse, gradually got worse. But it doesn't cause me any trouble.” (BR09M)*

> *“They [feet] were really, really out of shape. Every toe was … was straightened with a screw in. And it screwed it into the bone … er into the toe, every toe.” (NB03F)*

Conversely, some participants reported that joint deformity affecting the feet had never been a clinical feature for them. The absence of foot deformity was described by the two youngest participants and those with shorter disease duration:

> *“They [feet] seem like normal to me … I think.” (NB01F)*

4.4.2.1.3 Extra-articular: “When they are numb they're really sort of numb”

Some participants reported additional neurological symptoms of burning and numbness in their feet, which were not constant. Only one patient described the presence of nodules on his feet (BR05) and no participants reported any other extra-articular features being present in their feet such as bursae or a history of vasculitis:

> *“I couldn't really feel the fact that my toes were rubbing on shoes and things. So then I'd realise like when I took my shoes off there was like blood and blisters and stuff. But that does seem to have calmed down.” (BR10F)*

> *“Yeah it's only the numbness occurs now and again. It's not all the time. But when they are numb they're really sort of numb yeah.” (NB02F)*

4.4.2.1.4 Other Features RA: “Another symptom of rheumatoid arthritis”

Foot involvement was considered by most participants as an additional general feature of RA. However, this was disputed by a few participants who were surprised that foot symptoms could be a consequence of RA.

> *“I just thought it [referring to foot involvement] was symptomatic of rheumatoid arthritis. I just took it that it was another symptom of rheumatoid arthritis. Yeah it was just another one. Because I sometimes get it in the legs and sometimes I can’t walk.” (BR02M)*

> *"I thought as RA was a type of arthritis it would only attack some areas. My nan had arthritis but it was just in her knees. So I was surprised when my ankle started swelling and playing up he said [consultant rheumatologist] it [ankle] was due to the RA". (NB01F)*

Fear of feet being an additional clinical feature of RA was expressed by some. This was particularly evident for one patient (BR03F) who was provided with an information leaflet of foot symptoms and management when she was diagnosed with RA:

> BR03*: "Well they gave me a leaflet here how to look after your feet. Arthritis and how to look after your feet or something like that entitled. Well yes it made me aware of might lie ahead."*
> Researcher: "*Did you find the leaflet helpful?"*
> BR03: "*Bit alarming."*

Flare was mentioned as a feature of RA with some participants being more conscious of their foot symptoms during a flare. No participants discussed fatigue as a feature of RA and therefore no association was identified relating fatigue with the impact of foot symptoms:

> *"And when I get that [referring to a flare] I'm more conscious of my feet. Yeah and I feel that they are swollen and um... it's quite a relief to put them in the bath or... sometimes I just put them in a plastic bowl. When I'm not having a flare it's only when I've walked too far or ... stood for a long time. And then I become aware that my toes have become a bit stiff and my heels hurt a bit. ... um..." (NB03F)*

4.4.2.1.5 Cutaneous lesions: "I can see why I've got callus"

Additional symptoms that were foot specific included the development of secondary skin lesions (corn and callus formation, and toe nail pathologies):

> *"I can see why I've got the callus just merely by the way when I stand up the position of the foot under there. The nails have gone um … awful as well " (BR08F)*

> *"I was ending up with quite hard skin on the balls of my feet then." (NB02F)*

Soft tissue infections were reported by two participants. Of these, one patient recalled an episode of athlete's foot which they considered significant enough to source medical care. A second patient reported a bacterial infection in her toes as a result of an in-grown toe nail, which required medical review and antibiotics. No participants reported an episode of foot ulceration:

> *"It's like an athlete's foot, yeah I get that. I had a bad bout of athlete's foot about three years ago. Oh it was terrible I had to go to the walk-in centre. It was on a weekend and that and um what did I get for it ... [name of topical anti-fungal cream]". (BR02M)*

> *"I was getting quite a lot of um … toe nail infections. And it did … I did do one course of antibiotics." (BR10F)*

4.4.2.2 Consequences

The second organising theme 'Consequences' describes the effects of foot involvement in terms of: ability to complete tasks of daily living ('activities'), work related disability ('work'), walk ('walking'); participate in sport / structured physical activity ('exercise'), limitations in selection of shoes ('footwear') and impact on social interactions ('participation').

4.4.2.2.1 Activities: "I do get problems driving"

Some participants discussed the consequences their foot symptoms had on activity levels. Difficulty driving was reported, in particular driving a manual car. This related to the function of depressing the clutch and ability to perform an emergency stop. This situation appeared to vary and was associated with fluctuations of foot symptoms. One patient was considering changing his car from a manual to an automatic as a consequence of his foot symptoms:

> *"If I get it in the feet, if I get it in the left foot I can't … depress the clutch. If I get it in the right foot I can't use the brake or the accelerator. Well I can use the accelerator because that's easier. But if you had to brake suddenly then it just wouldn't because you can't apply enough pressure on the brake.*

> *Today I drove because … [BR05 laughs] for some reason, today is what I call a good day." (BR05M)*

> *"Yeah but I do get problems driving. Yeah we're thinking when we can afford it we could change the car for an automatic. I couldn't put me foot on the clutch, couldn't get the clutch down. That's only ever happened once though. That's quite … yeah that's a recent thing." (BR07M)*

4.4.2.2.2 Work: "I used to be able to work"

A small number of participants considered that their foot problems had consequences on their ability to work. This was in relation to the nature of their occupations, such as standing for long periods of time, having to wear safety footwear or driving for long periods. For other participants this was not considered to be an important issue as they were either retired or not working:

> *"I used to work. I gave up working I had quite a hectic job and I was having to move around quite a lot. I was up and down stairs and in and out of cabinets, and I just couldn't do it. So I had to give my job up." (NB02F)*

> *"So I was falling over in the yard. And then what happened, the company had cameras put in everywhere and then I was sort of being sort of asked what the problem was with me shoes and with the boots they supplied." (BR07M)*

> *"Couldn't go in any of the workshops because of the safety, I couldn't manage the safety shoes, they were too heavy for my feet." (BR05M)*

> *"I was 60 odd at the time and I was coming up to retirement. I wasn't you know like 25 or 30." (BR08F)*

4.4.2.2.3 Walking: "Some days I really can't walk"

All participants discussed the issues their foot problems had on their ability to walk. For some the consequences of foot symptoms and walking were related to variation in general RA disease activity:

> *"They're awful to walk on [feet], really, really uncomfortable. And it's just er … it's just everything just feels like it's grating against each other, like a bag of bones almost." (BR10F)*

> *"I was using a crutch at the time as I'm having problems with my hip and I think I went on using to support my other hip. But when I used it to support my right hip and the ankle pain, was very intense." (BR06F)*

The majority of participants considered that the distance that they could now walk had reduced. Distance walked was described and related to levels of foot pain, with some participants having an awareness of not being able to walk on uneven surfaces:

> *"Some days I really can't walk, the pain is so bad [referring to foot pain]. I've never broken a bone in my life. But if I had to imagine what a broken bone felt like, that's what it feels like when I walk." (NB02F)*
>
> *"I suppose it's [foot pain] stopped me from going for long walks." (BR03F)*
>
> *"They've [pavements] got those little like nodule tiles or slabs in obviously to let blind people know there's … well I can't walk on [small laugh] those. Yeah and cobble stones I couldn't. We'd been on holiday in a little village and there was cobble stones and [small laugh] I said oh I can't walk down there." (BR05M)*

The distance participants could walk was interlinked with the sub-theme of 'participation' (Figure 4.1). The use of self-management techniques when walking were disclosed by some patients. This was particularly evident for one patient who described no longer being able to go for a walk with her husband. Despite applying a pacing technique by slowing down the speed she walked, she was not able to continue. Others participants planned their walking levels around being able to take regular rest periods by being able to sit down:

> *"I'm not walking as much as I'd like and I'm not doing as much as I'd like. If my husband and I go for a walk, a little way down the road I say I'm going back now you carry on and I leave him to. And the pace that we go is incredible slow compared to what really would probably be good for you to you know so yes, I miss all that." (BR06F)*

> *"Because we've gone down the harbour on say like a Sunday if it's really nice. Because there's loads of seats." (BR07M)*

Additional aids were utilised to help with mobility and walking. One participant described the benefit of using a shopping trolley when visiting the supermarket in conjunction with self-management strategies of pacing and planning:

> *"And I might stop for a cup of tea or something half way round. But it's flat and the weight is all on the shopping is in the trolley. So you can lean on the trolley er you know" (BR10F)*

One participant described that even though it was painful she perceived walking as an important beneficial activity. Walking provided the opportunity for her to spend time with her young daughter as well as participating in physical activity:

> *"Yeah so sometimes even if it [ankle] hurt a little bit I'd still force myself just to go out with the buggy and take her for a walk. Even if it hurt just to … yeah exactly just because it does help I think." (NB01F)*

4.4.2.2.4 Exercise: "I've decided to pack it up"

Foot symptoms also affected participants' ability to participate in sport / exercise (structured physical activity). Exercise was considered to be a valued activity by some participants not only for the benefits of general health and psychological wellbeing but also as part of their social life. Not being able to participate in exercise was a negative experience for some. In contrast others adopted the approach of finding alternative leisure activities to participate in. For some participants the negative situation was in turn perceived as a positive situation. This was expressed by BR09M who felt that stopping a sport he had enjoyed for years, provided the opportunity to spend more time with his wife:

> *"Because I couldn't play it. And I remember trying once and I … I kicked the ball and I thought I'd broken an ankle. It wasn't in a tackle, I just kicked the football and oh, and I thought oh useless, and I felt useless. Because oh I don't know, I used to love football." (BR05M)*

> *"Well it just hurt er to … to walk. And I also do like … like running as well when I can. And so obviously I couldn't run [because of foot pain]". (NB01F)*

> *"I play outdoor bowls you know and I've been pretty successful with it since I … now I've stopped this year. Well the main reason is because of the ankle. I've stopped and I've decided to pack it up. But also perhaps I want to do other things. So I've said to my wife and she said 'Oh are you going to pack it in are you? You know, well you enjoy it so much.' I said 'Well I'm not bothered.' I said 'Because there's one thing, it's stopped us doing other things." (BR09M)*

Participating in physical activity was described by one participant as a self-care and self-management strategy to reduce the symptoms of metatarsalgia. This patient was a keen cyclist:

> *"When you move backwards and forwards, very, very slightly [referring to positioning foot on pedal]. So you don't end up with any pressures building up in your ankle. So that where the foot pivots the ball is right over the spindle, so you're putting all of the power into there. So it's almost as if that's your pivot point and it spreads the weight across the whole of the foot, or the pressure across." (BR04M)*

4.4.2.2.5 Footwear: "I get dressed from the bottom up"

Issues relating to the consequences of foot problems in relation to footwear were discussed at length by all participants. Many participants reported that they had to be selective about the shoes that they wore and recognised the importance of what they considered to be good shoes. This implied that there was personal awareness of the need for footwear to be comfortable and fit for purpose. Consequently footwear selection was an additional self-care and self-management strategy adopted:

> *"I'm quite a comfy shoe person but I buy shoes on how they feel rather than what they actually look like generally." (NB01F)*

Difficulties sourcing footwear that was comfortable, facilitated accommodating foot deformities and fluctuating symptoms such as swelling were issues for some participants:

> *“You have to be again careful what you put on as well. I like boots because I feel with boots they support my swollen ankles. Whereas I find these shoes, they don't. But boots I feel a bit of security there. And you have to make sure that they are sturdy.” (NB02F)*

> *“Well sometimes, it depends on the shoes, but you know they feel fine when you put them on and then like once you've worn them a few times you think oh that's not a good buy. And then they just get put away because they're just so uncomfortable to wear. But you just can't tell until you've actually started wearing them.” (BR10F)*

The visual appearance of footwear and being aesthetically acceptable was also an important consideration. Participants’ footwear also had consequences relating to their choice of clothing, and this was not gender-specific:

> *“Awful. Awful because I was always one that wore high heels and you know and to wear these [referring to current footwear]. And they were … they looked so ... clumpy you know. I was sort of begrudgingly wearing them. It was. It was... because they looked so old-fashioned.” (NB03F)*

> *“Most people get dressed from the top down; I get dressed from the bottom up” (BR06F)*

> *“Oh yeah I wouldn't want to wear a pair of trainers say on a Saturday night if I had to go out. If I'm able to go out, I wouldn't wear trainers on a Saturday. Maybe on a Friday night but er … never on a Saturday.” (BR05M)*

The importance of footwear was not just confined to choice of clothing but was interlinked with identity and body image. Some female participants described that they now wore trousers, which they had not previously done before they had been diagnosed with RA and developed foot problems. The influence of footwear and clothing choice was considered to have varying importance. Some participants who were not in paid employment had a more laissez-faire attitude towards the issue of clothing choice. They felt that by not being in the work environment it was acceptable to dress down by wearing more casual clothes. In contrast, the importance of footwear in relation to body image when attending social events was much greater:

> *“Because you didn't look very … you never looked dressed because you had these sort of clumpy shoes on. You know um … so I wore from … that was when I started to wear trousers. I never wore them before.” (NB03F)*

> *“Yes, yes I wear trousers practically all the time (BR3 giggles) practically the whole time. I think it was tied in with stopping work... and general trends I suppose. Yes, but yes I wouldn’t say it was a problem, particularly anyway but the shoes, the shoes have affected what I wear, yeah. When I was your age it would have been quite unusual to go to work in trousers” (BR03F)*

> *“When you've got to have something like my granddaughter's wedding … oh what am I going to wear for shoes? Not … I can find an outfit but what am I going to wear for shoes?” (BR08F)*

The issue of footwear was also interlinked with the ability to drive as described by one participant who found wearing trainers beneficial for walking but not for driving:

> *“I don't like driving the car with trainers. The extra kind of foam padding, I feel you can't feel the brake or the accelerator well. I don't know, it's just me.” (BR04M)*

4.4.2.2.6 Participation: “I’ll be sat and everybody else is having a conversation.”

The consequences of foot involvement were also reported to impact on participants’ social lives, often resulting in the feeling of isolation. Further, ‘Participation’ was also related to self-care and self-management strategies utilised by participants. Some participants acknowledged that they may need to sit down when partaking in activities if they were unable to stand due to their foot symptoms. The situation was anticipated, planned for and strategies put in place:

> *“But sometimes it might be standing watching football for a couple of hours. Well I take a chair. But I'll be sat and everybody else is having a conversation.” (BR10F)*

> *“Yeah because we don't go out very er … very often. No there's no point really. Well every time I go somewhere I've got to make sure there's somewhere for me to sit.” (BR07M)*

For some participants participation was considered in terms of not feeling they were fully able to perform important personal roles and therefore had negative consequences on their psychological wellbeing. This was particularly evident in BR10F's account of how she perceived her foot problems affected her role as a mother of young children:

> *"Yeah and I you know try and either leave early for school or late for school so that I can actually park as close as possible to drop the kids off. And sometimes I don't even get out of the car anymore because of my feet it's just um … I just drop them so that I know they don't have to cross any roads and they go in on their own." (BR10F)*

> *"Because I can drive, I can do quite adventurous things and get quite a long way but when I get there like I find that I'm missing out on things because actually I can't walk up those steps onto the ramparts of the castle. But I can look at it. You know people take my children off and go and do things and I sort of miss out because I can't actually do the final bit." (BR10F)*

4.4.2.3 Cost

The third organising theme 'cost' shows that foot involvement can have a negative influence on self-esteem, body image and identity ('Social and emotional well-being') and personal finances ('Financial detriment').

4.4.2.3.1 Social and emotional well-being: "I'd look like an old lady, Nora Batty ankles"

Participants referred to cost in terms of the effect on social and emotional well-being describing the feelings of depression, low mood and frustration in particular from the loss of not being able to participate in valued activities. However, some participants elected to participate in other activities that did not involve physical activity but facilitated the opportunity to socialise with others, such as joining a book club. Other participants related their low mood to embarrassment of the appearance of their feet due to the presence of deformity and swelling:

> *"So yes in the beginning especially frustrating and you know I had sort of given up on an awful lot of what I did really so. And I used to do tap dancing which was wonderful." (BR06F)*

> *"And er … and because I couldn't do like the physical activity that I would usually do, like well a lot of running and stuff, that made me quite depressed." (NB01F)*

> *"One of the best things about football was going for a drink with the boys afterwards. But I can't play anymore. I used to join them for a pint afterwards but didn't feel involved as I hadn't been part of the team on the pitch. So I stopped going. Not only could I not play anymore but the loss of the social side, not seeing my mates and all that made me feel really low." (BRO5M)*

> *"I probably would have stopped playing tennis by now anyway. You sort of move on because otherwise it's frustrating isn't it. You look for different things like a book club. I do more things like that like reading, the computer and so yeah this may have happened anyway but the fact that I'm getting older but I don't think it would have happened so soon." (BR03F)*

> *"Because my feet have got so wide and my toes have spaced out quite a bit. It doesn't look very nice either. This ankle is permanently swollen. But that [referring to toe deformity] looks awful as well." (NB02F)*

The youngest participant felt that foot symptoms had an aging affect, making her feel (and assume that others perceived) she was older than she was. Other participants described that their choice of clothing was limited, and feeling less dressed had a negative impact on their body image and self-esteem. The organising theme cost was interlinked with the sub-theme 'footwear' (presented in section 4.4.2.2.5) in relation to the aesthetics of and difficulty sourcing footwear:

> *"I'd look like an old lady, like Nora Batty ankles, that kind of thing. Yeah it was horrible." (NB01F)*

> *"It's a bit disheartening in a way because you can't get what you want. So it's not very often that I look at shoes. It's my least favourite thing." (BR08F)*

> *"Yeah I think shoes for a woman are quite a big part of her life really. Whatever you put on you put your little matching shoes on, sort of thing." (NB02F)*

4.4.2.3.2 Financial detriment: "To carry on my job was virtually impossible"

The organising theme of 'cost' was complex and multi-facetted. Some participants described the cost of the consequences of their foot symptoms in terms of financial implications. This included financial detriment as they were unable to continue with paid employment. Thus financial detriment was interlinked with the sub-theme "Work" (Section 4.4.2.2.2).

> *"And um … basically um … offered me retirement through ill health. Which I took because I knew … well [BR05 small laugh] to … to carry on my job was virtually impossible." (BR05M)*

Financial detriment was also linked with the sub-theme of 'Activities' (Section 4.4.2.2.1). This is supported by consequences of foot involvement in terms of ability to drive a manual car. Considering changing from a manual car to an automatic was discussed by one patient. However, such action would incur additional financial costs that he felt were unachievable. For others, although they could no longer drive a manual car, the financial burden was reduced as they were in receipt of financial assistance due to their level of disability:

> *"Yeah we're thinking when we can afford it we could change the car for an automatic." (BR07M)*

> *"I've got a Motability car. I have particularly chosen a car with very comfortable sitting position." (BR10F)*

Financial detriment also related to the cost of shoes with some participants considering the expensive shoes would be more helpful to self-care and self-manage their foot symptoms:

> *"It's not necessarily money. I would … if … you know if they [shoes] fitted me and they were all comfortable I wouldn't really care you know within reason paying quite a bit for them." (BR08F)*

Other participants reported that they were not able to wear their current shoes. One participant reported that even though her current footwear was uncomfortable she was unable to afford to buy alternative boots or shoes. Financial detriment was therefore interlinked with the sub-theme of footwear (Section 4.4.2.2.5):

> "*So I've thrown out, well they're a decent pair of shoes..... they're gone now. They're in the ash bin. The ones [shoes] I've just thrown away, down in town they were sixty pounds." (BR02M)*

> *"It's like my boots you know my low heeled boots, the ones that I've worn all the way through the winter, but they haven't been comfortable. But I couldn't afford to buy another pair so I just had to make do." (BR10F)*

Some participants adopted a range of self-care and self-management strategies to manage their foot symptoms. These strategies were not adopted through patient education and self-management programmes but through individual cognitive processes or by trial and error. The benefits of these acquired strategies (for example self-sourcing insoles) were considered to negate the financial cost:

> *"And just trying different insoles, well I don't know over the years I, I suppose they're not that expensive some of them so and I buy them as I need them. So if I have a shoe that's too, too big in some respects then I buy them but they're not that expensive to buy." (BR06F)*

4.4.2.4 Emergence of underpinning theme: Impact

The theme of 'Impact' underpins the themes of foot symptoms, consequences and cost, leading to decisions to access care. Impact highlights that foot problems in RA may not be static or constant ('Fluctuations and combinations') and appear to vary in severity and be influenced individual patient priorities ('Personal importance').

4.4.2.4.1 Personal importance: "Sometimes you feel trapped"

The variation of reported personal importance fluctuated around the general clinical features of RA. For some participants a balance was maintained, whilst for others the personal importance of foot symptoms were reduced when the feet were asymptomatic but increased when symptoms reoccurred or were more pronounced. Some participants perceived their foot symptoms as highly important and significant features of RA, with one participant reporting their foot symptoms as the most forefront aspect of their RA:

> *“It started … the pain really started in my feet and my hands. And then it seemed to go from my hands and feet for a long time. And it's come back with a vengeance.” (BR10F)*

> *“I think the biggest problem is the feet. Because it affects your mobility. Yeah sometimes you feel trapped. You know you can't do anything, can't go out the house, you can't do things around the house.” (BR05M)*

Varying levels of personal importance of the impact of foot problems were divulged. Some participants discussed their foot symptoms at length but considered that the impact of other clinical features RA, in particular other joint involvement were greater personal issues. The influence of participants’ RA being well-controlled also reduced impact and therefore the personal importance of foot symptoms:

> *“Pain, the pain I had was unbelievable I’ve got pain now. Yeah it’s more like an ache. More of a sharp ache. Yeah it doesn’t. It’s a body tooth ache.” (BR02M)*

> *“I feel, in myself I feel really well. And I know you might … and when I remember how terribly ill I was, I mean I went down to 8 stone 4 and I'd started off at 10 stone 10 or something, I felt terrible. Now I know I feel really good and I consider it [foot pain] slightly minor you know. I was glad to be feeling well, much better. I was glad to be mobile. Yeah in the grand scheme of things I consider it [foot pain] a minor inconvenience that I have to put up with to feel well. I feel that it's the least of my worries really, kind of thing. It's an inconvenience, yes it is”. (BR08F)*

In contrast, other participants considered higher levels of personal importance as their foot symptoms were having significant consequences on their levels of activity, choice of footwear and ability to participate socially (as reported in organising theme ‘Consequences’ 4.4.2.2).

> *“It's actually my feet is what's preventing me from getting around.” (BR09M)*

4.4.2.4.2 Fluctuations and combinations: “Not every day but the vast majority”

The overall impact of foot symptoms varied and fluctuated, often in combination with other clinical features of RA. Some participants recalled that their foot symptoms had resolved, whilst others described a deteriorating clinical presentation. Further, some participants described their feet were more symptomatic during a flare. These symptoms related predominately to pain and swelling (as described in the previous sub-theme ‘Other features of RA’ 4.4.2.1.4):

> *“So sometimes it [foot pain] can last 6-10 days. Other times it just lasts 24 hours or 36 hours. And some days there's no pain.” (BR05M)*

> *“I wouldn't go so far as to say every single day [referring to foot pain]. But the vast majority.” (BR08F)*

4.4.3 Decision to access foot care or not

The unique combination for each participant’s experience of foot symptoms, consequences and cost, underpinned by impact, led to decisions related to accessing foot care. However, decisions to access or not access foot care were complex. Participants who had accessed foot care services prioritised their foot symptoms as an important health-care need. In contrast, other participants, whilst reporting foot symptoms and the consequences and impact of foot involvement as important issues, did not access foot care services.

Therefore a global theme of ‘Decision to Access to Foot Care of Not’ emerged from 180 identified codes, drawn together into 14 sub-themes and 3 organising themes: ‘Access hindered by patient perceptions’, ‘Access perceived unnecessary by patient’ and ‘Access supported by patient and clinician’. A copy of the coding tree is in Appendix D4. Figure 4.2 presents factors influencing participants’ decisions to access foot care.

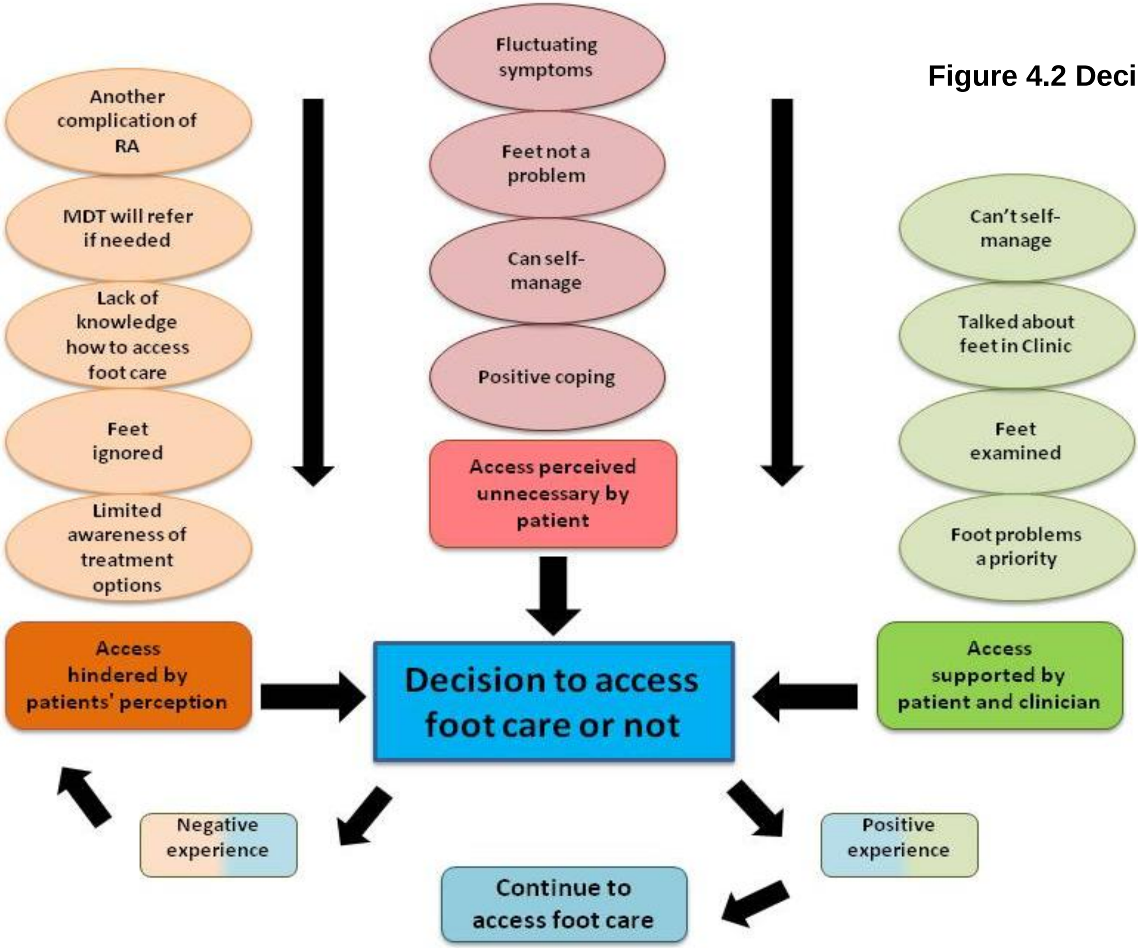


Figure 4.2 Decision to access foot care or not

4.4.3.1 Access hindered by patients' perceptions

The organising theme 'Access hindered by participants' perceptions comprised five basic themes: 1) 'Another complication of RA'; 2) 'MDT will refer if needed'; 3) 'Lack of knowledge how to access foot care'; 4) 'Feet ignored;' 5) 'Limited awareness of treatment options'.

4.4.3.1.1 Another complication of RA: "He said we can do something about it"

Participants acknowledged their foot symptoms were part of the umbrella of clinical features of RA. Further, many assumed that controlling and improving foot symptoms would be encompassed within the overall medical management of their RA. There was also recognition of the benefits of medication on reducing the risk of deformity:

> *"Since I had the medication update or the increase with all the meds on the methotrexate and had a steroid injection that was about a week and a half ago, I've been absolutely fine … touch wood. Huge improvement within kind of 24 to 48 hours. It seems to have done the trick, back to pretty much my old self." (BR04M)*

> *"And he said [consultant] the thing is years ago before these drugs came out that the chances are you would get severe deformity in the hands and feet and things like that but he said by catching it early enough and he said that we can do something about it. And he gave me um .. methotrexate tablets." (BR02M)*

4.4.3.1.2 MDT will refer if needed: "I leave things like that to him"

Confidence in the clinical team (multidisciplinary team (MDT)), was emphasised. Participants assumed that if their foot symptoms would benefit from further assessment and intervention, a member of the multidisciplinary team would arrange a referral:

> *"I am really grateful for the treatment I've received because it's completely changed my life really. And they always ask you know if you've got any problems, I mean every single time you come, without fail." (BR08F)*

> *"What I tend to do is wait until I see [doctor's name] and then he's the one who would recommend me then [referral to foot care]. It's like I've just had an ultrasound on my hand. So I leave things like that to him and then he will refer me then. Because obviously he's the expert." (NB02F)*

In contrast, other participants questioned the doctor's clinical judgement when they were referred to foot care services. This was evident by one patient describing how he was referred to orthotics when he considered the clinical reasoning and justification for the referral had not been explained:

> *"And he just looked at it [foot] and he just wrote on the note. I thought idiot. (BR07 laughs). What a thing to say about your doctor … well a doctor." (BR07M)*

4.4.3.1.3 Lack of knowledge how to access foot care: "I thought they were all private"

Participants had varying knowledge of foot care services in general terms. However, for some there was awareness that help was available if the need arose. This was contradicted by others regarding uncertainty about which foot care services would be available particularly in relation to podiatry, and how the service could be accessed.

> *"No, no I was aware from this leaflet that if I did have trouble they could refer me to a po... po... podiatrist. Yes, I'm aware that there is help, there if I need it. I think if they got worse then I might seek some help, yes um I think they would help but ... have to be quite a lot worse before I started asking but it is something I'm aware of." (BR03F)*

> *"Well I thought they were all private actually. I didn't know you could access them [podiatrists] in the NHS." (BR08F)*

Professional titles used in relation to foot care services influenced participants' perceptions in relation to professional clinical remits. This was particularly evident in the dual use of professional titles of podiatry and chiropody. Some participants considered the role of a podiatrist was for the management of a single episode of care such as nail surgery for an in-growing toe nail. In contrast, chiropody was viewed by some as a service that was sourced privately and which provided more general, on-going care (toe nail cutting, corn and callus reduction). Beliefs regarding the benefit and efficacy of treatment received also hindered decisions to access to foot care:

> *“I went to my GP and she referred me to um … they've got like a foot clinic. And she did some work trying to you know prevent sort of like in growing toenails and things like that.” (BR10F)*
>
> *“Started to go to a podiatrist first in the same practice [GP practice] um... but then I believe (BR06 giggles) that there is quite a difference yes but yep.” (BR06F)*
>
> *“I've always associated like a chiropodist with if you've got corns and things like that. And I don't seem to have any of those.” (BR07M)*
>
> *“I've heard varying things about the standard of [private chiropodists]...Yeah exactly. Yes and I begrudge paying for the bad. Well my husband went, for an example, when he had a corn between his toes. Well his toes are knobbly and so they rubbed together. And he had it and he went to see him [private chiropodist]. And it was back in next to no time, just as bad. And it kind of puts you off in a way.” (BR08F)*

The beauty industry was also utilised for basic foot care such as nail cutting. This was considered to be beneficial therefore the need for further professional intervention was not required:

> *“So what I've been doing is going to have my um … sort of my toes and feet looked at you know actually just have a pedicure every sort of three months just to keep them in better condition. And that's really worked.” (BR10F)*

4.4.3.1.4 Feet ignored: “They get neglected”

There was a common assumption by participants that feet were generally ignored by rheumatology clinicians. This was perceived both positively and negatively.

Some participants reported that the feet were not included in the overall assessment of disease status (for example joint counts). Additionally, one patient suggested the clinical team acknowledged the benefits of the use splints for hand involvement but concluded that there was not the same emphasis placed on the management of foot symptoms. Other participants appeared to question clinicians' clinical expertise in conducting foot assessments.

> *"Because it's [feet] not on any sort of thing. You know it's not on any score thing is it. It sort of stops at your knees doesn't it?" (BR07M)*

> *"Your feet I know they get neglected, they support you but they get neglected. Don't they? You know what I mean. If it is orthotics or if it is like you got problems with your feet or like when they made the splints up for my hands and that. I've got splints for my hands and wrist splints and all that you know that was done here and that but it didn't seem to be the same sort of thing for gravity on the uh ...feet. (BR02M)*

> *"And it's like my GP said as well, apart from if you study how somebody walks he said you know it's not a visible thing either is it?" (BR07M)*

Positive perceptions were linked with participants' confidence in their rheumatology clinicians. These participants recalled their clinical consultation involving being asked about their feet and having their feet examined: The perception of the feet being ignored by the clinical team was then interpreted by some participants as being because there were no further care options available:

> *"Right at the beginning when um, when um, *[Consultant] was trying to decide whether I did have RA or not he gave me quite a thorough examination and looked at my feet then." (BR03F)*

Foot symptoms were also ignored by some participants. Some participants elected to ignore their foot symptoms as they did not wish to proceed with treatment interventions, particularly prescribed footwear. There were negative perceptions of prescribed footwear which included the visual appearance of the shoes. Participants therefore declined the opportunity to be referred for orthotic review:

> *"It's not where I wanted to go [referred for prescribed footwear] it was another nail in the coffin so to speak um... yes another nail in the coffin, I didn't want to go there." (BR06M)*

> *"Perhaps when I'm about 70 I might wear them [prescribed footwear]. But I don't want to wear shoes like that, oh no."* (BR05M)

> *"I've been resisting going down that line [prescribed footwear]. But I … you know I can see myself getting there at one point." (BR10F)*

Assumptions that prescribed footwear magnified the presence of foot symptoms, in particular the presence of deformity, were discussed. This was reflected by one patient who had a family member who also had RA and foot involvement. This patient acknowledged that his family member's foot problems were severe requiring prescribed footwear. However, the aesthetic of the footwear was not referred to positively:

> *"Yeah he's got rheumatoid arthritis and his feet are terrible. His feet are absolutely terrible. He's got to wear special, really special shoes. They look like; well they look like Frankenstein's boots." (BR02M)*

The potential for a more organised approach to review and management of foot symptoms to be beneficial was suggested by one patient:

> *"Possibly to have all the people who could help you under one roof? Yes I think it might actually be quite helpful I mean I'm not backward in coming forward so I would ask for help. But there are probably people who wouldn't so I think it might be once you've been diagnosed have someone check them [feet] every now and maybe a year. Um... as part of the backup service, which is very good in other areas, such as hydrotherapy and physiotherapy." (BR03F)*

4.4.3.1.5 Limited awareness of treatment options: "There isn't anything that could be done"

Participants reported a limited knowledge of treatment options for foot symptoms. Although the use of insoles had been recommended by the clinical team, previous negative experiences of accommodating devices in footwear were raised as a concern. Some participants reported the development of blisters and areas of skin irritation following the use of insoles provided. Others recalled difficulty accommodating the devices in their own footwear (self-sourced footwear). Of the participants who had negative experiences of prescribed insoles, most concluded that alterations to the design and prescription of insoles would be not possible:

> *"I wasn't really sure that there was anything you could do to actually relieve the pain particularly in the feet .Other than to reduce the activity. I've just sort of plodded on assuming that there isn't anything that could be done" (BR10F)*

> *"I think quite a few years ago when I first started having foot problems it was suggested that I try um insoles. Which were quite difficult actually because the type of shoes I'd got even at that point were, I just couldn't accommodate. They made my shoes too uncomfortable because they were too thick. I would have had to have bought different types of shoes and I think at that point I wasn't ready to for you know um you know the type of shoe that I probably needed basically." (BR06F)*

Surgical intervention was discussed by some participants. However, despite previous successful surgery for other joint involvement, participants were reluctant to proceed with surgical review of their foot symptoms. A number of reasons were provided regarding reluctance for surgical review, which included length of time to recover:

> *"About the November, year gone, I finished up having the right knee replacement. Which went very well, very successful." (BR09M)*

> *"It was quite difficult to recover from that operation ...it took me quite a long time. Then in the end I had to use a wheelchair because I couldn't support... because I'd had shoulder problems and one had been replaced at that point so I couldn't really support my own weight very well. Because I wasn't supposed to put it [foot] to the floor at all." (BR06F)*

Concerns that further surgery would not improve foot symptoms, having undergone numerous surgical interventions previously were described. This was evident in BR09 whilst he reported significant ankle pain that was reducing his ability to walk. However, when surgical intervention was suggested as a treatment option, he declined to proceed with further surgery:

> *"But what's stopped me perhaps coming back or whatever, there's no way I feel like having another operation. Two reasons: I've had three and I think three is enough" (BR09M)*

4.4.3.2 Access perceived unnecessary by patient

The second organising theme 'Access perceived unnecessary by patient' displays the varying nature of foot involvement in RA ('Fluctuating Symptoms' and 'Feet not a problem') in conjunction with acquired self-care and self-management strategies ('Can self-manage' and 'Positive coping').

4.4.3.2.1 Fluctuating symptoms: "Two or three days I'll be on crutches"

The fluctuating nature of foot symptoms influenced decisions that access to foot care was not necessary. This related in particular to the short duration of foot symptoms for some participants who considered that as their foot symptoms were intermittent, it was possible their symptoms would improve or resolve. Accessing foot care was therefore considered unnecessary:

> *"There will be two or three days when I'm on crutches... and then I can't walk and then it leaves. Um little bit. I had a bit of pain, well a lot of pain Tuesday. Yeah they were quite rough then. But then it goes and I would be ok, so there was no need to see anyone about it [foot pain]". (BR02M)*

> *"I couldn't really feel the fact that my toes were rubbing on shoes and things. So then I'd realise like when I took my shoes off there was like blood and blisters and stuff. But that does seem to have calmed down." (BR10F)*

4.4.3.2.2 Feet not a problem: "It's the least of my worries"

Some participants considered that access to foot care was unnecessary as their foot symptoms were not a major concern. Despite having current foot problems, some participants described other symptoms of RA to be more important issues than their feet:

> *"No not really, no. It's probably because it's not a big problem [feet] you know just uncomfortable" (BR03F)*

> *"I feel that it's [feet] the least of my worries really, kind of thing. It's an inconvenience, yes it is. And um … from the shoes perspective well that's a nuisance but you know we get by" (BR08F)*

4.4.3.2.3 Can self-manage "I just know how to look after my feet"

The ability to self-care and self-manage was also provided as a reason not to access foot care. Participants applied practical self-care and self-management strategies when their feet were symptomatic. The strategies selected were influenced by previous beneficial experiences of self-care and self-management strategies used to manage other symptoms of RA. Applying heat to painful foot joints was helpful for some whilst others considered cold modalities to be more useful. The benefit of the application of heat and cold to swollen joints was disputed by one patient who perceived topical modalities to be more helpful:

> *"I just know how to look after my feet. I've always done it." (NB02F)*

> *"What I tend to do is I keep thermal socks at home and I go and put thermal socks on. And that helps a bit. Just give them a rub to warm them back up and then put thermal socks on. Once I've got the coldness and the numbness in my feet I just get up and move around and try and get the circulation moving back in my … I think perhaps get the circulation you know once that starts going it's not too bad." (NB03F)*

> *"And I just put that [ice] in a bag and put it on my shoulder or on my knee or on the top of the foot. And it's like even after I've had like the ice, I'll get a bowl of water I'll put my foot in for 20 minutes and then after 10 minutes I'll put the ice back on." (BR05M)*

> *"I never really … never really found any of it helped [referring to hot and cold]. I used to use something like Ibuprofen gel." (NB01F)*

Participants also adopted selection of footwear as acquired self-care and self-management strategies by altering the shoes they wore for different activities. This took into account wearing shoes that were more comfortable and to allow for fluctuating symptoms such as pain, swelling and accommodating deformity. Electing not to wear shoes at home was also adopted as a self-care and self-management strategy by one patient:

> *“So I gone to a pair of shoes now that is giving me a little bit of, a bit more room. On there at the widest part.” (BR02M)*

> “*Oh I've got a pair of slippers or something. Don't wear shoes at home. Feet more comfortable when I’m not wearing shoes” (BR04M)*

Complementary therapies such as aromatherapy oils were found to be helpful for one patient. Other considered the benefits of alternative therapies although they had not utilised them:

> *“Well getting into a warm bath. I use a lot of aromatherapy oils as well um … to try and sort of er … sort of relax my swollen joints as well. And lots of salt in the bath I find salt is quite good.” (NB02F)*

> *“Something like reflexology would probably be lovely” (NB03F)*

Massage was reported by some participants as having merits in managing foot symptoms. However, the need for caution regarding the amount of pressure applied when conducting massage needed to be considered. Applying too much pressure to painful, tender and swollen joints could result in symptoms being more pronounced:

> *“It is painful and you know exactly where you can touch and how much pressure you can use. Whereas someone else, it's like no, no I'll just do it myself. (BR04 giggles) So it's easier just to do that.” (BR04M)*

Participants also used of additional self-care and self-management techniques such as filing areas of callus, and self-sourcing insoles. However, the use of some strategies had negative consequences by exacerbating pain levels:

> *“I just very gently just do that with them [demonstrating using a foot file]. And I sort of try to keep the hard skin under control by doing that. Put cream on them, moisturiser. And then I give them a rub with my file.” (NB02F)*

> *“When my feet were playing up I’ve used liners [insoles]. You know the ones you can buy in the shops. They cost me but I didn’t mind. If they helped I didn’t mind how much they cost.” (BR06F)*

> *"Well I've tried the [refers to trade name] remover of hard skin on it [area of callus]. I've tried rasping it off. Perhaps I'm too vigorous with the rasping, I don't know. Sometimes it hurts after. It's a fine line between what to take off and what not to yeah." (BR08F)*

If participants were unable to self-care and self-manage their foot care, some asked for help from friends or a family member; on occasions this was considered a negative experience as it highlighted lack of independence. Some participants perceived that there was reluctance for family members to assist with foot care (cutting toe nails):

> *"A friend of mine did it [cut toe nails] then for me." [NB03F]*

> *"I don't like the idea of someone having to do it for me [cut toe nails]. It's like I don't like the idea of that I can't get in the bath" (BR02M)*

> *"I'll get my wife to do it [cut toe nails].She don't like doing it. She says feet are horrible. (BR07M)"*

4.4.3.2.4 Positive Coping: "You have to try".

There was an interwoven salient basic theme of positive coping. This was whereby participants felt that a positive attitude of helping oneself by utilising self-care and self-management were important factors in managing foot symptoms. Other participants reported a more general positive approach to managing their foot symptoms and RA generally. Some discussed active participation and concordance in their care as an important factor:

> *"Think it was a process of I knew what for example if I wore trainers they were more comfortable than the shoes I was wearing. I can't go around in trainers all the time so, so I then started to um I bought a pair similar to this and it went from there really. Yes I think you've just got to help yourself a bit." (BR03F)*

> *"If I felt unwell in myself generally I might think 'Oh God me feet as well on top of it all'. But I suppose because I'm quite … I think 'Oh well. Well I think my life's good actually' (BR08 giggles) considering how awful it was at the time." (BR08F)*

> *"You have to try. You've got to meet … I mean you have these ops and things but you've got to meet them [clinicians] half way. You've got to do your bit I think anyway." (NB03F)*

4.4.3 3: Access supported by patient and clinician

The third organising theme 'Access supported by patient and clinician' illustrates the influence of feet being included in clinical consultations and foot symptoms being an important health care need ('Can't self-manage', Talked about feet in clinic', 'Feet examined' and 'Foot problems a priority').

4.4.3.3.1 Can't self-manage "I can't do it"

Inability to undertake foot care [cut toe nails] was described and linked with reduced dexterity when RA involved the hands. General disability levels also impacted on participants' ability to self-care and self-manage their foot health. When functional disability reduced the ability to perform foot care, participants accessed foot care services, in particular podiatry:

> *"I mean I can't do it [cut toe nails] with the feet because … well again it all depends how much pressure I could … like sometimes there's no way I'm able to massage my hands because my fingers won't let me do it." (BR05M)*

> *"But I have problems reaching my toes because I can't actually get down there you know for any length of time to do anything properly". (BR10F)*

> *"When I had my hip done I couldn't really get down to cut my toe nails and my husband said "oh I'll do those for you" (BR06 laughs). Then I said no it's all right I'll go to the clinic" (BR06F)*

4.4.3.3.2 Talked about feet in Clinic: "He asked me"

Being asked about foot symptoms in clinical consultations was reported. This recognition by the clinical team validated foot involvement as consequence of RA. However, not all participants recalled being asked about foot symptoms as a regular part of their clinical consultation. One patient (NB01F) reported that she raised the issues of her foot symptoms herself during a clinical consultation.

> *“He asked me he did … and this was [consultant's name] ’Did that hurt?’ you know. And I said it does hurt. It's difficult to walk on and you get a big callus on the bottom.” (NB03F)*

> *“Most of the times I've mentioned the pain in my feet because it's … that' s been like the joint worst with my arthritis” (NB01F)*

4.4.3.3.3 Feet examined: “I took my shoes off and showed the woman”

Clinicians conducting foot examinations legitimised that foot problems can be clinical features of RA for some participants. Having x-rays taken of the feet was perceived as validation of foot problems as a clinical feature of RA, along with recognition by clinicians of the impact of foot pathology. One patient concluded the clinical value of foot x-rays at diagnosis provided an opportunity for baseline assessment and monitoring progression of foot problems. However, the justification for re x-raying feet was not fully understood by some participants:

> *“Well I suppose because they were always checking (BR09 laughs) my feet it became fairly obvious that um … problems do occur with one's hands and fingers and feet.” (BR09M)*

> *“I had an x-ray on my feet and my hands; I think it was er as I was diagnosed, just to check if there were any problems or not. I think they use it as a … you know as a baseline.” (BR04M)*

> *“Yeah I've had like foot x-rays. The main x-rays I've had have been my hands and feet 'cos that's where it's been worst. But when they decide to x-ray again it’s not clear, it’s not clear to me.”(NB03F)*

Participants recalled having their feet examined whereby a member of the clinic team carried out a visual inspection and assessed the foot joints. In some instances the foot examination was instigated by the patient. The examination and inspection of the feet was not considered a regular occurrence in clinical reviews:

> *“I took my shoes off and showed the … the woman [specialist nurse]. So that's when she would have inspected, looked at them.” (NB01F)*

> *“Nobody specifically has gone for my feet.” (BR02M)*

4.4.3.3.4 Foot problems a priority: “It affects everything”

There was a range of views expressed in relation to importance and impact of foot problems. For some participants, foot symptoms were considered to be a priority and an important health need. Although there was an acknowledgement of the presence of symptoms, some participants appeared to be able to cope and manage, therefore considered their feet were not a priority:

> *“Um [BR05 sighs] very important. Because it [foot pain] just affects everything.” (BR05M)*

> *“I think with me because I look after my feet I … I don't … I don't let them get that bad.” (NB02F)*

4.4.3.4 Experience of foot care and decision to continue accessing foot care or not

The participants who accessed foot care prioritised their foot symptoms as an important issue. For those who accessed foot care there was variation in the benefit of the care they received. Participants who perceived foot care received to be beneficial and therefore a positive experience, continued to access care. However, others had negative experiences whereby they felt that their foot health care needs were not fully addressed or the care they received was sub-optimal. As a consequence these participants discontinued accessing care. In these circumstances the negative experiences of foot care were therefore inter-linked with the sub-theme of “Access hindered by patients’ perception’ (Section 4.4.3.1):

> *“As for going to the podiatrist then yes I suppose every six weeks or so then that does cost me but I think it’s worth the money really.” (BR06F)*

> *“Well they didn't cut your nails, they didn't do that. But they just really shaved all the skin off. But I really didn't find them very … you know I could do that myself.” (NB03F)*

4.5 Discussion

4.5.1 Overall findings

This chapter has presented a rich description of the experience of foot problems from the patients’ perspective. The findings of this study support previous reports that foot problems are common in patients with RA and have consequences for patients in relation to activity, footwear, and participation. Further, these data have elucidated that foot problems can also incur cost to patients in terms of financial detriment and social and emotional well-being. Additionally, foot problems appear to impact on many aspects of patients' lives, for example their ability to work. Foot problems can be variable and follow a fluctuating clinical pattern, including remission for some patients. In contrast other patients described their foot symptoms developed gradually and once evolved, were persistent. Furthermore, many patients recalled that their foot problems were early symptoms of RA and at least some patients can recognise clinical foot pathologies such as callus formation. Nonetheless, the impact of foot problems is variable and influenced by fluctuating personal priorities and patients' decisions to access foot care were more complex than anticipated.

That foot problems affect patients' ability to walk has been described (Grondal *et al,* 2008; van der Leeden *et al*, 2008). However, this study has highlighted that foot problems can also affect other activities such as ability to drive, exercise and work (paid employment). These findings provide new insight into the wider nature of the impact of foot problems. Metsios *et al* (2008) concluded that the evidence for the benefits of exercise in improving functional ability and disease-related characteristics in patients with RA is strong. However, if patients are unable to exercise due to experiencing foot problems, the clinical and personal benefits of physical activity for patients will not be achieved. The consequence of RA for work disability have been reported (Barret *et al*, 2000; Verstappen *et al,* 2004; Olofsson *et al,* 2014), but previous studies have reported predictors of work related disability relating to general patients demographics (e.g. gender), clinical variables (e.g. disease severity) and work characteristics (e.g. manual worker). However, this study highlights the importance of foot problems as a cause of work related disability, not only through problems of mobility, but also for some patients their inability to comply with contractual obligations of employment such as health and safety requirements (e.g. wearing protective footwear). The overall contribution of foot problems in relation to work disability in RA has not been established.

The consequences of foot problems in relation to footwear were discussed by all patients. Some patients described difficulty in sourcing footwear that was comfortable, accommodated deformities and was aesthetically acceptable. Additionally, footwear influenced clothing choice which subsequently resulted in negative self-perceptions in relation to identity and body image. This confirms earlier work that footwear can be an important issue for patients (Goodacre and Candy, 2011; Naidoo *et al,* 2011). Gutwengier *et al* (1998) suggested footwear selection can have negative effects on self-perceived body image, especially for women. The findings from the present study confirm that sourcing accommodative, comfortable and aesthetically acceptable footwear is a challenge for patients with RA. However, consequences of foot symptoms in relation to footwear did not seem to be gender specific in the interviews in the present study. Previous work has tended to focus on the experience of female patients with RA and issues of footwear for male patients have not been previously considered. Male patients facing challenges sourcing accommodative footwear that is aesthetically acceptable is therefore a novel finding.

Variation between patients' and clinicians' priorities in relation to overall treatment outcomes in RA has been reported (Hewlett, 2003; Sanderson *et al*, 2010), and patients and clinicians also have differing priorities in relation to outcomes of foot care interventions such as foot surgery. Backhouse *et al* (2012) propose patients evaluate the benefits of foot surgery in relation to post-surgical appearance of their feet and their ability to wear acceptable footwear. In contrast, clinicians judged the benefits of surgery in terms of reduction in pain and improved function. Although clinicians need to consider the challenges that many patients encounter in relation to footwear patients have additional priorities. This study highlights that patients consider a range personal priorities regarding having orthopaedic surgery which are not just related to post operative appearance and accommodating feet in footwear. For example some patients discussed: limited weight bearing during rehabilitation, length of recovery time and negative past experiences of previous orthopaedic surgery as important issues. Clinicians need to consider personal priorities of patients when planning and evaluating foot care interventions.

Qualitative studies have previously reported the consequences of RA impacting on many aspects of patients' personal lives (Lemmp, Scott and Kingsley*,* 2006; Lütze and Archenholtz, 2007). This study has also shown that foot problems have consequences for patients in relation to their everyday personal lives. Some patients described their foot problems affected their relationships with others and affected their personal roles. These experiences lead to a sense of isolation and negative consequences for psychological well being. The association between reduced functional capacity and foot problems impacting on patients' quality of life has been reported (Wickerman *et al,* 2004). However, the findings of this study more closely support the conclusions of Galer, Gianas and Jensen (2000) where painful diabetic neuropathy had negative effects on patients' recreational activities and social interactions. Clearly, from previous studies but especially from the content of the interviews in the present study, the consequences of foot involvement in RA are complex and can impact on many aspects of patients' lives, which would not be fully captured by functional status alone.

In order to capture this wider impact of foot problems in patients with RA, the Foot Impact Scale (FIS) was developed by Helliwell *et al* (2005). The FIS comprises of two subscales: Foot Impact Scale Footwear / Impairment (FIS_{IF}) and Foot Impact Scale Activities / Participation (FIS_{AP}). The FIS includes many of the concepts captured in the present study under the organising theme of "Consequences": the sub-themes of walking, exercise footwear, activities, and participation. However, the consequences of foot problems in relation to ability to work is not an item included in the FIS. Further the underpinning theme of "Impact" generated was influenced by fluctuations of symptoms and personal importance. Sanderson and colleagues (2011) postulate that the personal impact of RA may be influenced by patients' ability to cope, the perceived severity and personal importance (Impact Triad). Almost all of the patients in this study described that their foot problems (at some time) were severe, important and that they had difficulty self-managing. Therefore these data support Sanderson's proposed theory of the Impact Triad. Some of these items, and aspects of the impact of foot problems, are not captured by the FIS, and these additional items related to foot problems have not previously been explored in patients with RA. It would be important to include them in the survey to be conducted in Study 2.

Factors influencing patients' decisions to access foot care were complex. Patients who accessed foot care considered their foot problems to be an important health care need. These patients recalled having had their feet examined and discussions relating to foot problems had occurred during clinical consultations. Therefore some patients considered their foot problems were legitimised by clinicians ("Access supported by patients and clinicians"). In contrast, other patients reported that their foot problems were important issues but they had not accessed foot care. The organising theme of "Access hindered by patients perceptions" illustrates that some patients felt their feet had been ignored in clinical practice. Failure of clinicians to examine or discuss foot problems during consultations was considered by some patients to indicate that no interventions were available. Further, patients assumed clinicians would instigate a referral if access to foot care was indicated. This finding supports similar conclusions in earlier work on foot problems (Williams and Graham, 2012) and on fatigue (Hewlett *et al*, 2005). The organising theme “Access hindered by patients’ perceptions”, related to limited awareness of treatment options and lack of knowledge of how to access care. Lack of patients’ knowledge on how to access care has been proposed as a barrier to utilisation of foot care services (Blake, Mandy and Stew, 2013). However, some patients described how, although they had current or past experience of foot problems, access to foot care was considered unnecessary (“Access perceived unnecessary by patient”). These patients reported that their foot problems were not severe, they were able cope and could self-care and self-manage. This adds further support to the Impact Triad theory of Sanderson *et al* (2011) and the influence of the personal impact of foot problems on how people access foot care has not been previously explored. The fluctuating nature of foot symptoms was also an emergent basic theme sometimes causing access to care to be perceived as unnecessary. It is possible that if symptoms persist for a relatively short time period then patients may be unlikely to access foot care. Indeed, work conducted by Flurey *et al* (2014) in relation to help seeking behaviours and flares in the overall symptoms of RA suggests patients will only access medical care when symptoms are overwhelming, when they are no longer able to cope and as a last resort.

Previous experience of foot care appeared to influence patients’ decisions whether or not to continue with utilising foot care services. Positive experiences of foot care appeared to favour continued utilisation of foot care services. In contrast, previous negative experiences of foot care were associated with discontinuation. These findings seem logical, and are supported by the Behavioural Model and Access to Health Care (Andersen, 1995) in which continued utilisation should be influenced by levels of customer (service user) satisfaction. Foot health and rheumatology clinicians need to consider the perceived benefits of care from the patient perspective. If patients are dissatisfied with care received and/or do not consider interventions to be effective, the clinical effectiveness of foot care cannot be established.

4.5.1.2 Limitations and strengths of overall findings

A total of 12 patients with RA and self-reported foot problems participated in the study. The sample size may be considered small, limiting generalisability of findings. However, the sample was purposively diverse and data saturation was achieved. Qualitative enquiries such as this study provide the opportunity to explore the deeper understanding of the topic of interest (Mays and Pope, 1995). The findings of this study elucidated a rich description in relation to the spectrum of the experience, impact and care of foot problems from the patients' perspective. A quantitative approach is required to establish the extent to which these experiences reflect those of the overall RA population, and is presented in Study 2.

The conduct of the analysis was rigorous. A subset of transcripts was independently analysed by two experienced qualitative researchers and the patient research partner. Consensus was achieved by all members of the researcher's academic team in relation to emergent themes from the data set. Further, the researcher adapted an iterative approach in which emergent themes from the initial interviews, not included in the topic guide could be explored in subsequent interviews. Analyses also involved constant comparisons comparing emergent themes from both within and across the whole data set.

Responder validation (member checking) techniques are proposed to improve the rigour of qualitative research (Mays and Pope, 2000; Barbour, 2001). No responder validation was conducted in this study and not providing participants an opportunity to comment on the analyses and overall findings could be considered a limitation. However, the aim of this study was to inform the content of a postal survey, and was not to test underlying theory, or develop a patient reported outcome measure. Therefore additional demands on the patients' time were considered to be unnecessary and consequently unethical.

It is possible that patients in this study could have been describing the consequences and subsequent impact of more general features of RA. However, it was considered that this was unlikely. During the interviews the researcher used prompts and active listening strategies to confirm patients were disclosing experiences relating to foot problems.

4.5.2 Informing the postal survey (Study 2)

This study (Study 1) has provided an in-depth description of the patient experience of foot involvement in RA and patients' reasons for accessing or not accessing foot care services. An important reason for performing this study was to inform the content of a subsequent postal survey (Study 2), ensuring that it included issues not captured by standard measures or questionnaires. The Foot Impact Scale (FIS) developed by Helliwell *et al* (2005) is a validated questionnaire designed to capture the impact of foot problems in patients with RA. Overall the findings of this study concur with many of the items included in the FIS (e.g. footwear, activities, and participation). However, it is clear that some important issues relating to impact are not included in the FIS. In particular, some patients described that their foot problems were impacting on their ability to work (paid employment). Further, nearly all patients described their foot problems as having (at some time) been severe, and linked this to their inability to cope (self-manage). The survey would need to capture aspects of this interaction (as described in the Impact Triad). Therefore in the postal survey, questions in addition to the FIS would be included.

Most patients described the conduct of foot examinations and the role of clinicians in initiating discussions regarding foot problems to be variable. When discussions regarding foot problems did occur, they were often patient initiated. Although an annual assessment of patients' feet is recommended in national guidelines (Luqmani *et al*, 2006) the conduct of foot examinations in patients with RA is variable (Otter *et al,* 2010). It is not known how frequently clinicians ask patients about foot problems in clinical consultations. Therefore questions enquiring about the conduct of foot examinations and discussions about foot problems in clinical consultations would be included in the postal survey.

Patients who had accessed foot care services reported a range of foot care interventions. However, some patients perceived that their foot health care needs had not been fully addressed. In order to investigate the types of foot care interventions received (e.g. insoles, treatment for cutaneous lesions) questions regarding foot care received would be required in the postal survey. The majority of patients reported using a variety of self-care and self-management strategies to manage their foot problems. This was a novel finding. The extent of self-care and self-management strategies that patients utilise to address their foot health needs in RA is currently unknown, and so questions capturing these activities would be included in the postal survey.

Some patients who accessed foot care services had done so through independent sector podiatry (non NHS providers), which was a finding unexpected to the research team. To date the researcher's clinical career has been within the NHS and has no personal clinical experience of working within the independent health care setting. The researcher had not considered the potential for patients to source and self-fund independent sector foot care. In order to fully capture access to all foot care services in the postal survey questions asking if independent foot care had been accessed would be required.

4.6 Summary

The findings of this study confirm that foot problems are common in patients with RA and can impact substantially on many aspects of patients' lives. Patients who had accessed foot care services prioritised their foot problems as an important health care need. However, despite having foot problems some patients had not accessed care. Factors associated with decisions to access and utilise foot care services or not appear to be multifaceted and complex. Quantifying the extent to which these factors affect overall access to foot care in RA patients in general would be the main aim of the postal survey conducted in Study 2.

The data generated in Study 1 provided novel findings to inform the content of Study 2 in relation to: (1) patients recognising common foot pathologies; (2) patients' perception' that feet can be ignored in clinical practice; (3) additional factors of impact emerged not included in FIS (such as ability to work); (4) a broad description of foot care interventions received; (5) patients adopt a range of self-care and self-management strategies to their manage foot problems. These novel findings provided information for additional questions included in the survey (Section 5.2.3 Postal Survey Box 5.1). An additional consequence of Study 1 was the inclusion of independent sector care (private podiatry) to the definition of foot care. As a direct result of Study 1, access to foot care definition used in this thesis was amended to having accessed NHS podiatry, independent sector podiatry, orthotics and/or orthopaedics. These novel findings could not have been anticipated *a priori*, supporting the value of including the patient perspective at an early stage to ensure all appropriate and important issues were addressed.

An abstract of the Study findings Decision to Access Foot Care' has been presented as a poster at the British Society for Rheumatology and British Health Professionals in Rheumatology conference in 2012 and the Society of Chiropodists and Podiatrist annual conference in 2012 (Wilson *et al,* 2012 Appendix J1).

Chapter 5: Study 2 – Survey of foot problems in patients with RA.

The one-to-one interviews in Study 1 provided an initial understanding of the potential and scope of the presence and the impact of foot problems from the patient perspective, and of patients' reasons for accessing or not accessing foot care services. The overall research questions for this thesis: "What is the impact of foot involvement in RA and what determines if patients with RA receive foot care?" In order to estimate the prevalence of foot problems in patients with RA and to measure access to foot care, a survey of a large sample representative of patients with RA was required. The organisation of patient care in Bristol is such that a clear sampling frame could be established which included all patients with RA in a defined geographical area who had (in theory) equal access to foot care services. Using the results from Study 1 as a starting point, the content of the postal survey (Study 2) could be designed to ensure no important aspects were omitted from the questions. Before the survey could be implemented, the sampling frame, sampling methodology, data collection plan and analysis plan were required. This chapter describes how these were developed, how the content of the survey questions was finalised, how the survey was conducted, and the analysis and results of the survey.

5.1 Aims of Study 2

1. Measure the prevalence of self-reported foot problems in RA in a large sample of patients using a postal survey.
2. Quantify the nature and types of foot problems experienced by patients.
3. Assess the impact of current foot problems.
4. Identify the proportion of patients who have accessed foot care services.
5. Identify factors associated with accessing foot care.
6. Provide a description of the foot care patients have received.
7. Identify self-care and self-management strategies adopted by patients to manage foot problems.

These aims address the overarching question for Study 2 "What is the prevalence, impact and care of foot problems in patients with RA" and the thesis aims 1-4 and 6-8 as described in Chapter 3 section 3.4.2.

5.2. Methods

5.2.1. Study design

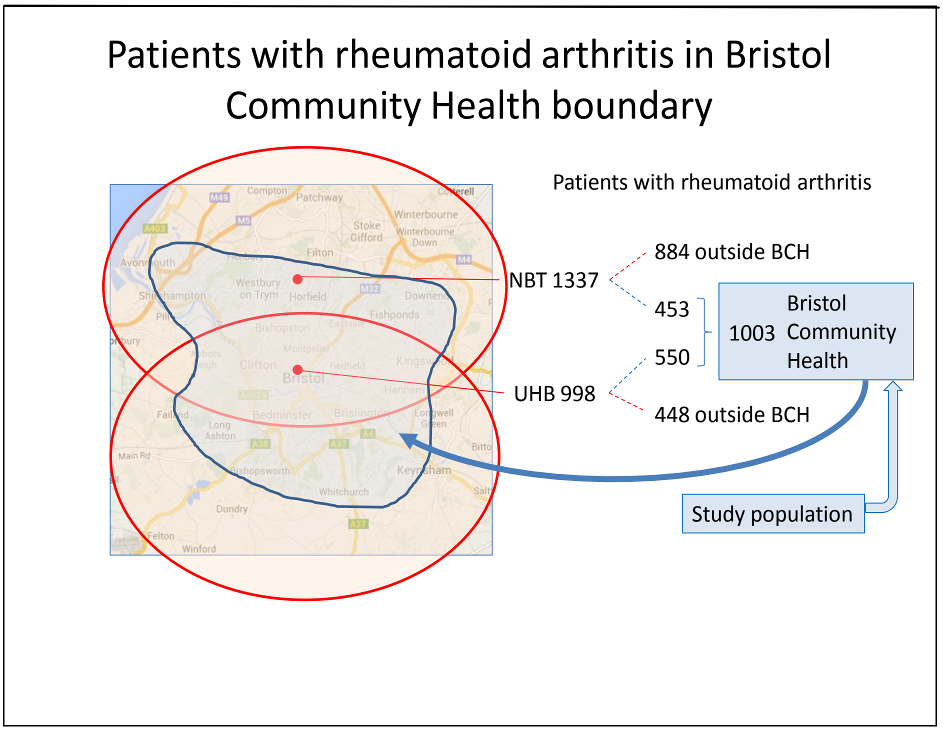
The traditional approaches to conducting survey research are: 1) face-to-face structured interviews; 2) telephone interviews; 3) self-completed electronic questionnaires; 4) postal questionnaires (Kelly *et al,* 2003). Each approach was considered. Surveys which employ direct contact with the researcher may have higher participation rates and provide the opportunity to clarify ambiguous questions (Kelley et *al*, 2003), but the presence of the researcher may influence participants' responses and therefore introduce an unacceptable bias (Davies *et al,* 2010). Telephone interviews provide the opportunity for sampling geographically diverse populations, but participation rates have been reducing with the emergence of market research company telephone surveys and therefore they may no longer reflect the general population of interest (Boland *et al,* 2006). Conducting the survey electronically was considered and the proportion of adults in the UK having access to the internet at home is increasing (National Statistics Omnibus Survey, 2013). Nonetheless, access is not universal and participation in electronic based surveys is influenced by gender and social deprivation (Fricker and Scholau, 2002), two issues which might be important to the present research question. It was therefore decided to use postal questionnaires as the method for data collection. This method provides the opportunity to: 1) sample a large population over a wide geographical area; 2) provide patients with the opportunity to consider responding in their own time; 3) maintain confidentiality and anonymity; 4) allow patients to consider their responses without the influence of the researcher being present. There are important potential biases in differential response rates (for example in relation to social deprivation), so consideration of response biases would be needed.

5.2.2 Identifying the patient population

Bristol has a mixed population and is the seventh largest city in the UK. It has typical secondary care services and long term RA follow-up patients are similar to those in other parts of England (Kirwan *et al,* 2003). The Rheumatology Departments serving South Bristol (Rheumatology Centre at University Hospitals Bristol NHS Foundation Trust (UHB)) and North Bristol (Rheumatology Department at North Bristol NHS Trust (NBT)) provide all the rheumatology services to the City of Bristol and the surrounding areas. There are slight difference in general patient demographics (e.g. variation in proportions of patients residing in areas of high deprivation) and foot care service provision (variation in podiatry service provision) between the hospitals.

These issues will be considered in data analysis and interpretation of the results. Both hospital catchment areas overlap across the middle of the city. NHS foot care services in Bristol are provided by secondary care based services (orthotics, orthopaedics) at both hospital sites. A single community based service provides NHS podiatry care (Bristol Community Health Social Enterprise (BCH)) and the boundaries of BCH fall well within the catchment area of the two hospitals taken together (Figure 5.1).

Figure 5.1 Identifying patients with RA in Bristol within Bristol Community Health Boundary



Patients with rheumatoid arthritis in Bristol Community Health boundary

By identifying as the sampling frame all RA patients attending either hospital and who were registered with a GP served by BCH a postal survey would capture the frequency of foot problems (self-report) and access to all foot care services in one geographical area covering both primary and secondary care provision. The patient population for Study 2 was therefore defined as consultant-based diagnosis of RA (Arnett *et al,* 1988), over the age of 18 years attending for rheumatology medical care at UHB and NBT Rheumatology Departments within the BCH geographical boundary (i.e. registered with a GP within the BCH boundary).

Patients registered for their rheumatology medical care at UHB were identified from departmental databases and screened for inclusion criteria by the researcher. Information about patients meeting the study inclusion criteria was then recorded in a study data base, including: patient demographics (name, age, gender and home address including postcode), hospital identification number and the name of each patient’s consultant rheumatologist. Patients registered for their rheumatology medical care at NBT were identified from departmental databases and screened for inclusion criteria by members of the NBT rheumatology clinical team. The patient details (as listed above) were entered into a spreadsheet by the NBT clinical team, sent to the researcher by NHS password protected email, and amalgamated with the study database. Each patient was allocated a number by random number generation by the computer random number function and the list arranged in ascending numerical order. These random numbers were then used as the study identifiers (study ID). The database was stored on University computers and was password protected, the password known only to the researcher and her academic supervisor (JK) to maintain patient confidentiality. All other data manipulation and computation procedures used only the study ID.

The RA patient population in Bristol was defined as all patients registered for medical care at both hospital sites (n=2335). The target population was defined as all patients within the BCH geographical area (n=1003) as shown in Figure 5.1. The study sample was a random sample of the target population.

5.2.3 Questionnaire design

The content of the questionnaire was developed from three sources. Firstly, from data generated from the one-to-one interviews in Study 1. Secondly, from a narrative review of the literature in relation to studies reporting foot problems in RA to identify any disparity in the nature and types of foot problems reported. Thirdly, the inclusion of validated questionnaires (scales) measuring the impact of foot problems in RA (Foot Impact Scale (FIS) Helliwell *et al,* 2005) and general disability (Health Assessment Questionnaire, HAQ, Fries *et al,* 1980; Kirwan and Reeback, 1986).

Box 5.1 presents the content, source and rationale for each item included in the questionnaire. The content of Section A (age, gender, disease duration, arthritis medications and additional morbidity) and Section D (HAQ) were required to describe the demographic and clinical characteristics of responders. Information about additional morbidity was also required in order to attribute foot problems to RA, as foot problems can be important clinical features of other long term conditions such as diabetes.

Assessment of patients' feet and access to foot care services is recommended in national guidelines (Luqmani *et al,* 2006). However, the findings of Study 1 indicated that patients' perceive the inclusion of feet (examination and discussions) in clinical consultations to be variable. Additionally the findings indicated that patients feel able to recognise many foot problems such as callus formation and presence of deformity. Items in Section B of the questionnaire establish the frequency of foot examinations, capture all clinical features of foot problems in RA, enquire about which foot care services have been accessed and a description of the care received. This section also includes questions developed to specifically enquire about areas of impact omitted from current questionnaires but identified in Study 1. Section C comprised the two subscales of the FIS (FIS Impairment Footwear (FIS_{IF}) and FIS Activities Impairment (FIS_{AP}) and Section D the HAQ, all presented in their original formats. Each item included in the questionnaire was given a unique identification number, though these were not all shown on the printed questionnaire sent to the patients.

Box 5.1 Content, source and rationale of items included in postal survey

Section	Item included	Source	Rationale
A: About you	Patient demographics age and gender (A1 & A2)		Data required for description of sample
	Clinical data (A3 to A5)	Disease duration, arthritis medications and co-morbidities	Data required for description of sample. Co-morbidity data were include because some conditions have foot problems as clinical features e.g. diabetes
	Date survey completed (A6)		For recruitment for Study 3, this aimed for conduct of foot examination to be within approximately 2 months of completing questionnaire. It decided that this was the most practical minimum time interval to achieve recruitment for Study 3
B: Your feet	Talked about feet (B1 to B3)	Study 1 interviews (Section 4.4.3.3.2)	Discussions about feet appear to influence decisions to access foot care
	Feet examined (B4)	National guidelines, literature and Study 1 interviews (Section 4.4.3.1.4)	Recommended in national guidelines, Study 1 findings indicate patients perceive variable in clinical practice
	Foot problems (B5)	Literature, clinical observations and Study 1 interviews (Section 4.4.2.1)	To measure prevalence of foot problems in a large sample of patients. Was decided that patients recognise common foot problems
	Personal importance of foot problems (B6)	Study 1 interviews (Sections 4.4.2.4.1& 4.4.3.3.4)	Additional impact of foot problems not capture by FIS
	Ability to cope with foot problems (B7)	Study 1 interviews (Section 4.4.3.2.3)	Additional impact of foot problems not captured by FIS
	Severity (magnitude) of problem (B8)	Study 1 interviews (Sections 4.4.3.2.2 & 4.4.3.3.4)	Additional impact of foot problems not captured by FIS

B: Your feet	**Item included**	**Source**	**Rationale**
	Impact of foot problems on ability to work (B9)	Created from discussions with PRP and Study 1 interviews (Section 4.4.2.2.2)	Additional impact of foot problems not captured by FIS
	Foot care services accessed (10A, 10B, 10C)		Dependant variable
	Foot care received (B11)	Best practice guidelines (Williams *et al,* 2011)	Data required capturing description of foot care interventions received in sample
	Self-care and self-management strategies adopted (B12)	Study 1 interviews (Sections 4.4.3.2.3)	Data required capturing self-care and self-management strategies adopted by patients
	Ankle / foot surgery (B13)		Dependant variable
	Additional comments		Opportunity for responders to disclose any important issues relating to foot problems not covered by previous questions (O'Cathain and Thomas, 2004)
C: Impact of foot problems	Foot Impact Scale (FIS)	Validated Scale (Helliwell *et al,* 2005)	Standard questionnaire to measure current impact of foot problems in RA
D: Daily Activities	Health Assessment Questionnaire (HAQ)	Validated scale (Fries *et al,* 1980; Kirwan and Reesback, 1986) Gold standard scale of disability in RA.	Standard questionnaire to include to measure current disability in research and clinical practice

Box 5.1 continued

5.2.3.1 Collaboration with patients on survey content

To maximise response rates from the postal survey detailed consideration was given to various aspects of the survey materials by the PRP and also by seven patients with RA who fed back on the second draft of the survey. Three of the patients were PRPs, two from UHB and one from NBT. The other patients did not have any research training and were invited to provide comments from outpatient rheumatology clinics at UHB. The purpose was to make all the information as accessible as possible for patients to interpret and answer (Streiner, Norman and Cairney, 2014). The review patients considered: the patient information sheet (PIS); instructions for completing the questionnaire; the wording of questions in the questionnaire; and the layout of the survey. Time taken to complete the draft survey by individual patients was between five and ten minutes. Their comments were considered before the final version of the questionnaire was constructed. Six points emerged from patients' feedback on the questionnaire these were useful in determining the final format (Table 5.1).

Table 5.1 Modifications to the draft postal survey after patient feedback

Section of postal survey	Patient Comments	Research team decision
Front sheet	• Add sentence "You may want to sit down with a cup of coffee while you fill this in"	• Included in final version
Section A Demographic and clinical data	• No comments	
Section B Foot problems and foot care	• Re-order questions B2 and B3 • Anchors to B7 inconsistent with B6 and B8 anchors	• Re-ordered in final version • Decision not to change anchors to B7
Section C FIS	• Addition of "sometimes" as a response option to FIS	• This was not possible as FIS is a validated scale
Section D HAQ	• No comments	
Overall comments	• No measure of psychological impact of foot symptoms • Ring bind surveys to make it easier for patients with hand involvement	• Decision made not to include as not a primary aim of the study • This was not possible due to financial constraints

A second PRP (CS) joined the researcher's study team at the development stage of Study 2. The PRPs (EQ and CS) were members of the initial Research Advisory Group. Both PRPs actively participated in the researcher's supervisory team meetings and provided valuable contribution on the content, wording and ordering of questions included in the survey (see Box 5.1). The final version of the questionnaire was agreed with all members of the researcher's research team (academic supervisors and PRPs) and can be found in Appendix F2.

5.2.4 Scoring the scales

Full guidance on the scoring of the FIS (for example how to deal with missing data) has not been published. It was therefore considered that a pragmatic approach was required in relation to scoring the scale. The two subscales of the FIS, $\mathrm{FIS}_{\mathrm{IF}}$ and $\mathrm{FIS}_{\mathrm{AP},}$ were therefore scored and reported as separate scores. Each subscale was scored for the number of "true" answers. (maximum 21 and maximum 30; respectively). Hooper *et al,* (2012) propose $\mathrm{FIS}_{\mathrm{IF}}$ scores ≥14 and/or $\mathrm{FIS}_{\mathrm{AP},}$ scores ≥20 to indicate severe impact respectively. For the purpose of this study it was decided that a minimum of 90% of all questions had to be completed for both subscales for the scores of the FIS to be admissible ($\mathrm{FIS}_{\mathrm{IF}} > 18$ and $\mathrm{FIS}_{\mathrm{AP}} > 27$ questions completed). Missing values were given the average of the score for the other questions. It was decided if any returned FIS questionnaires were not sufficiently completed to meet the defined admissible criteria, incomplete FIS scores would be excluded from analyses. For HAQ scores to be considered admissible standard guidance was used (Fries *et al*, 1980). Scores were admissible if there was at least one response in a least 7 sections and the missing section was given the average score for the other sections. Additional measures of impact of (severity, ability to cope and importance) were measured using an 11 point numerical rating scale (e.g. 0=not important, 10=very important). Impact of foot problems and ability to work were captured by nominal (categorical) variables (e.g. yes, no or not applicable).

5.2.5 Social deprivation

The link between social deprivation (e.g. low, income, inadequate housing and unemployment, ill health), access to health care and associated health outcomes in general is well established (Smith, Bartley and Blane, 1990; Munro, 2006). Social deprivation has also been suggested as a risk factor for developing RA (Bengtsson *et* *al*, 2005; Pedersen *et al,* 2006). However, the influence of social deprivation in relation to accessing foot care services in general or in RA populations is not known. It is also possible that patients from socially deprived areas would be less likely to take part in the survey (Urwin *et al,* 1998). Social deprivation can be measured using individual level indicators (education level, income, occupation- based indicators, and/or household measures) or area level indicators (capturing the social deprivation of an area or population in relation to crime rates, proportion of population unemployed, barriers to housing and services, and living environment (Macintyre, Ellaway and Cummings, 2002). Each approach has weaknesses, for instance, income level may not reflect an individual's financial position or represent their level of disposable income. Grundy and Holt (2001) suggest using a combination of individual and area level indicators to capture health inequalities in older people.

A brief review of available measures which include individual and area levels indicators of deprivation was therefore conducted. The Townsend Deprivation Index (Townsend*,* Phillimore and Beattie, 1988) is constructed from four domains: 1) households with a car; 2) overcrowded households; 3) households not owner occupied; 4) male unemployment. The Townsend Deprivation Index is based on the 1991 UK national (Census.ac.uk) and being over 20 years out of date may not reflect the current population of an area. The Index of Multiple Deprivation (IMD) 2007 for England (English Indices of Deprivation, 2007) is composed of a number of indicators to cover a range of measures of deprivation (economic, housing and social issues) and combine them in a weighted manner into a single numerical score. The IMD is calculated for areas with a minimum population of 1000, referred to as Lower Layer Super Output Areas (LSOA). The indicators / domains of the IMD 2007 are (with weight allocation given in brackets): 1) income deprivation (22.5%); 2) employment deprivation (22.5%); 3) health deprivation and disability (13.5%); 4) education skills and training deprivation (13.5%); 5) barriers to housing and services (9.3%); 6) crime and disorder (9.3%); 7) living environment (9.3%) (Nobble *et al,* 2007). One benefit of the IMD is the ability to compare small neighbourhood areas at both local and national levels by ranking LSOA scores. However, the IMD reflects deprivation of the area and may not be applicable to a particular individual who lives in that area. Not all people residing in a deprived area will be deprived (low affluence) and not all deprived individuals will live in deprived areas. Nonetheless, the IMD can be used as a geographical measurement of local deprivation. IMD scores are obtained from post codes and therefore negate the need to ask respondents for further information. The IMD 2007 was selected as a measure of social deprivation for Study 2. IMD scores were obtained from postcodes utilising GEOConvert software (http://geoconvert.mimas.ac.uk, accessed 09/10/13). (Since completion of this work, IMD 2010 and its associated software packages have been published). IMD scores were taken for the whole sampling frame and were converted into categories. (Category 1 least deprived (most affluent) was defined as the lowest 20% of scores, Category 2 represent the second fifth (21%- 40%), and so on up to category 5 most deprived (least affluent (81-100%)). The categories were therefore an index of comparative deprivation within the population sample (Roberts *et al,* 2008).

5.2.6 Response rate

Low response rates can increase the risk of bias and reduce generalisibility (Galea and Tracy 2007; Lorant *et al,* 2007). To optimise response rate the questionnaire was reviewed by a convenience sample of 10 patients with RA as described above. Another important aspect of conducting postal surveys relates to response bias. For example differences in general and clinical characteristics of responders and non-responders can threaten the generalisability of the findings to the whole target population. In particular if the characteristics of responders are not similar to the characteristics of non-responders, systematic errors may occur. The influence of gender, age and social deprivation on participation rates in survey studies has been widely reported (e.g. Korkeila *et al,* 2001). Additionally this study recruited patients from two hospital sites with small variation in general patient characteristics and varying levels of dedicated podiatry provision. Each of these factors could influence the interpretation of the survey results, so Research Ethics Committee approval was obtained to record the following (anonymised) information on all patients within the target population hospital site; gender, age and social deprivation. Comparisons between the target population and study sample, and the response rates could then be made.

5.2.7 Study procedures

Ethics approval was granted by Central Bristol Medical Research Ethics Committee (reference 11/SW/0327) and the University of the West of England Research Ethics Committee (reference HLS/12/01/12). Research and development approval was obtained from both hospital sites (NBT and UHB).

The eligible target population was defined as all patients meeting the study inclusion criteria. As described above, eligible patients were listed in random order. The study sample was identified by starting at the top of the list and progressing in batches until an appropriate number of responses had been received (see below). The study sample was the patients posted a questionnaire. Questionnaire packs were posted to patients at their home address. The pack included: 1) an invitation letter (signed by the patient's rheumatology consultant); 2) patient information sheet (PIS); 3) a copy of the questionnaire; 4) a FREEPOST return envelope (see Appendix E and F1). If no response was received within 3 weeks, the questionnaire pack was sent again. As approved by the Research Ethics Committee, informed consent to participate in the study was inferred by the return of the questionnaire.

Patients were invited in blocks of approximately 50 at a time to aid administration, commencing with the lowest study ID. Before a questionnaire pack was sent out, hospital records were checked to see if the recipient patient had a pending rheumatology out-patient appointment within 4 weeks. In order to reduce potential bias related to changes in any clinical consultation process brought about by bringing foot problems to mind. For example completing the questionnaire prior to a clinical consultation may have influenced patients to initiate discussions about their foot problems. If any patients had a pending rheumatology clinic appointment, a questionnaire pack was not sent until after the date of the pending appointment.

5.3 Analysis plan and sample size

5.3.1 Statistical analyses

Descriptive statistics were used to describe the study sample. The underlying frequency distribution for each continuous variable was visually inspected to assess for normality (Pallant, 2010). Normally distributed continuous data were expressed as means and standard deviations (SD) or 95% confidence intervals (CI) and compared using independent sample t-tests. Skewed continuous data were expressed as medians with their inter-quartile range (IQR) and compared using the Mann-Whitney U test. For categorical data, proportions were calculated and expressed as percentages and were compared using the chi-square test applied to the original numbers. Spearman's rank order correlation coefficient (Spearman's rho) was performed to compare how the additional impact scores included in the survey related to the FIS scores. P values were considered statistically significant if they were less than 0.05.

Comparisons of the general and clinical characteristics of responders who accessed foot care (AFC) and responders who had not accessed foot care (NAFC) used descriptive and inferential statistics as stated above. The type of foot care accessed and the route by which this was done were analysed in relation to general and clinical characteristics of respondents with descriptive and inferential statistics (stated above).

Multivariate analyses were undertaken to determine the statistical significance of contributory factors as independent variables influencing access to foot care (AFC/NAFC) as the dependent variable. Logistic regression was selected as the method for multivariate analyses as the dependent variable of interest was binary (ever accessed foot care versus not ever accessed foot care) and the independent variables were a combination of categorical and continuous variables (e.g. disease duration and social deprivation). Additionally, logistic regression does not assume a linear relationship between the dependent variable and independent variables selected for the model. As an assumption of logistic regression analyses is that the independent variable is independent of the dependent variable (Pallant, 2010), foot related variables were not considered for multivariate analyses (e.g. FIS scores).

Initial selection of the independent variables included in the logistic regression model was conducted after univariate analyses identifying differences (non-foot related) between the accessed foot care group (AFC) and the not accessed foot care group (NAFC). Logistic regression analyses were then performed to assess the predictive ability of each independent variable by controlling for the effects of the other independent variables in the model. Analyses were performed utilising binary entry (block entry) whereby all the independent variables were entered in to the model simultaneously. The statistical analyses were conducted using SPSS 19.0 (SPSS Inc. Chicago, Illinois).

5.3.2 Free text data analysis

Data in relation to arthritis medications and additional morbidity (other health conditions) were collected by free response text. Consensus of the classification and categorisation of arthritis medications and other health conditions was agreed in discussion between the researcher and her academic supervisor (JK).

Content analysis was selected as an approach to analyse free text responses to a general open ended question (“If you have any other comments about foot problems in RA that you would like to make, please add them here?”). Content analysis is a method for systematically describing textual data (free text response in questionnaires), verbal communication (transcripts of interviews) and non-verbal communication (observations of video diaries) (Graneheim and Lundman, 2004). It can be applied to qualitative and quantitative data and be inductive (data driven) or deductive (theory driven) in approach (Elo and Kyngäs, 2008; Hsieh and Shannon, 2005). The guidance of O’Cathain and Thomas (2004) was followed:

1. The researcher reads the free text data for familiarisation with the data.
2. Devises a coding frame to describe the content (thematic) of the text.
3. Assigns codes (labels) to all comments.
4. Codes can then be entered into a data base and treated as quantitative data for analyses.

Following reading and re-reading all the free text data for familiarisation, data relating to similar issues were grouped together in categories assigned with comment labels (codes). Comment labels of similar meaning were then grouped to form comment categories to produce a coding frame. All free text data (verbatim) and the coding frame were entered into SPSS and treated as variables in a quantitative analysis. The results of the content analysis are presented as descriptive statistics (frequencies, proportions of responders) and exemplars from the free text used to illustrate emergent comment categories accompanied by study identifiers (ID), gender (e.g. F- female) and age (in years) of the respondent.

5.3.3 Sample size

This thesis adopted a sequential concurrent research design, whereby Study 1 was conducted first to identify important issues from the patient perspective to inform the content of a postal survey (Study 2). Recruitment for Study 2 (survey) and Study 3 (clinical assessment) were then conducted simultaneously. Patients invited to participate in Study 3 were a selected sub-sample of responders to Study 2. Sample size estimates for Study 3 were based on the expectation that there will be a maximum of 5 to 6 main determinants of access to foot care, which would be adequately identified by multivariate analyses conducted in Study 2 (Belle, 2008). The sample size for Study 3 was therefore based on recruiting 60 patients classified as AFC and 60 patients classified as NAFC in Study 2. (The methods for Study 3 are fully described in Chapter 6). Therefore Study 2 recruitment continued until recruitment to Study 3 had been achieved.

The Sample size requirements for Study 2 were difficult to estimate as the extent of variation in access to foot care (and possibly foot care needs) was unknown *a priori*. Additionally, the number of patients who were required to be invited to participate and the number of patients required to respond to Study 2 to achieve the forecasted sample size for Study 3 were not known. It was estimated (based on epidemiology data) that approximately 2000 patients with RA would be attending both NHS sites for their rheumatology care. Of these it was estimated 1,500 would be within the geographical area (registered with GP within BCH boundaries). A previous survey on fatigue conducted at one of the hospital sites achieved a response rate of 79% (Nicklin *et al*, 2010) but this was initiated by direct contact with the patient at the hospital department. It was therefore estimated a 70% response rate might be achievable. Initially 500 hundred patients would be randomly selected but if less than 350 responses were returned, further random samples of patients would be invited to participate in batches of 100. Recruitment to Study 2 therefore overlapped with invitations to participate in Study 3 and continued until recruitment to Study 3 was achieved.

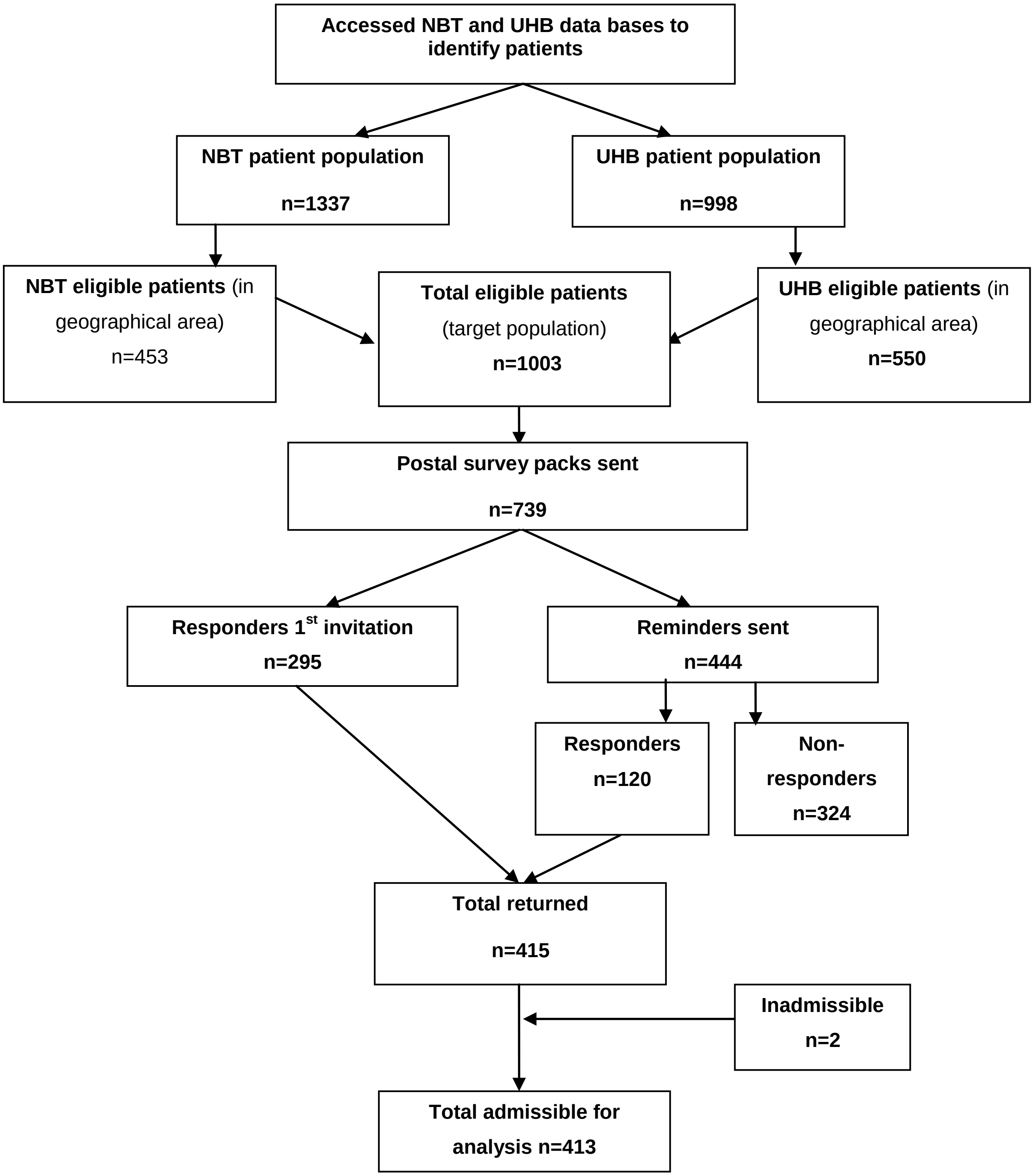
5.4 Results: Quantitative analysis

5.4.1 Response rates

Data were collected from December 2011 to February 2013. A flow diagram of study recruitment is shown in Figure 5.2. There were 1003 eligible patients in the target population (Figure 5.1). Recruitment stopped when 415 questionnaires were returned (as at that point recruitment to Study 3 had been achieved), by which time 739 survey packs had been posted. Of these responses, 295 (39.9%) were returned directly and 120 (16.2%) were returned after a reminder, giving an overall response rate of 56.2%. Two questionnaires (responses) were inadmissible (not adequately completed) and 413 (55.9%) were admissible responses.

Each returned questionnaire was checked for completeness by the researcher. Missing data were clarified by a telephone call (by the researcher) with the responder. If telephone contact was not achieved missing data were coded as 999. Accuracy of data entry was checked firstly by duplicate entry of a random sample of 10% completed questionnaires; and secondly by reviewing for errors using frequencies, minimum and maximum values for each variable. Apparent errors were checked against returned questionnaires and corrected. Analyses were conducted using “exclude case pairwise” to account for missing data. The responses of “not applicable” were coded as 888 to reflect completeness of the data sets.

Figure 5.2 Flow diagram of recruitment Study 2 (postal survey)



5.4.2 Characteristics of responders and non-responders

In order to check for responder bias the general characteristics (hospital site, gender, age and social deprivation) of the responders were compared to those of the non-responders. (See Appendix F2 for questionnaire)

5.4.2.1 Hospital site

Table 5.2 illustrates the comparison of responses by hospital site. Despite differences patient demographics and foot care service provision, response rates were very similar.

Table 5.2 Response rates by hospital site

	NBT (n=381) **Number (%)**	**UHB (n=358)** **Number (%)**
Returned no reminders	137 (36.0)	158 (44.1)
Reminder sent	244 (64.0)	200 (55.9)
Returned after reminder	74 (30.3)	46 (23.0)
Inadmissible	2 (1.0)	0 (0)
Admissible questionnaires	209 (54.9)	204 (56.9)

Table 5.3 presents the response rates in relation to general characteristics by hospital site. Overall general patient characteristics are broadly similar for both sites, although NBT had a lower proportion of IMD category 5 participants.

Table 5.3 Response rates general characteristics by hospital site

		Target population		**Responders**	
		NBT (n=381)	**UHB (n=385)**	**NBT (n=209)**	**UHB (n=204)**
Female number (%)		289 (75.9)	263 (73.5)	156 (74.6)	151 (74.0)
Age mean (SD)		63 (14.1)	62 (13.1)	63 (13.9)	64 (11.6)
Social deprivation	1 (least deprived)	94 (24.7)	85 (23.7)	60 (28.7)	56 (27.5)
(IMD LSOA	2	166 (43.6)	124 (34.6)	83 (39.7)	60 (29.4)
categories)	3	89 (23.4)	74 (20.7)	51 (22.4)	48 (23.5)
Number (%)	4	25 (6.6)	41 (11.5)	14 (6.7)	22 (10.8)
	5 (most deprived)	7 (1.8)	34 (9.5)	1 (0.5)	18 (8.8)

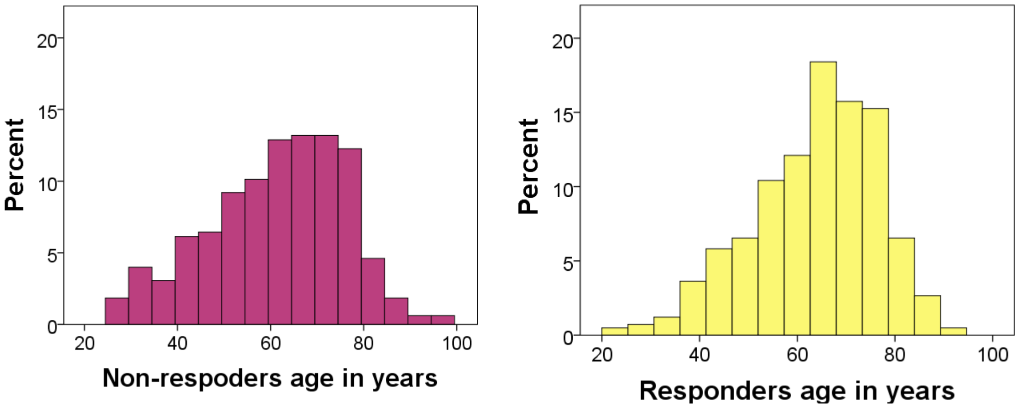
5.4.2.2 Gender (A1)

Of the 739 patients invited to participate (target population), 552 (74.7%) were female. Of 413 responders, 306 (74.1%) were female. The number of men invited was 187 (25.3%), and of these 107 (25.9%) responded. There was no statistically significant response bias in relation to gender ($x^2 =$ 0.65, df=1, p=0.865).

5.4.2.3 Age (A2)

The mean age for the target population was 62.6 years (SD =13.6; range 25 - 99); responders 63.5 years (SD=12.8; range 25 - 91); and non-responders 61.5 years (SD=14.6; range 27 - 99). Figure 5.3 presents the comparisons of age distribution between responders and non-responders. There was a statistically significant difference between responders and non-responders for age (t= -2.1, df=737, p=0.04), but this was small (difference between means 2 years; 95% CI 1.0, 4.1).

Figure 5.3 Age distribution comparisons responders (n=413) non-responders (n=326)



5.4.2.4 Social deprivation (postcodes)

To investigate if response varied according to social deprivation comparisons of responders and non-responders area level deprivation were computed. IMD 2007 categories for the target population, responders and non-responders are presented in Table 5.4. The majority of the target population resided in areas of relatively low deprivation (high affluence). Although a Chi-squared test indicated an overall difference between responders and non-responders in relation to social deprivation ($x^2 = 14.0$, df=4, p=0.007). The proportions of responders residing in categories 3, 4 and 5 combined were equal.

Table 5.4 Representation of area level deprivation in which patients reside

Deprivation categories	Target population (n=739) Number (%)	Responder (n=413) Number (%)	Non-responder (n=326) Number (%)
1 (least deprived)	179 (24.2)	116 (28.1)	63 (19.4)
2	290 (39.2)	143 (34.6)	147 (45.1)
3	163 (2.1)	99 (24.0)	64 (19.6)
4	66 (8.9)	36 (8.7)	30 (9.2)
5 (most deprived)	41 (5.5)	19 (4.6)	22 (6.7)

5.4.2.5 Overview of responder bias

There was a small difference in age and in overall postcode-level social deprivation index between responders and non-responders. However, there were adequate responses from patients living in relatively high areas of deprivation. Responders therefore reflected the study target sample. Additionally, the general patient characteristics (gender, age and social deprivation) of responders and non-responders were broadly similar for both hospital sites. Responders were consequently regarded as one population for subsequent analyses. The study responders were therefore considered to be broadly representative of the patients with RA in Bristol.

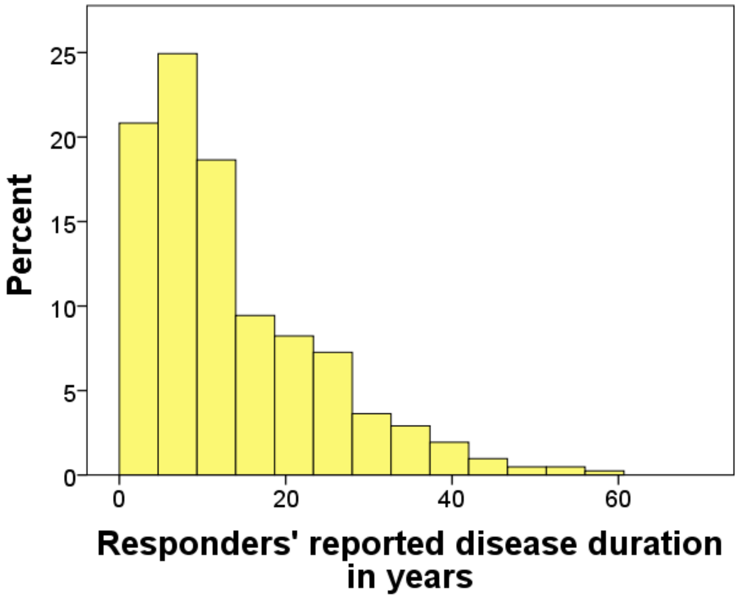
5.4.3 RA clinical data of responders

The clinical characteristics of responders are set out below

5.4.3.1 Disease duration (A3) and age at diagnosis

The frequency distribution of responders' self-report of disease duration is presented in Figure 5.4. The median was 10 years (IQR 5 to 20, range 1- 60).

Figure 5.4 Disease duration in questionnaire responders



The mean age at diagnosis was 50.3 years (SD=14.9; range 1 - 85). A small number of responders (7, 2%) reported they had been diagnosed with RA before the age of 16 years but none of these reported a different diagnosis (e.g. juvenile idiopathic arthritis).

5.4.3.2 Medication (A4)

The majority of responders were taking arthritis medications (pharmacological therapy) for their RA (n = 394, 95.4%). The classification of arthritis medications were: non-steroidal anti-inflammatory drugs (NSAIDs), disease modifying anti-rheumatic drugs (DMARDs), glucocorticoids, and biologic therapies. The frequency of responders taking each category of medication was: NSAIDs 128 (31.0%), DMARDS 339 (82.1%), glucocorticoids 122 (29.5%) and biologic therapies 74 (17.9%). Many responders were taking more than one category of arthritis medications (n=210, 50.8%) (Table 5.5).

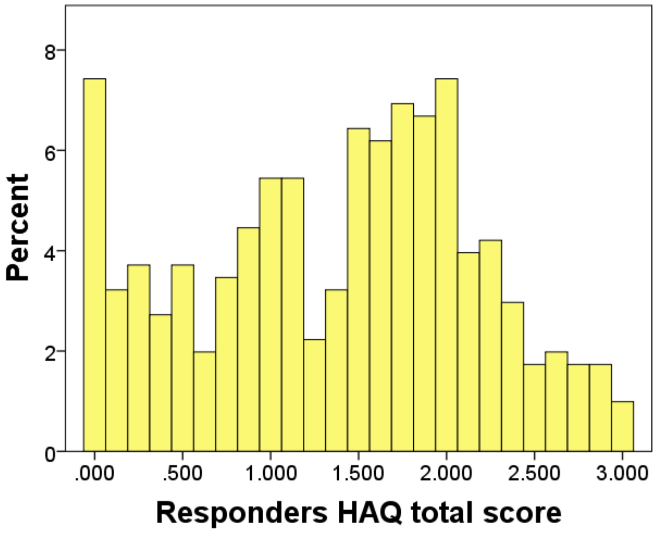
Table 5.5 Frequencies and categories of RA medications (n=413)

	NSAIDs	DMARDs	Glucocorticoids	Biologics	Total
Taking no RA medication	-	-	-	-	19
Taking 1 category of RA medication	17	142	12	13	184
Taking 2 categories of RA medication	68	147	69	28	156
Taking 3 categories of RA medications	38	45	36	28	49
Taking 4 categories of RA medication	5	5	5	5	5
Total	128	339	122	74	413

5.4.3.3 Disability (Section D)

A total of 404 (97.8%) responders completed the Health Assessment Questionnaire (HAQ). Figure 5.5 presents the frequency distribution of HAQ scores. Median score was 1.5 but there was a wide range of reported levels of disability (IQR 0.750 to 2.0) with some patients (n=30, 7.4%) reporting no current disability.

Figure 5.5 Frequency of HAQ scores (n=404)



5.4.3.4 Co-morbidities (A5)

A total of 266 responders (64.4%) reported other health conditions (co-morbidity). Of these, 92 (34.6%) reported having more than one morbidity as illustrated in Table 5.6. Table 5.7 summaries the frequencies of co-morbidities according to disease categories. Diabetes, an important cause of foot problems, was reported by 28 responders (6.8%).

Table 5.6 Frequency of co-morbidity categories (n=413)

Co-morbidity category	Co-morbidity category Number (%)
No other co-morbidity	147 (35.6)
1 co-morbidity	174 (42.1)
2 co-morbidities	70 (16.9)
3 co-morbidities	17 (4.1)
4 co-morbidities	4 (1.0)
5 co-morbidities	1 (0.2)

Table 5.7 Co-morbidity classification categories (n=413)

Co-morbidity condition	Type of co-morbidity	Number (%)
Diabetes Thyroid disease Paget's disease Osteopinia	Endocrine	63 (15.3)
Myocardial infarction Cerebrovascular accident Hypertension Arrythmia Deep vein thrombosis Raynaud's Peripheral vascular disease Hypercholesterolemia	Circulatory disease	137 (33.2)
Asthma Chronic obstructive pulmonary disease Bronchiectasis Sleep apnea	Respiratory disease	54 (13.1)
Anxiety Depression Schizophrenia	Mental health	13 (3.1)
Eczema Psoriasis Herpes simplex Urticaria	Dermatology	7 (1.7)
Glaucoma Retinopathy Ocular toscocariasis	Eye	8 (1.9)
Basal cell carcinoma Breast cancer Prostate cancer	Cancer	7 (1.7)
Anaemia Thrombocytopenia	Haematology	8 (1.9)
Ulcerative colitis Crohn's disease Hiatus hernia Oesophageal reflux	Gastrointestinal	19 (4.6)
Multiple sclerosis Dystonia	Neurology	3 (0.7)
Ankylosing spondylitis Juvenile idiopathic arthritis Gout Osteoarthritis Osteoporosis Giant cell arteritis Systemic lupus erythematosus Sarcoidosis Sjogrens	Other rheumatological diagnosis	47 (11.4)
Spinal stenosis Sciatica Degeneration of spin	Back problems	12 (2.9)
Fibromyalgia	Chronic pain	6 (1.5)
Primary bilary cirrhosis	Heptology	1 (0.2)
Tendinopathy Fracture Foot deformity not RA related	Other musculoskeletal conditions	3 (0.7)
Chronic kidney disease	Renal disease	3 (0.7)
	Any category	266 (64.4)

5.4.3.5 Overview of clinical data

Overall a wide range of disease duration and age at diagnosis of RA was reported. The great majority of responders were taking one or more arthritis medications and a fifth were taking biologic therapies. No current disability was reported by less than 10% of responders. Additionally, and of interest of itself, almost two thirds of responders reported the presence of other health conditions, and the proportion reporting diabetes was 6.8% (n=28).

5.4.4. Foot-related characteristics

5.4.4.1 Talked about feet (B1 – B3)

The majority of responders (n=314, 76.0%) reported they had talked to someone about problems with their feet (Table 5.8). Of those who had talked about their feet, 230 (73.2%) had raised the issue themselves while 84 (26.8%) reported that someone else had raised the issue (Table 5.9). Of these 84, 23 (26.8%) reported two categories of people who initiated talking about feet. The number of responders reporting three or more categories of people initiating discussions about feet was small (n=3, 3.6%).

Table 5.8 Frequency of talked about feet (n=413)

Talked about feet	Number (%)
Patient initiated	230 (55.7)
Other person initiated	84 (20.3)
Not talked about feet	99 (24.0)

Table 5.9 Categories of people talking about feet (n=314)

Person who initiated talking about feet	Number (%)*
Family	8 (2.5)
Practice nurse	2 (0.6)
Rheumatology nurse	13 (4.1)
Friends	3 (1.0)
Rheumatology Doctor	55 (17.5)
Other	7 (2.2)
GP	16 (5.1)
Podiatrist / chiropodist	11 (3.5)
Patient initiated	230 (73.4)

*Some responders indicated more than one person who initiated discussions about feet

5.4.4.2 Feet examined (B4)

A total of 412 responders completed the question, “Has a health professional examined your feet?” Overall 312 (75.7%) reported having had a foot examination. Of the 100 who reported not to have had a foot examination, 59 (59.0%) indicated that they thought a foot examination should have been conducted. Table 5.10 presents the time period frequencies of last recalled foot examinations. Of the 312 responders who reported a foot examination, 150 (48.1%) reported their feet had been examined in the last twelve months. A small number of responders who had had a foot examination were unable to recall when the examination was conducted (n=31, 7.5%). Data were not collected on which health professionals conducted the examination.

Table 5.10 Time interval of foot examinations (n=413)

Time interval of last recalled foot examination	Number (%)
0-6 months	89 (21.6)
>6 -12 months	61 (14.8)
>12-18 months	34 (8.3)
>18 months	97 (23.5)
Can’t remember	31 (7.5)
Never had feet examined	100 (24.3)
Not completed	1 (0.2)

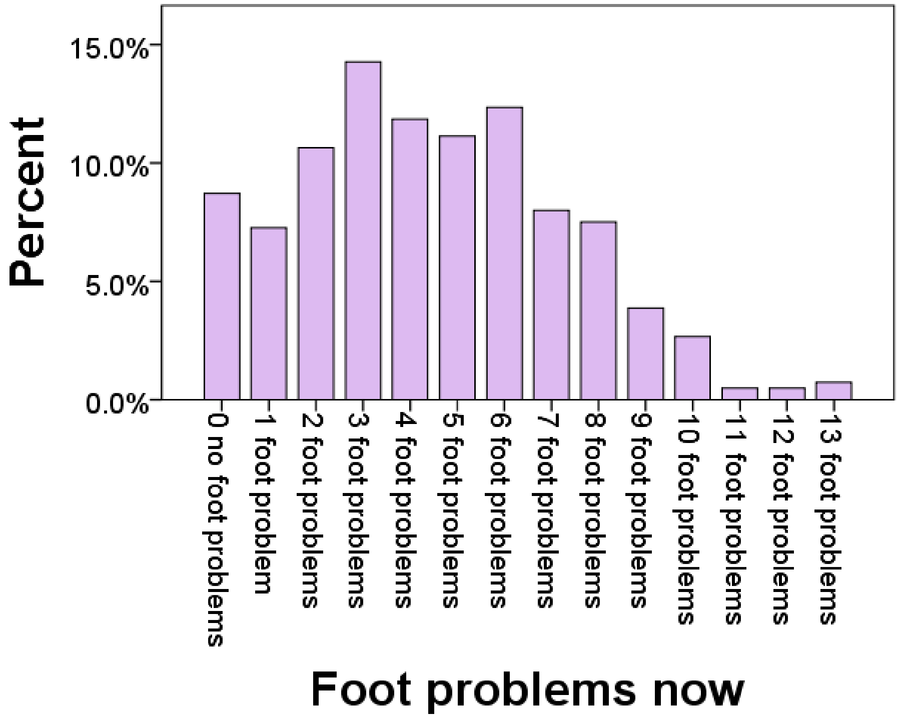
5.4.4.3 Foot problems (B5)

Almost all respondents reported they had experienced foot problems at some time since developing RA. Only 14 (3.4%) reported never having experienced any foot problems. The majority of responders (n=377, 92.1%) reported the current presence of one or more foot problems (Table 5.11). The rates of current foot problems between women and men were similar (n=279, 90.0% versus n=91, 85.8%). The highest frequency of foot problems was in the articular features category, followed by cutaneous lesions and structural deformity. Figure 5.6 presents the frequencies of the number of foot problems reported by individual responders. Half of responders reported five or more current foot problems (n=215, 52.1%).

Table 5.11 Reported foot problems (n=413 (%))

Foot problem category	Foot problems	Foot problem now	Foot problem ever	Never had foot problems
Articular features	Pain	263 (63.7)	342 (82.8)	71 (17.2)
	Stiffness	224 (54.2)	277 (67.1)	73 (17.8)
	Swelling	218 (52.8)	286 (69.2)	127 (30.8)
	Any articular feature	**305 (73.8)**	**373 (90.3)**	40 (9.7)
Cutaneous lesions	Blisters	28 (6.8)	73 (17.7)	340 (82.3)
	Callus	171 (41.4)	206 (49.9)	297 (50.1)
	Corns	72 (17.4)	109 (26.4)	304 (73.6)
	In-grown toe nails	59 (14.3)	106 (25.7)	307 (74.3)
	Thickened Toe nails	168 (40.7)	190 (46.0)	223 (54.0)
	Ulcers	13 (3.1)	38 (9.2)	375 (90.8)
	Any cutaneous lesions	**270 (65.4)**	**303 (73.4)**	110 (26.6)
Structural deformity	Bunions	111 (26.9)	141 (34.1)	272 (65.9)
	Fallen arches	93 (22.5)	121 (29.3)	292 (70.7)
	Misshaped toes	180 (43.6)	199 (48.2)	214 (51.8)
	Any structural deformity	**238 (57.6)**	**265 (64.2)**	148 (35.8)
Extra-articular features	Nodules	96 (23.2)	122 (29.5)	291 (70.5)
	Numbness	118 (28.6)	153 (37.0)	260 (63.0)
	Any extra articular feature	**176 (42.6)**	**212 (51.3)**	**201 (48.7)**
Other	Infection	31 (7.5)	76 (18.4)	337 (81.6)
Any foot problems		**377 (91.2)**	**403 (97.6)**	10 (2.4)

Figure 5.6 Number of foot problems reported by individual responders (n=413)



5.5.4.4 Overview of foot-related characteristics

Nearly all the responders reported one or more current foot problem and over half reporting to have 5 or more current foot problems. These data also indicate foot problems are very common in patients with RA but may fluctuate. For some patients, once foot problems have developed, they appear to be persistent and for others, foot problems appear to follow a variable clinical course. The data also suggest that patients considered their feet to be important health care needs as, when discussions regarding foot problems were conducted; they were often initiated by patients. However, although patients indicated that clinicians do not routinely initiate talking about feet, the majority (n=312, 75.7%) recalled having a foot examination at some time.

5.4.5 Impact of foot problems

The impact of foot problems was captured by the FIS and by numerical rating scales addressing: importance of foot problems, ability to cope with foot problems, magnitude (severity) of foot problems and ability to work.

5.4.5.1 Foot Impact Scale (Section C)

The FIS Impairment / Footwear (FIS_{IF}) scores from 0-21 and. the FIS Activities / Participation (FIS_{AP}) scores from 0-30. Of the 413 responders, 400 (96.7%) FIS scores were admissible. The median (IQR) FIS_{IF} and FIS_{AP} scores were 10 (6 to 14) and 16 (7 to 23), respectively. Figure 5.7 and Figure 5.8 present the frequency distribution of the FIS_{IF} scores and FIS_{AP} scores.

Figure 5.7 Foot Impact Scale Impairment Footwear (FIS_{IF}) scores (n=400)

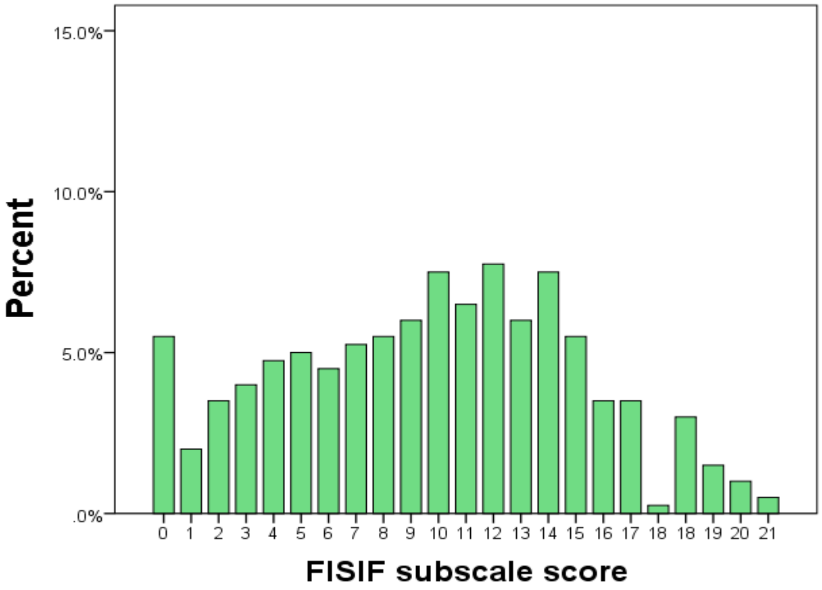
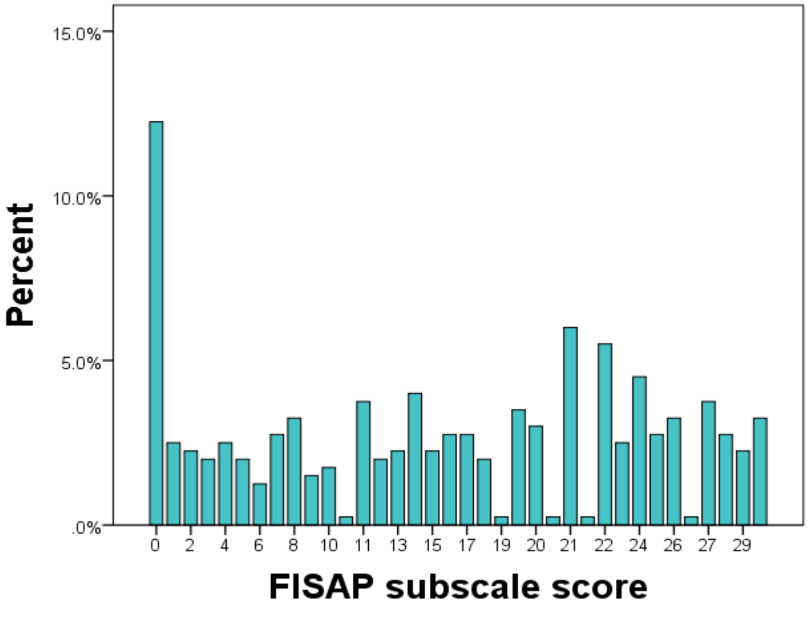


Figure 5.8 Foot Impact Scale Activities Participation (FIS_{AP}) scores (n=400)

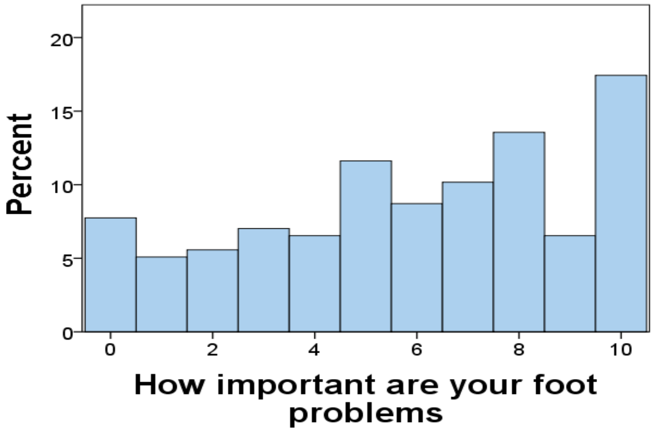


FIS_{IF} scores were normally distributed but FIS_{AP} scores were negatively skewed. The proportion of responders scoring 0 on the FIS_{AP} was 12.3% (n=49).

5.4.5.2 Importance of foot problems (B6)

The importance of foot problems was measured by an 11 point numerical rating scale range 0 (not important) to 10 (very important), which all responders completed. The median (IQR) score was 6 (3 to 8), with the distribution of importance scores presented in Figure 5.9.

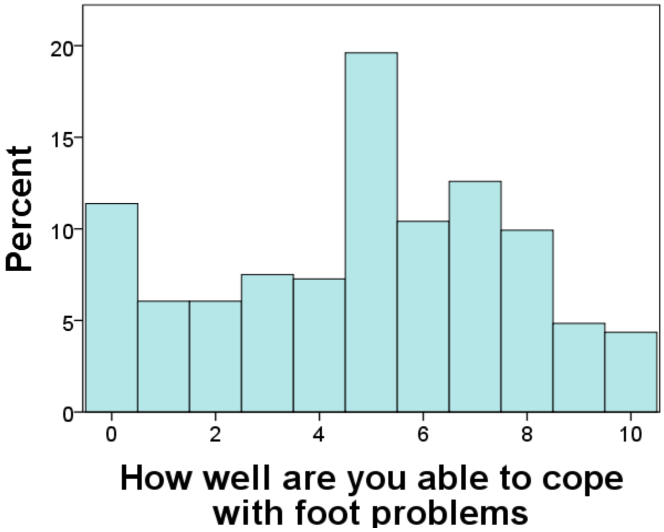
Figure 5.9 Importance of foot problem scores (n=413)



5.4.5.3 Ability to cope with foot problems (B7)

All responders completed the 11 point numerical rating measuring self-perceived ability to cope with foot problems (0, coping very well to 10, not coping very well). The median (IQR) coping score was 5 (3 to 7). The frequency distributions of coping scores are represented in Figure 5.10.

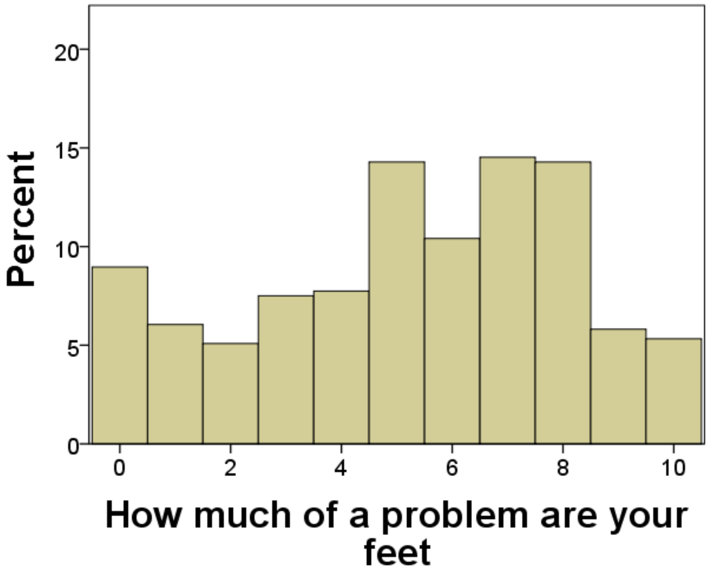
Figure 5.10 Ability to cope with foot problems (n=413)



5.4.5.4 Magnitude of foot problems (B8)

An 11 point numerical rating scale captured current severity (magnitude) of foot problems and was completed by all responders (0, no problem to 10, severe problem). The median (IQR) severity score was 6 (3 to 8). The frequency distribution of severity scores are presented in Figure 5.11.

Figure 5.11 Magnitude of foot problems scores (n=413)



5.4.5.5 Comparisons of measures of impact

The findings of Study 1 indicated that not all important issues regarding the impact of foot problems are included in the FIS, a validated questionnaire. Although the NRS measuring the additional impact of foot problems in RA in this survey (importance, ability to cope and magnitude) were developed in close consultation with patients they have not been formally validated. To investigate if the additional measures of impact did indeed provide additional information not included in the FIS_{IF} and FIS_{AP}, the association of additional measures of impact with the FIS sub-scale scores was examined.

As the additional measures of impact scores were not normally distributed, Spearman's rank order correlation coefficient (Spearman's rho) was calculated to examine associations of impact scores. Table 5.12 presents a correlation matrix for these measures. There were statistically significant positive relationships between all measures of impact, indicating that they were probably reflecting a common construct. Squaring the correlation coefficient indicated that 49.8% of the variance of FIS_{IF} scores was explained by FIS_{AF} scores. The variance of FIS_{IF} scores explained by importance, ability to cope and magnitude scores were 40.4%, 41.6%, and 46.1%, respectively. The variance in FIS_{AP} scores explained by importance, ability to cope and magnitude was only moderate 26.9%, 30.5% and 31.4%, respectively, indicating that these additional measures of impact are providing information not included in the FIS.

Table 5.12 Correlation of measures of impact of foot problems (n=400)

			Importance (B6)	Ability to cope (B7)	Magnitude (B8)
Spearman's rho	FIS_{IF} (Impairment / Footwear)	Correlation Coefficient Explained variance %	.636** 40.4	.645** 41.6	.679** 46.1
	FIS_{AP} (Activities / Participation)	Correlation Coefficient Explained variance %	.519** 26.9	.553** 30.5	.560** 31.4
	Importance (B6)	Correlation Coefficient Explained variance %		.761** 57.9	.844** 71.2
	Ability to cope (B7)	Correlation Coefficient Explained variance)			.841** 70.7

** rho significant p= 0.01 level

5.4.5.6 Impact of foot problems on ability to work (B9)

Of the 254 responders who were working, 156 (61.4%) reported foot problems impacting on their ability to work and 98 (38.6%) reported no impact. Higher median impact scores were detected in responders who reported foot problems affecting their ability to work (Table 5.13). The majority of responders not working indicated in free text responses that the reason for not being in paid employment was retirement or personal choice.

Table 5.13 Comparisons of impact scores and ability to work (n=413)

	Impact of foot problems on ability to work		
Impact scores	**Yes (n=156) Median (IQR)**	**No (n=98) Median (IQR)**	**Not applicable (n=159) Median (IQR)**
FIS_{IF}	12.0 (10.0 to 15.0)	6.0 (3.0 to 9.5)	9.0 (5.0 to 13.0)
FIS_{AP}	21.0 (14.0 to 24.0)	5.0 (0 to 14.0)	16.0 (7.0 to 23.5)
Importance of foot problems (B6)	8.0 (6.0 to 10.0)	3.0 (1.0 to 6.0)	6.0 (4.0 to 8.0)
Ability to cope with foot problems (B7)	6.0 (5.0 to 7.0)	3.0 (0.0 to 5.0)	5.0 (2.5 to 7.0)
Magnitude of foot problems (B8)	7.0 (5.0 to 8.0)	3.0 (1.0 to 5.0)	6.0 (3.0 to 8.0)

5.4.5.7 Overview of impact of foot problems

There was a wide range of impact scores in relation to current foot problems. A number of responders reported that their foot problems were impacting on their personal lives in terms of: impairment (e.g. pain on standing), footwear (e.g. limiting choice of shoes), activity levels (e.g. walking) and participation in valued activities (e.g. social isolation). Further, some responders reported their foot problems to be very important and severe, and that they were not coping well with the problems (scoring 10 on the NRS). The relatively weak relationships between the FIS_{IF} and FIS_{AP} and the additional measures of impact indicate that these additional measures do capture information not included in the FIS. A further indication of this was that one third of responders reported that their foot problems were affecting their ability to work.

5.4.6 Self-care and self-management of foot problems (B12)

A wide range of self-care and self-management strategies were reported (Table 5.14). Of the 413 responders, 188 (45.5%) reported having to use one or more aids (e.g. shoe horn, device to put on hosiery) to self-care and self-manage their foot health care needs. While the self-care and self-management strategies used were generally similar in men and women, more females reported using cutaneous treatments and complementary treatments.

At first sight the use of self-care and self-management strategies could be interpreted as being beneficial to their foot health. However, 79 (19.1%) responders had used self-sourced (non-prescribed) topical keratolytics (cuticle softeners and corn plasters) which contain chemical agents (e.g. salicylic acid). Further, 79 (19.1%) responders had used hot treatments (e.g. compresses) or cold treatments (e.g. ice packs) to manage their foot problems. These strategies can be detrimental to foot health, particularly in relation to patients with impaired tissue viability, and are usually not recommended.

Table 5.14 Self-care and self-management strategies used by responders according to gender (n=413)

Self –care and self-management categories	**Self-care and self-management strategies**	**Female (n=306) Number (%)**	**Male (n=107) Number (%)**
Aids	Aid / device to put hosiery on	50 (16.3)	13 (12.1)
	Shoe horn	101 (32.9)	36 (33.6)
	Long handled nail scissors / nippers	55 (18.0)	19 (17.8)
	Any aids	139 (45.4)	49 (45.8)
Cutaneous treatments	Foot file	152 (49.7)	28 (26.2)
	Cuticle softener	24 (7.8)	4 (3.7)
	Moisturisers	199 (65.0)	32 (29.9)
	Hard skin corn removal plasters	43 (14.1)	8 (7.5)
	Any cutaneous treatments	224 (73.2)	44 (41.1)
Complementary treatments	Acupuncture	14 (4.6)	5 (4.7)
	Aromatherapy	7 (2.3)	1 (0.9)
	Homeopathic remedies	10 (3.3)	1 (0.9)
	Reflexology	30 (9.8)	4 (3.7)
	Other complementary	11 (3.6)	1 (0.9)
	Massage	51 (16.7)	7 (6.5)
	Any complementary treatments	81 (26.5)	15 (14.0)
Devices	Bunion protectors	22 (7.2)	2 (1.9)
	Bunion night splints	2 (0.7)	1 (0.9)
	Foot pads	40 (13.1)	10 (9.3)
	Padded socks	42 (13.7)	12 (11.2)
	Insoles	176 (57.5)	59 (55.1)
	Shoes not available in shops	46 (15.0)	11 (10.3)
	Toe splints / separators	21 (6.9)	8 (7.5)
	Toe protectors	35 (11.4)	6 (5.6)
	Any devices	208 (68.0)	67 (62.6)
Thermal treatment	Heat treatments	22 (7.2)	8 (7.5)
	Cold	43 (14.1)	6 (5.6)
	Any thermal treatment	50 (16.3)	14 (13.1)
Pharmacological	Athlete’s foot creams	47 (15.4)	22 (20.6)

5.4.7 Comparing those who have accessed foot care with those who have not access foot care

Responders were categorised as having accessed foot care (AFC, 287, 69.5%) if they had attended one or more foot care service (NHS podiatry, independent podiatry, orthotics and/or orthopaedics) or not accessed foot care (NAFC, 126, 30.5%). The AFC group formed a greater proportion of patients than had been anticipated from the literature review undertaken before the survey.

5.4.7.1 Hospital Site

Although the two hospital sites have slightly different provisions for foot care, the proportions of responders having accessed foot care overall were similar for each hospital site (Table 5.15).

Table 5.15 Access to foot care according to hospital site (n=413)

Hospital site	NBT (n=209) Number (%)	UHB (n=204) Number (%)
AFC	149 (71.3)	138 (67.6)
NAFC	60 (28.7)	66 (32.4)

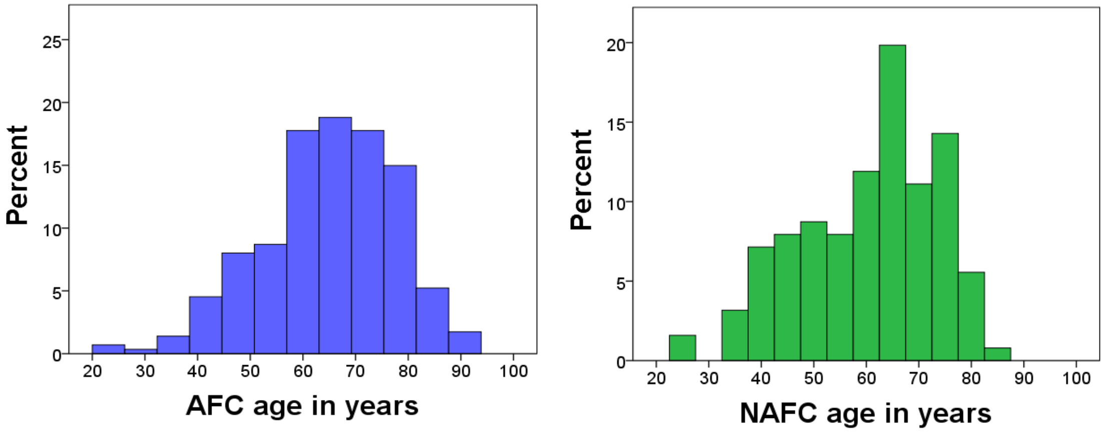
5.4.7.2 Gender (A1)

Of the 107 male responders, 66 (61.7%) had accessed foot care while of the 306 female responders, 221 (72.2%) had accessed foot care. This was a statistically significant difference ($x^2 =$ 3.51, df=1, p=0.04).

5.4.7.3 Age (A2)

There was only a small difference between the mean age of the AFC group (64.9 years, SD=12.5, range 26 - 91) and that of the NAFC group (60.4 years, SD=13.0, range 25 - 84) which was statistically significant (t=-3.35, df=411, p=0.01) (Figure 5.12)

Figure 5.12 Comparisons of age distribution AFC (n=287) and NAFC (n=126)



5.4.7.4 Social deprivation

The distribution of local deprivation categories for the AFC group and the NAFC group are shown in table 5.16 and are similar (x^2 =4, df=4, p=0.363). In particular the proportions from more deprived areas (categories 3, 4 and 5) are similar for the AFC group (36.2%) and the NAFC group (39.7%).

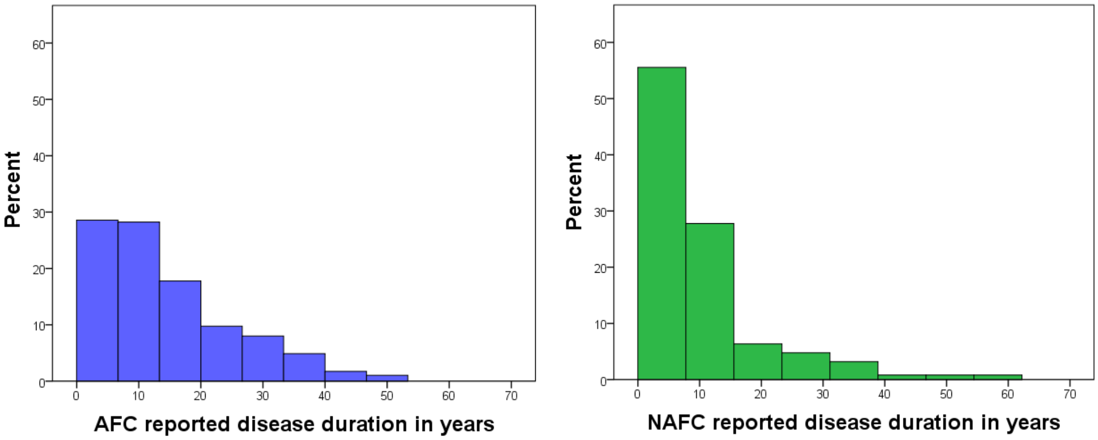
Table 5.16 Access to foot care according to area level deprivation in which patients reside (n= 413)

Deprivation categories	AFC (n=287) Number (%)	NAFC (n=126) Number (%)
1 (least deprived)	89 (31.0)	27 (21.4)
2	94 (32.8)	49 (38.9)
3	67 (23.3)	32 (25.4)
4	25 (8.7)	11 (8.7)
5 (most deprived)	12 (4.2)	7 (5.6)

5.4.7.5 Disease duration (A3) and age at diagnosis

The median reported disease duration for the AFC group was 12 years (IQR 6 to 21, range 1 - 53) and for the NAFC group was 7 years (IQR 3 to 12, range 1 - 60). The difference in medians of 5 was statistically significant (U =12677.5, P<0.001). The frequency distribution of disease duration is presented in Figure 5.13. This illustrates a peak in disease duration of RA between 20 - 30 years in the AFC group while only 20 (15.9%) of the NAFC group, reported disease duration of >20 years. The mean age at diagnosis (of RA) for the AFC group and the NAFC group was 50.2 years (SD=14.7) and 50.2 years (SD=15.2), respectively.

Figure 5.13 Disease duration comparisons AFC (n=287) and NACF (n=126)



5.4.7.6 Medication (A4)

The numbers (proportions) of the AFC group taking arthritis medications were: NSAIDs 93 (32.4%), DMARDs 230 (80.1%), glucocorticoids 79 (27.5%) and biologics 51 (17.7%). The equivalent numbers for the NAFC group were similar: 35 (27.8%), 109 (86.5%), 43 (34.1%) and 23 (18.3%). The number of categories of arthritis medications being taken by the AFC group and the NAFC group are presented in Table 5.17. The proportions of patients taking two or more arthritis medications were similar in both groups.

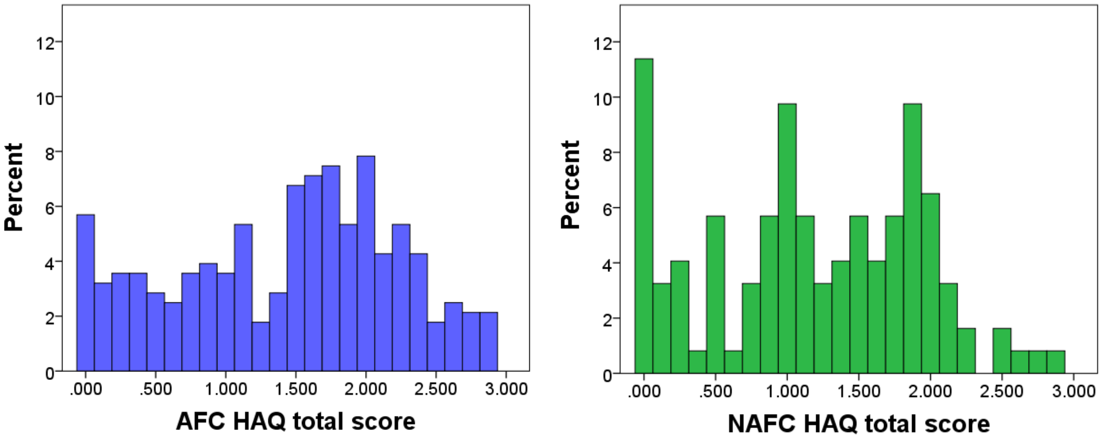
Table 5.17 Frequency of RA medication categories (n=413)

Number of arthritis medication	AFC (n=287) Number (%)	NAFC (n=126) Number (%)
Not taking RA medication	13 (4.5)	6 (4.8)
Taking 1 category of medication	133 (46.3)	51 (40.5)
Taking 2 categories of medication	106 (36.9)	50 (39.7)
Taking 3 categories of medication	32 (11.1)	17 (13.5)
Taking 4 categories of medication	3 (1.0)	2 (1.6)

5.4.7.7 Disability

The HAQ was adequately completed by 404 (97.8%) responders. Incomplete HAQs were returned by 6 (2.1%) of the AFC group and 3 (3.4%) of the NAFC group. There was a wide range of reported levels of disability in both groups (Figure 6.14). The median (IQR) score for the AFC group was 1.625 (0.8125 to 2.0) compared to the NAFC group of 1.125 (0.5 to 1.875). Although the difference in medians of 0.5 between was statistically significant (U =14243, p=0.005), it was a relatively small difference

Figure 5.14 Distribution of HAQ scores for AFC (n=281) and NAFC (n=123)



5.4.7.8 Co-morbidities (A5)

The presence of additional morbidity (other health conditions) was reported by two thirds of responders (Table 5.18). An apparent tendency for the responders with additional health conditions to be more likely to access foot care was not statistically significant (x^2=6.73, df=3, p=0.08). Table 5.19 presents the classification and categories of the presence of other health conditions. Of the 28 patients reporting diabetes, 22 (78.6%) had accessed foot care.

Table 5.18 Frequency of co-morbidity categories (n=413)

Number of co-morbidity	**AFC (n=287) number in this category Number (%)**	**NAFC (n=126) number in this category Number (%)**
No other co-morbidity	97 (33.8)	50 (39.7)
1 co-morbidity	116 (40.4)	58 (46.0)
2 co-morbidities	56 (19.5)	14 (11.1)
> 3 co-morbidities	18 (6.3)	4 (3.2)
Any co-morbidity	190 (66.2)	76 (60.3)

Table 5.19 Co-morbidity condition categories (n=413)

Co-morbidity condition	**Type of co-morbidity**	**AFC (n=287) in this category Frequency (%)**	**NAFC (n=126) in this category Frequency (%)**
Diabetes Thyroid disease Paget's disease Osteopinia	Endocrine	48 (16.7)	15 (11.9)
Myocardial infarction Cerebrovascular accident Hypertension Arrythmia Deep vein thrombosis Raynaud's Peripheral vascular disease Hypercholesterolemia	Cardiovascular disease	104 (36.2)	33 (26.2)
Asthma Chronic obstructive pulmonary disease Brochiectasis Sleep apnoea	Pulmonary disease	39 (13.6)	15 (11.9)
Anxiety Depression Schizophrenia	Mental health	10 (3.5)	3 (2.4)
Eczema Psoriasis Herpes simplex Urticaria	Dermatology	7 (2.4)	0 (0)
Glaucoma Retinopathy Ocular toscocariasis	Eye	5 (1.7)	3 (2.4)
Basal cell carcinoma Breast cancer Prostate cancer	Cancer	4 (1.4)	3 (2.4)
Anaemia Thrombocytopenia	Haematology	4 (1.4)	4 (3.2)
Ulcerative colitis Crohn's disease Hiatus hernia Oesophageal reflux	Gastrointestinal	12 (4.2)	7 (5.6)
Multiple sclerosis Dystonia	Neurology	0 (0)	3 (2.4)
Ankylosing spondylitis Juvenile idiopathic arthritis Gout Osteoarthritis Osteoporosis Giant cell arteritis Systemic lupus erythematosus Sarcoidosis Sjogrens	Other rheumatological diagnosis	36 (12.5)	11 (8.7)
Spinal stenosis Sciatica Degeneration of spine	Back problems	8 (2.8)	4 (3.2)
Fibromyalgia	Chronic pain	5 (1.7)	1 (0.8)
Primary bilary cirrhosis	Heptology	1 (0.3)	0 (0)
Tendonipathy Fracture Foot deformity not RA related	Other MSK	3 (1.0)	0 (0)
Chronic kidney disease	Renal disease	3 (1.0)	0 (0)
	Any category	**190 (66.2)**	**76 (60.3)**

5.4.7.9 Talked about feet (B1 – B3)

Of the 413 responders, 314 (76%) reported to have talked about their feet to someone (Table 5.20). Of these, 245 (78.0%) were in the AFC group. The majority of the 287 responders in the AFC group indicated they had talked about their feet (n=245, 85.4%) while in contrast only half of the 126 in the NAFC group had talked about their feet with someone (n=69, 54.8%). Data were not collected in relation to the circumstances when discussions regarding feet occurred (e.g. during a clinical consultation). Further some patients may have found the question ("Have you talked to anyone about your feet?") confusing as 14.6% of the AFC group did not report having talked to anyone about their feet.

Over half of the responders reported that they themselves had initiated talking about feet (n=230, 55.7%), implying that foot problems are important issues for patients. The proportion of the AFC group initiating discussions was higher compared to the NAFC group (60.6% versus 44.4%).

Table 5.20 Frequency of talked about feet (n=413)

Talked about feet	AFC (n=287) Number (%)	NAFC (n=126) Number (%)
Patient initiated	174 (60.6)	56 (44.4)
Other person initiated	71 (24.7)	13 (10.3)
Not talked about feet	42 (14.6)	57 (45.2)

Of the 84 responders who reported that someone else initiated talking about feet, it was most frequently a rheumatologist (Table 5.21). The proportion of the AFC group reporting a rheumatology clinician had initiated discussions about feet was 60% (n=59). The equivalent numbers for the NAFC group was 53% (n=9). The inclusion of the podiatrist as a category is ambiguous, as for the question to be raised by a podiatrist the patient would have had to have had a clinical consultation with a podiatrist.

Table 5.21 Categories of other person initiating talking about feet* in 84 responders

Person who initiated talking about feet	AFC (n=98) Number (%)	NAFC (n=17) Number (%)
Family	6 (6.1)	2 (11.8)
Practice nurse	2 (2.0)	0 (0)
Rheumatology nurse	12 (12.2)	1 (5.9)
Friends	1 (1.0)	2 (11.8)
Rheumatology Doctor	47 (48.0)	8 (47.1)
Other	6 (8.5)	1 (5.9)
GP	13 (13.3)	3 (17.6)
Podiatrist / chiropodist	11 (11.2)	0 (0)

*Some patients indicated more than one person who initiated discussions about feet

5.4.7.10 Feet examined (B4)

Of the 413 responders, 312 (75.5%) recalled having their feet examined (Table 5.22). Of the AFC group (n=287), 238 (76.3%) reported having their feet examined in contrast to only 74 (58.7%) of the NAFC group (n=126) (x^2=27, df=1, p=<0.001). A third of responders (n=150, 36.3%) reported they had undergone a foot examination in the last 12 months. In the AFC group, 116 (40.4%) had their feet examined in the previous 12 months but only 43 (26.9%) of the NAFC group recalled an examination for the same time period.

Of the AFC group, 49 reported they had not had their feet examined. Although it seems likely their feet would have been examined during their foot care consultation, more than half of them (n=27) went on to comment that they felt an examination of their feet should have been performed, suggesting that a foot examination was not done or patients did not recognise that their feet had been examined.

Table 5.22 Time interval of foot examinations (n=413) responders

Time interval of last recalled foot examination	AFC (n=287) Number (%)	NAFC (n=126) Number (%)
0-6 months	74 (25.8)	15 (11.9)
>6 -12 months	42 (14.6)	19 (15.1)
>12-18 months	29 (10.1)	5 (4.0)
>18 months	65 (22.6)	32 (25.4)
Can’t remember	28 (9.8)	3 (2.4)
Never had feet examined	49 (17.1)	51 (40.1)
Not completed	0 (0)	1 (0.8)

5.4.7.11 Foot problems

Table 5.23 presents the frequencies of self-reported current and previous foot problems. The proportions of responders reporting any current foot problems were 93.7% (n=269) in the AFC group versus 80.2% (n=101) in the NAFC group. This was a significant result (x^2=17, df=1, p=<0.001). Nonetheless, the great majority of the AFC group and the NAFC group reported they had experienced foot problems at some time since developing RA.

Table 5.23 Reported foot problems AFC (n=287) versus NAFC (n=126) (%)

Foot problem category	Foot problems	Foot problem AFC Now	Foot problem NAFC now	Foot problem AFC ever	Foot problem NAFC ever	Never had foot problem AFC	Never had foot problem NAFC
Articular features	Pain	193 (67.2)	70 (55.6)	244 (85.0)	98 (77.8)	43 (15.0)	28 (22.2)
	Stiffness	162 (56.4)	62 (49.2)	191 (66.6)	86 (68.3)	96 (33.4)	40 (31.7)
	Swelling	156 (54.4)	62 (49.2)	199 (69.3)	87 (69.0)	88 (30.7)	39 (31.0)
	Any articular feature	**220 (76.7)**	**85 (67.5)**	**263 (91.6)**	**110 (87.3)**	**24 (8.4)**	**16 (12.7)**
Cutaneous lesions	Blisters	19 (6.6)	9 (7.1)	50 (17.4)	23 (18.3)	237 (82.5)	103 (81.7)
	Callus	136 (47.4)	35 (27.8)	160 (55.7)	46 (36.5)	127 (44.3)	80 (63.5)
	Corns	61 (21.3)	11 (8.7)	87 (30.3)	22 (17.5)	200 (69.7)	104 (82.5)
	In-grown toe nails	45 (15.7)	14 (11.1)	62 (21.6)	14 (11.1)	225 (78.4)	112 (88.9)
	Thickened Toe nails	127 (44.3)	41 (32.5)	141 (49.1)	49 (38.9)	146 (50.9)	77 (61.1)
	Ulcers	9 (3.1)	4 (3.2)	50 (17.4)	23 (18.3)	237 (82,6)	103 (81.7)
	Any cutaneous lesions	**206 (71.8)**	**64 (50.8)**	**230 (80.1)**	**73 (57.9)**	**57 (19.9)**	**53 (42.1)**
Structural deformity	Bunions	88 (30.7)	23 (18.3)	109 (38.0)	32 (25.4)	178 (62.0)	94 (74.6)
	Fallen arches	81 (28.2)	12 (9.5)	98 (34.1)	23 (18.3)	189 (65.9)	103 (81.7)
	Misshaped toes	145 (50.5)	35 (27.8)	158 (55.1)	41 (32.5)	129 (44.9)	85 (67.5)
	Any structural deformity	**184 (64.1)**	**54 (42.8)**	**204 (71.1)**	**61 (48.4)**	**83 (28.9)**	**65 (51.6)**
Extra-articular features	Nodules	73 (25.4)	23 (18.3)	90 (31.2)	32 (25.4)	197 (68.4)	94 (85.5)
	Numbness	93 (32.4)	25 (19.8)	114 (39.7)	39 (31.0)	143 (49.8)	87 (69.5)
	Any extra articular feature	**134 (46.7)**	**42 (33.3)**	**157 (52.3)**	**55 (43.7)**	**130 (45.3)**	**71 (56.3)**
Other	Infection	25 (8.7)	6 (4.8)	62 (21.6)	14 (11.1)	225 (78.4)	112 (88.9)
Any problems		**269 (93.7)**	**101 (80.2)**	**284 (99.0)**	**115 (91.3)**	**3 (1.0)**	**11 (8.7)**

5.4.7.12 Foot Impact Scale (Section C)

There were 400 admissible FIS scores. The FIS_{IF} scores for the AFC group and NAFC group (Figure 5.15) had medians (IQRs) of 11 (7 to 14) and 8 (4 to12) respectively. Although this was significant (U =13284.5, p=0.01), the result indicates that foot problems were impacting on many patients in both groups in relation to impairment and footwear.

Figure 5.15 Frequency distribution of FIS_{IF} scores (n=400)

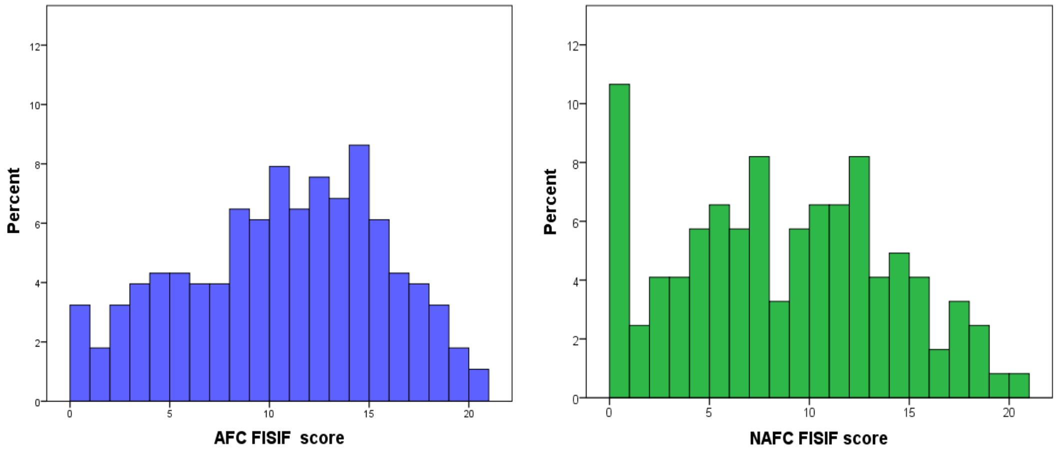
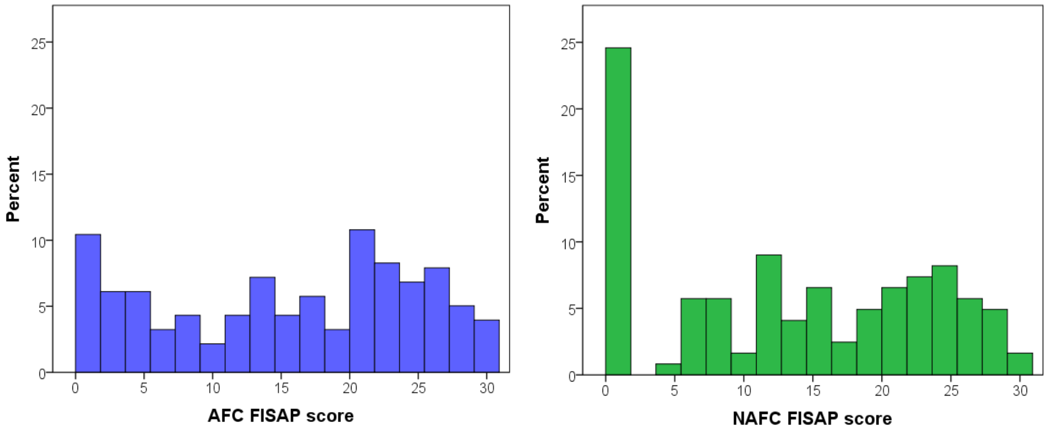


Figure 5.16 presents the distribution of FIS_{AP} scores for the AFC group and NAFC group. The median (IQR) for the AFC group was 17 (7 to 23) and for the NAFC group was 13.5 (7 to 23). This result indicates that foot problems were impacting on many patients in terms of activity and participation.

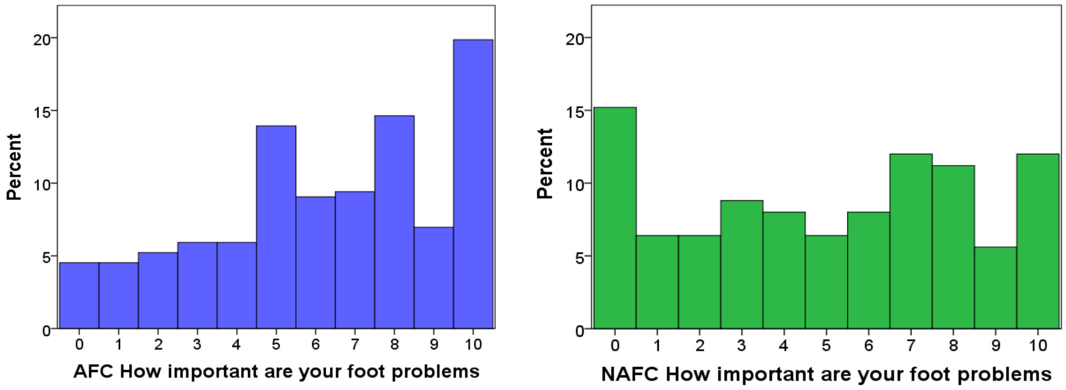
Figure 5.16 Frequency distribution of FIS_{AP} scores responders (n=400)



5.4.7.13 Importance of foot problems (B6)

Figure 5.17 presents the distribution of the importance scores for the AFC group and NAFC group. The median (IQR) importance score for the AFC group was 7 (4 to 9) and for the NAFC group was 5 (2 to 8) (U=14227.5, p=0.001). Though the AFC reported greater importance, a third (n=36, 28.9%) of the NAFC reported their foot problems to be important (scoring ≥8).

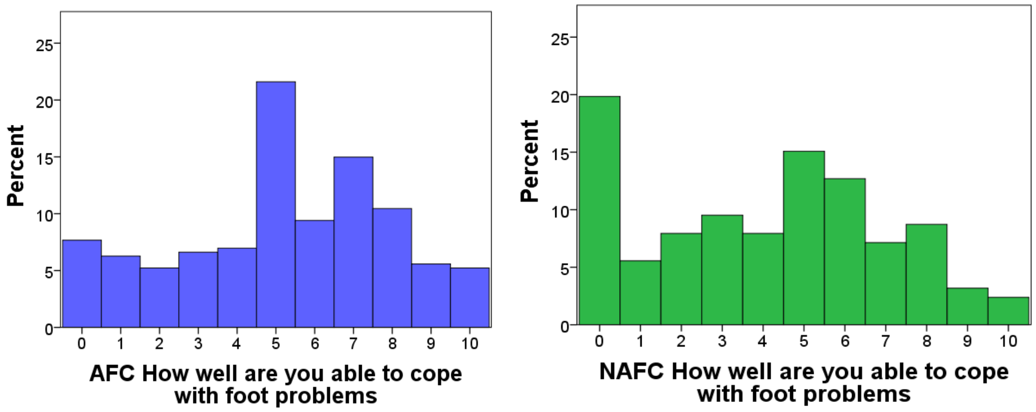
Figure 5.17 Importance of foot problem score (n=400) responders



5.4.7.14 Ability to cope with foot problems (B7)

Figure 5.18 presents the distribution of ability to cope with foot problems scores for the AFC group and the NAFC group. The median (IQR) for the AFC group was 5 (3 to 7) and for the NAFC group was 4 (1 to 6) (U=14054.0, p<0.001). The AFC reported greater difficulty coping and many patients (n=61, 21%) were not coping well with foot problems (scoring ≥ 8) and a sixth of the NAFC group (n=18, 14.3%) reported not being able to cope well with foot problems.

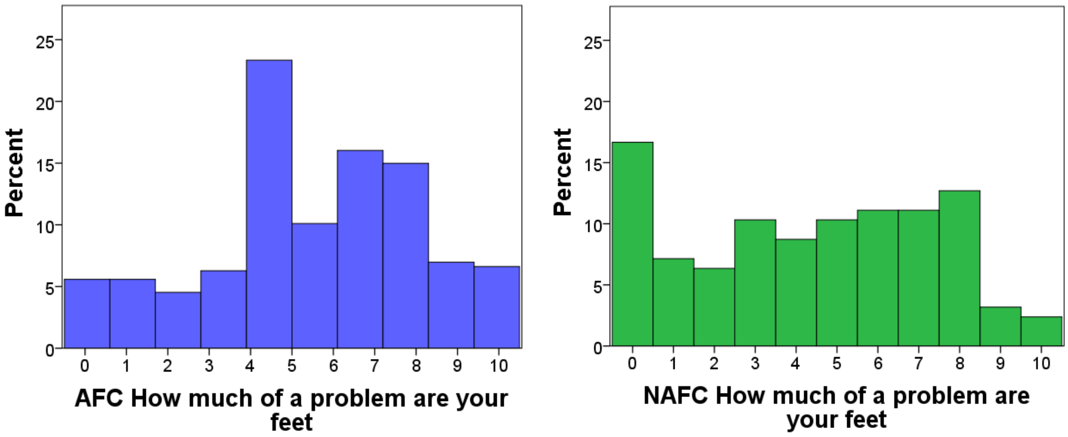
Figure 5.18 Ability to cope with foot problems score (n=400) responders



5.4.7.15 Magnitude of foot problems (B8)

Figure 5.19 presents the magnitude of foot problem scores for the AFC group and the NAFC group. The median (IQR) for the AFC group was 6 (4 to 8) and for the NAFC group was 5 (2 to7) (U=13653.0, p<0.001). Many patients of the AFC group considered their foot problems were severe (scoring ≥8) (n=80, 28%). A fifth of the NAFC group reported their foot problems were severe (n=18, 14.3%).

Figure 5.19 Severity of foot problems distribution scores (n=400)



5.4.7.16 Comparisons of measures of impact

Table 5.24 and Table 5.25 present the Spearman's rank order correlation coefficient (Spearman's rho) matrix for: FIS$_{IF}$, FIS$_{AP}$, importance of foot problems, ability to cope with foot problems and magnitude of foot problems for the AFC group and the NAFC group. There were statistically significant moderate relationships between all measures of impact for both the AFC group and the NAFC group. Approximately 50%.of the variance in FIS$_{IF}$ scores was explained by the FIS$_{AP}$ scores. The proportion of variance for FIS$_{IF}$ and FIS$_{AP}$ scores explained by importance, ability to cope with foot problems and magnitude scores was between 28% and 63%. This result indicates that the additional measures of impact are providing information not included in the FIS. Correlations between the additional measures of impact were higher with explained variance between 53% and 83%. This suggests that while there is some overlap, these data may be reflecting some differences between the additional measures of impact with the FIS.

Table 5.24 Correlation of measures of impact in the AFC group (n=287)

Spearman's rho			**FIS$_{AP}$ AFC**	**Importance AFC**	**Ability to cope AFC**	**Magnitude AFC**
	FIS$_{IF}$	Correlation	$.710^{**}$	$.614^{**}$	$.619^{**}$	$.645^{**}$
		Explained variance %	50.4	37.7	38.3	41.6
	FIS$_{AP}$	Correlation		$.526^{**}$	$.565^{**}$	$.551^{**}$
		Explained variance%		27.7	31.9	30.4
	Importance	Correlation			$.726^{**}$	$.836^{**}$
		Explained variance %			52.7	69.9
	Ability to cope	Correlation				$.838^{**}$
		Explained variance %				70.2

n= 278, ** p=<0.001

Table 5.25 Correlation of measures of impact in the NAFC group (n=126)

Spearman's rho			FIS$_{AP}$ NAFC	Importance NAFC	Ability to cope NAFC	Magnitude NAFC
	FIS$_{IF}$	Correlation	.709**	.735**	.771**	.794**
		Explained variance%	50.3	54.0	59.4	63.0
	FIS$_{AP}$	Correlation		.544**	.574**	.601**
		Explained variance%		30.0	32.9	26.1
	Importance	Correlation			.847**	.911**
		Explained variance %			71.7	83.0
	Ability to cope	Correlation				.905**
		Explained variance %				81.2

n=122, ** p<0.001

5.4.7.17 Impact of foot problems and ability to work (B9)

Of the 413 responders, 159 (38.5%) did not answer this because they had chosen to not work in paid employment (for example were retired). Reasons for not working were provided by self-initiated free text responses. Of the remainder in the AFC group (n=164) the proportion reporting foot problems affecting their ability to work was 62.8% (n=103). The proportion of the NAFC group indicating that foot problems were affecting their ability to work was similar (58.9%, n=53). The difference between the groups was not statistically significant ($x^2 = 0.38$, df=1, p=0.54). Foot problems were affecting the ability to work in well over a third of responders. Further, many patients had not accessed foot care despite reporting foot problems affecting their ability to work (Table 5.26).

Table 5.26 Impact of foot problems and ability to work

Impact of foot problems affecting ability to work	AFC (n=164) Number (%)	NAFC (n=90) Number (%)
Yes	103 (62.8)	53 (58.9)
No	61 (37.2)	37 (41.1)

5.4.7.18 Overview of comparison of AFC and NAFC responses

Those responders who had accessed foot care: were female, older, had longer disease duration, higher levels of disability and had additional morbidity. However, these differences were relatively small and do not provide a strong indication of which patients are likely to access foot care. Overall foot problems were important issues for many patients in both groups. For example when discussions about feet are conducted; it appears they are often initiated by patients. The frequencies of patients initiating discussions were broadly similar for both the AFC group and the NAFC group. Although as might be expected, a greater proportion of the AFC group reported having had a foot examination (76.3% versus 58.7%) patients in both groups reported never having had a foot examination. A quarter of the AFC group reported they had not had a foot examination indicating that some patients considered a foot examination to be part of their rheumatology care rather than when foot care was accessed. This supports the notion (as identified in Study 1) that asking about feet and conducting a foot examination may not occur in all rheumatology clinical consultations. Annual review of patients' feet and assessment of foot health care needs is recommended in rheumatology national guidelines (Luqmani *et al*, 2006). Validation of the self-report with rheumatology medical records of the conducted foot examination was not conducted in this study. Therefore these data are not a clinical audit of local practice meeting national guidelines.

In relation to foot problems, almost all of the AFC group and the NAFC group reported having one or more current foot problems. However, despite accessing foot care many foot problems continued. Additionally, a third of patients reported their foot problems were affecting their ability to work. Of these, two thirds had accessed foot care. Thus despite accessing foot care a large number of patients' ability to work was still restricted by their foot problems. These data therefore raise issues regarding the quality and/or effectiveness of care received. The quality and effectiveness of foot care cannot be quantified by these data but it is an issue that was investigated further in the embedded clinical assessment study (Study 3, Chapter 6) where direct examination of the feet was undertaken. It is not possible to draw firm conclusions regarding the clinical significance of impact of foot problems in this study. Nonetheless, these data further support the inclusion of additional measures of impact to capture aspects relevant to patients not included in the FIS. The detailed validation of additional measures of impact could be explored in future work.

5.4.8 Multivariate analysis of determinants of access to foot care

Univariate analyses comparing the AFC group and the NAFC group were conducted to identify non-foot related variables for inclusion in a logistic regression model (Table 5.27). Predictor variables with p=<0.4 were selected as variables in a series of logistic regression models. Selection of predictor variables which are statistically significant at $p<0.05$ may fail to identify variables of known importance (Mickey and Greenland, 1989). See results Table 5.27.

Table 5.27 Independent variables as determinants of AFC

Variable based AFC (n=287) versus NAFC (n=126)	Univariate analyses [a]	Multivariate analyses [b]
Hospital site	Proportions similar AFC versus NAFC according to hospital site	Excluded from model
Gender	p=0.04	Included in model
Age	p=0.01	Included in model
Social deprivation	p=0.363	Included in model
Disease duration	p=>0.001	Included in model
Arthritis medications	Proportions similar AFC versus NAFC according to arthritis medications	Excluded from model
Disability	p=0.005	Exclude from model, as 1 section captures lower limb disability

[a] Univariate analyses of demographic and clinical variables to identify factors associated as predictors of AFC.

[b] Variables with p=< 0.4 in univariate analyses were entered into a series of logistic regression models to identify independent predictors of AFC

Logistic regression analyses were then conducted to measure the independent relationships of demographic (age, social deprivation and gender) and clinical characteristics (disease duration) to compare the adjusted odds for accessing foot care. Adjusted odds ratios were used for comparisons of the independent variables as predicators of the dependent variable (accessed foot care).

Table 5.28 presents the results of the binary logistic regression analyses. Employing the statistical significance of p<0.05 female gender, age and disease duration made a statistically contribution to the model. The model as a whole explained between 7% (Cox and Snell R square) and 10% (Nagelkerke R squared) of variance in access to foot care. Analyses revealed increased odds of AFC in those with longer disease duration of 4% (on average) and in those who were older of 2% (on average). This indicates an increased chance of accessed foot care for disease duration and age was 4% and 2% per year (on average); respectively. Although these results demonstrate disease duration and age to be independent factors of access to foot care the effect for both was mild. The strongest predictor of AFC was female gender, with an odds ratio of 1.72 (95% CI 1.059 2.790). The OR for gender indicates that when holding all the other variables constant, women were 1.7 times more likely to access foot care compared to men

Table 5.28 Results of logistic regression analyses

Predictive variable	*B* (co-efficient of determinant)	P	Exp (B) Adjusted odds ratio (CI 95%)
Gender	0.542	0.03	1.719 (1.059-2.790)
Age	0.021	0.02	1.021 (1.003-1.031)
Disease duration	0.041	<0.01	1.042 (1.017-1.067)
Social deprivation (average of 3 categories)	-0.374	0.27	0.691 (0.365-1.314)

5.4.9 Details of foot care services accessed

5.4.9.1 Access to services

Of the 413 responders, 287 (69.5%) had at some time accessed foot care services 204 (71.1%) podiatry, 192 (66.7%) orthotics and 92 (32.1%) orthopaedics. Of the podiatry group (n=204), over half had sourced independent sector care (n=107, 52.5%). Of AFC group, 140 (48.8%) had accessed two or more services (Table 5.29).

Table 5.29 Number of foot care services accessed (n=287 of 413)

Foot care services accessed	Number (%)
1 Foot care service	146 (50.9)
2 Foot care services	79 (27.5)
3 Foot care services	61 (21.3)
Missing data*	1(0.3)
Total	287

*Missing data for one respondent not completing accessed orthotics

Of the 413 responders, 209 had not accessed podiatry. Of these 122 (58.4%) indicated that they would have liked to have been referred to podiatry. The equivalent numbers for orthotics group (n=214) and orthopaedic group (n=311) were 58 (27.1%) and 43 (13.8%); respectively. Therefore of the foot care services not accessed, podiatry was the most frequent service responders would have liked to have been referred to.

5.4.9.2 Foot care received (B11, B13)

Of the group AFC (n=287), 278 (96.9%) competed the questions relating to care received. It is possible that 9 (2.1%) patients inadvertently failed to complete the questions due to the layout of the questionnaire (responses are on the reverse page of services accessed).

The frequency of care categories received is presented in Table 5.30. Device prescriptions were the most frequent care category reported. However, data were not collected on which service provided the intervention (devices). Of 72 patients who had undergone foot surgery, 54 (75.0%) reported that their foot problems had improved after surgical intervention (in answering question B13 C in the questionnaire). Data were not collected on the responders, perceptions on the improvement of foot problems after accessing orthotics or podiatry.

Table 5.30 Foot care interventions received

Foot care category	Foot care interventions	AFC (n=287) Number (%)
Devices	Hospital shoes	73 (25.4)
	Insoles	190 (66.2)
	Padding	58 (20.2)
	Toe protectors	11 (3.8)
	Any devices	**222 (76.4)**
Non-pharmacological	Advice	69 (24.0)
	Foot exercises	42 (14.6)
	Any non-pharmacological	**93 (32.4)**
Pharmacological	Antibiotics for infection	24 (8.4)
	Creams for infection	22 (7.7)
	Steroid injection	40 (13.9)
	Any pharmacological	**74 (25.8)**
Treatment cutaneous lesion	Nail care	53 (18.5)
	Treatment for corn /callus	62 (21.6)
	Wound care	19 (6.7)
	Any treatment cutaneous lesions	**99 (34.5)**
Other	Foot surgery	**72 (25.1)**

*Missing data 9 (3.1%) AFC group

5.4.9.3 Access by hospital site

Overall the proportions of responders accessing the separate foot care services were similar for both hospital sites (Table 5.31).

Table 5.31 Access to foot care by hospital site

Hospital site	NBT (n=209) Number (%)	UHB (n=204) Number (%)
Podiatry	100 (47.8)	104 (51.0)
Orthotics	106 (50.7)	86 (42.2)
Orthopaedics	50 (23.9)	42 (20.6)

5.4.9.4 Access to foot care by gender

Table 5.32 presents access to foot care services according to gender. Of the 107 male survey questionnaire responders, 46 (43%) had accessed podiatry while of the 306 female responders, 158 (51.6%) had accessed podiatry (x^2 = 2.74, df=1, p=0.124). There was also no significant difference between genders in access to orthotics (x^2=1.5, df=1, p=0.46), though a slightly larger proportion of women (25.2%) than men (14.1%) had accessed orthopaedics (x^2=6, df=1, p=0.017).

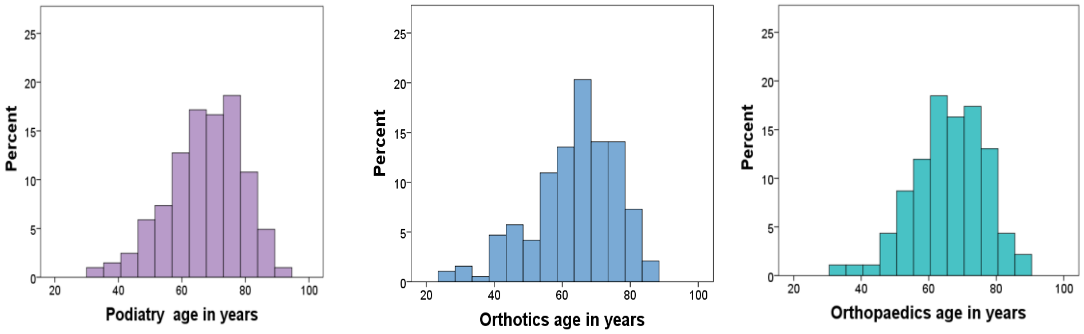
Table 5.32 Access to foot care by gender

	Female (n=306) Number (%)	Male (n=107) Number (%)
Podiatry (n=204)	158 (51.6)	46 (43.0)
Orthotics (n=192)	151 (49.3)	41 (38.3)
Orthopaedics (n=92)	77 (25.2)	15 (14.1)

5.4.9.5 Access to foot care by age

Figure 5.20 presents the age distribution of the AFC group in relation to individual foot care services accessed. Median (IQR) for age in years for each service was: podiatry 68 (60 to 76); orthotics 65 (53 to 73); and orthopaedics 67 (60 to74).

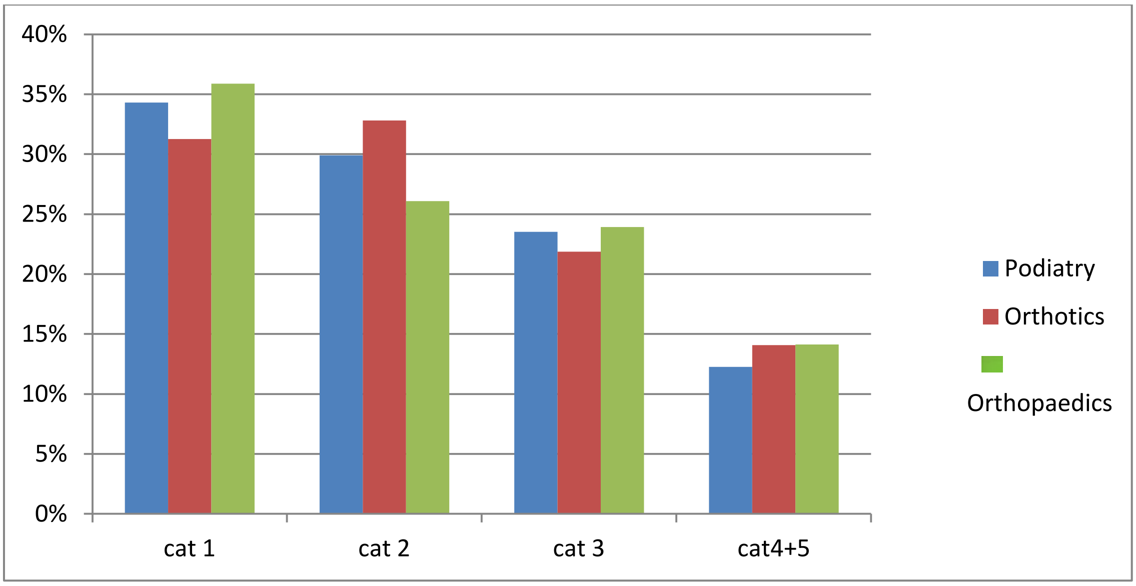
Figure 5.20 Age distribution of responders and access to foot care services



5.4.9.6 Access to foot care services by social deprivation

Of the AFC group (n=287), 55 (19.2%) resided in local social deprivation categories 4 and 5. Figure 5.21 presents access to each foot care service in relation to social deprivation and shows a similar distribution for all three services.

Figure 5.21 Access to foot care services by social deprivation

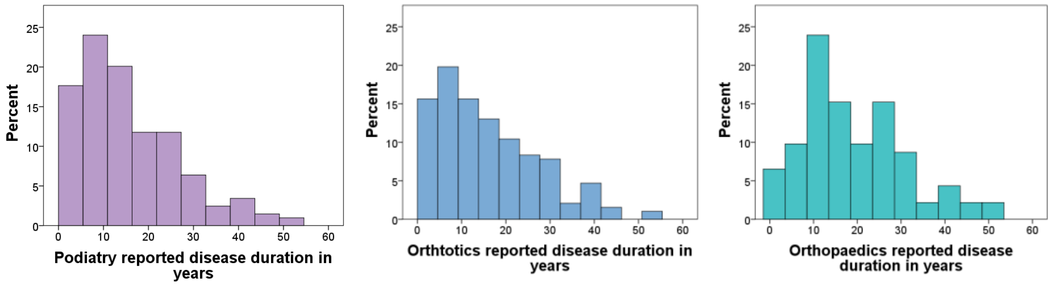


Cat 1- local deprivation category 1 – low deprivation
Cat 4+5 - local deprivation categories 4 and 5 – high deprivation

5.4.9.7 Disease duration

The median (IQR) disease duration (years) reported for the podiatry group was13 (7 to 23), for the orthotics group was 13 (6 to 24) and for the orthopaedic group was greater as might be expected at 16 (10 to 28) (Figure 5.22).

Figure 5.22 Disease duration distribution for foot care services accessed



5.4.9.8 Medication

The number (proportions, %) of the podiatry group (n=204) taking different types of arthritis medications were: NSAIDS 69 (33.8%), DMARDS 164 (80.4%), glucocorticoids 61 (29.9%) and biologics 34 (16.7%). The equivalent numbers for the orthotics (n=192) and the orthopaedics groups (n=92) were similar: NSAIDS 66 (34.4%) versus 36 (39.1%); DMARDS 152 (79.2%) versus 69 (75.0%); glucocorticoids 51 (26.6%) versus 28 (30.4%); Biologics 38 (19.8%) versus 24 (26.1%). The frequencies of medication categories being taken by the podiatry, orthotics and orthopaedics groups are presented in Table 5.33. They were similar for all three groups.

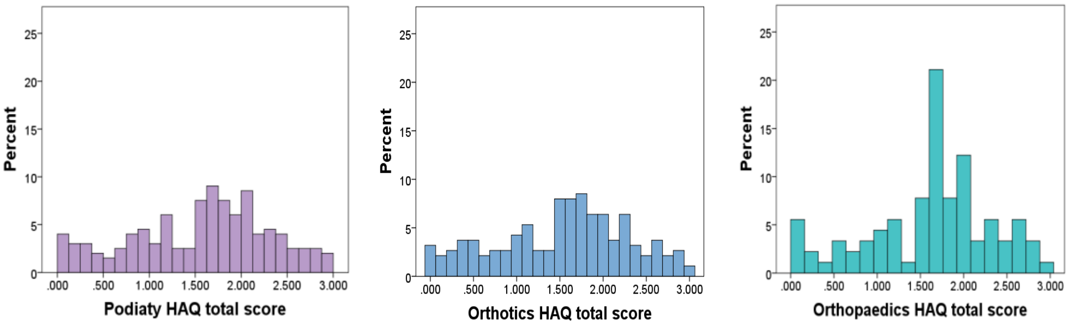
Table 5.33 Frequency of RA medication categories by foot care service

Medication category	**Podiatry (n=204) Number (%)**	**Orthotics (n=192) Number (%)**	**Orthopaedics (n=92) Number (%)**
Not taking RA medication	7 (3.4)	8 (4.2)	4 (4.3)
Taking 1 category of medication	94 (46.1)	88 (45.8)	38 (41.3)
Taking 2 categories of medication	78 (38.2)	71 (37.0)	33 (35.9)
Taking 3 categories of medication	22 (10.8)	23 (12.0)	15 (16.3)
Taking 4 categories of medication	3 (1.5)	2 (1.0)	2 (2.2)

5.4.9.9 Disability

A wide range of disability was reported by patients in all three groups (Figure 5.23). Median (IQR) HAQ scores for each service was: podiatry 1.625 (1.0 to 2.0), orthotics 1.625 (1.0 to 2.063) and orthopaedics 1.750 (1.0 to 3.0) indicating a trend for patients who have accessed orthopaedics to have greater disability, as might be expected.

Figure 5.23 Distribution of HAQ scores according to foot care services accessed



5.4.9.10 Co-morbidities

Tables 5.34 presents the self-report frequencies of additional co-morbidities by foot care service accessed and similar proportions of additional health conditions were detected for patients accessing each foot care service. Almost all (20/22, 91%) of the AFC patients with diabetes had accessed podiatry. See Appendix I for supplementary data for categories of co-morbidities according to foot care service accessed.

Table 5.34 Frequency of co-morbidity according to foot care service accessed

Number of co-morbidity	Podiatry (n=204) in this category Number (%)	Orthotics (n=192) in this category Number (%)	Orthopaedics (n=92) in this category Number (%)
No other co-morbidity	59 (28.9)	66 (32.8)	26 (28.3)
1 co-morbidity	88 (43.1)	47 (40.1)	47 (51.1)
2 co-morbidities	42 (20.6)	38 (19.8)	13 (14.1)
> 3 co-morbidities	15 (7.4)	14 (7.3)	6 (6.5)
Any co-morbidity	145 (71.1)	99 (51.6)	66 (71.7)

5.4.9.11 Foot problems according to foot care service

It was anticipated that there would be variation in categories of foot problems in relation to services accessed (e.g. the proportion of patients experiencing cutaneous lesions would be greater in the podiatry group). However, as shown in Table 5.35 there was similar distribution of foot problems in all the foot care groups.

Table 5.35 Frequency of self-reported foot problem categories according to foot care services accessed

	Podiatry (n=204) Number (%)	Orthotics (n=192) Number (%)	Orthopaedics (n=92) Number (%)
Articular features ever	184 (90.2)	183 (95.3)	92 (100)
Extra-articular features ever	112 (54.9)	110 (57.3)	58 (63.0)
Cutaneous lesions ever	169 (82.8)	154 (80.2)	79 (85.9)
Structural deformity ever	153 (75.0)	150 (78.1)	75 (81.5)
Other ever	44 (21.6)	44 (22.9)	21 (22.8)
Any foot problems ever	202 (99.0)	191 (99.5)	92 (100)

5.4.9.12 Summary of services received

As might be expected patients who had accessed orthopaedics had longer disease duration and higher levels of disability compared to those who had accessed podiatry and orthotics. Patient characteristics were otherwise similar.

5.4.10 Routes of access to foot care services

5.4.10.1 Overview of routes of access

Table 5.36 presents access routes to foot care services.

Table 5.36 Foot care services accessed and referral route categories

Referral route		Podiatry (n=204) Number (%)	Orthotics (n=192) Number (%)	Orthopaedics (n=92) Number (%)
Self	NHS	53 (26.0)	3 (1.6)	1 (1.1)
	Privately	39 (19.1)	2 (1.0)	3 (3.3)
GP		54 (26.5)	25 (13.0)	25 (27.2)
Hospital		50 (24.5)	159 (82.8)	60 (65.2)
Community nurse		2 (1.0)	0 (0)	1 (1.1)
Other		3 (1.5)	3 (1.6)	2 (2.2)

Of particular note are the patients who accessed podiatry, where nearly half (46.1%) had self-referred and this included 19.1% who had accessed independent sector care. The majority of orthotics and orthopaedic referrals had been through hospital based clinician referrals, indicating that most of these patients had talked about their foot problems with clinicians in order for a referral to be generated. However, almost half of the patients who had accessed podiatry had not been referred by a clinician. Further it would appear hospital based clinicians are more likely to refer patients to hospital based foot care services than the community based podiatry service. Only a quarter of patients who had accessed podiatry reported to have been referred by a hospital based clinician.

5.4.10.2 Gender and routes of access

There were differences in access routes to some foot care services between genders (Table 5.37).

Table 5.37 Access routes to foot care by gender

Referral route		Podiatry (n=204) (Number (%)		Orthotics (n=192) Number (%)		Orthopaedics (n=92) Number (%)	
Gender		**Female n=158 (77.5)**	**Male n=46 (22.5)**	**Female n=151 (78.6)**	**Male n=41 (23.4)**	**Female n=77 (83.7)**	**Male n=15 (16.3)**
Self	NHS	47 (29.7)	9 (20.0)	3 (2.0)	0 (0)	1 (1.3)	0 (0)
	Privately	30 (19.0)	9 (20.0)	2 (1.3)	0 (0)	2 (2.6)	1 (6.7)
GP		35 (22.2)	19 (41.3)	19 (12.6)	6(14.6)	16 (20.7)	9 (60.7)
Hospital		42 (26.6)	8 (17.4)	126 (83.4)	33 (80.2)	55 (71.4)	5 (33.3)
Community nurse		2 (1.3)	0 (0)	0 (0)	0 (0)	1 (1.3)	0 (0)
Other		2 (1.3)	1 (2.2)	1 (0.7)	2 (1.0)	2 (2.6)	0 (0)
Missing data		0 (0)	0 (0)	1 (0.7)	0 (0)	0 (0)	0 (0)

For podiatry the differences were that a greater proportion of women self-referred compared to men (48.7% versus 40.0%), that a greater proportion of the men (41.3% compared to 22.2% for women) had been referred by their GP while a lesser proportion (17.4% compared to 26.6% for women) had been referred via the hospital. These results indicate a tendency for men to discuss their foot problems with their GP while women are more likely to self-refer or discuss their foot problems with hospital based clinicians.

There was a similar (more marked) pattern for referral to orthopaedics. The proportion of men referred to orthopaedics by GP generated referrals was greater than the proportion of women referred. In contrast hospital based clinicians referred more women than men to orthopaedics. Most referrals to orthotics are through the hospital, which reflects local foot care service access criteria at the time of data collection, when access to orthotics services was restricted to hospital based clinicians. In contrast referrals to orthopaedics were accepted from both hospital based clinicians and GPs.

5.5 Qualitative analysis of patients' experiences

Of the 413 responders, 158 (38.3%) completed a free text response question, “If you have any other comments about foot problems in rheumatoid arthritis that you would like to make, please add them here”. Of these, 82 (51.9%) responses described current foot problems. Additionally, foot problems following a fluctuating clinical pattern were reported by 26 (16.5%), and a small number of responders (n=9, 11.0%) reported their current foot problems were not related to RA. The impact of foot problems on daily life was mentioned by 66 (41.8%) responders.

The most common free text data relating to foot care services accessed related to orthopaedics (n=30, 19.0%). It is possible that responders who accessed orthopaedics may have been influenced to complete free response by the ordering of the questions in the questionnaire (question relating to foot surgery preceded the free text response question). Of the 30 responders providing free text data relating to orthopaedics, a third (n=8, 27%) indicated that the foot surgery was not related to RA.

Of the 287 AFC patients 113 (39.4%) completed the free text question while 45 (35.7%) of the 126 NAFC patients did so.

In Table 5.38 presents descriptive statistics (frequencies, proportions of responders completing free text response question) and quotes from textual data (accompanied by study identifiers, gender and age) as exemplars of emergent response categories.

Table 5.38 CA free text response data

If you have any other comments about foot problems in rheumatoid arthritis (n= 158: 38.3%)			
Response category	**Response sub category**	**Frequency (%)**	**Qualitative data**
Foot problems (problems)	Articular features	48 (30.4)	“*Always have pain in my foot and ankle joints. The tablets do not do anything”* ID21235M33
	Extra articular features	15 (9.5)	*“Continuous pins and needles”* ID22654F76
	Structural deformity	10 (6.3)	“*Big toe on Left foot has slipped sideways. 2nd toe slipped up and rubs on shoes, have to wedge the toes together to get shoes on. Foot falling inwards, causing pain in ankles, poor posture affecting knees.”* ID5937F62
	Foot problems not related to RA	9 (5.7)	*“Numbness in feet is not due to RA. Have compression on lower 4 /5 discs in my back”* ID5976M76
Fluctuating foot problems	Feet first	5 (3.2)	*“First symptom of RA I noticed was pain in the soles of my feet after standing / walking for extended periods”* ID22589M61
	RA medications	11 (7.0)	“*Had problems with pain and swelling in the feet but that has now gone since starting [name of biologic agent]”* ID22356M64
	Flare	3 (1.9)	*My foot problems are always worse in a flare. I dread having to stand on them. The pain is intense on soles of feet and ankles.”* ID20763F73
	Come and go	7 (4.4)	“*Foot problems come and go, few days to a week. Most problems related to stiffness which is almost constant*.” ID1214M65
Impact of foot problems	Activities	23 (14.6)	*“My feet pain constantly especially after walking and standing for long periods. They will then be very painful the following day.”* ID4436M42
	Participation	24 (15.2)	“*Curtails my activities due to pain after walking for a short distance. Social life affected. Extra weight due to limited exercise.”* ID21241F74
	Footwear	14 (8.9)	*“Clothes I wear are governed by my footwear. Would like to wear a summer dress but can't with clumpy shoes. Wear sandals in to winter to save squashing my feet in shoes.”* ID22654F76
	Work	2 (1.3)	*“Feet very painful, still trying to work but it is hard, can't give up.”* ID3021F59
	Foot Impact Scale	3 (1.9)	“*FIS questions are very black and white and not a true reflection of how someone with RA may feel”* ID22886F43
Access to foot care perceived unnecessary by responders	Feet not a problem	10 (6.3)	*“No RA in feet.”* ID1362M63
	Can self-care / self-manage	1 (0.6)	*“Have to put foam between big toe and 1 next to other wise a painful corn develops”* ID20671F65
Access to foot care hindered by responders’ perception	Limited awareness of treatment options	3 (1.9)	“*Don't know what an orthotist is”* ID21367F61
	Feet ignored by clinicians	11 (7.0)	“*My RA tends to float. Get frustrated because assessments don't include my feet. Been told hands count. Pain in feet so bad sometimes I can't walk. But I don't have pain in my hands - this seems to be ridiculous.”* ID22714F58
	Past negative experiences of foot care	8 (5.1)	*“Shoes supplied by orthotics department were too heavy. Rocker soles seem pointless. Trainers more helpful. Sole on orthotic shoes were too thin*.” ID22981F78

Access to foot care supported	Can’t self-care / self-manage	7 (4.4)	*Fortunately I'm not experiencing any feet problems apart from I can't bend to cut my toe nails so I see a podiatrist privately. Current medication having positive effect on RA”* ID10014F75
	Positive experiences of foot care	5 (3.2)	*“The insoles I've been given are a great help.”* ID23247F61
Foot surgery	Had foot surgery	17 (10.8)	*“Since foot surgery appearance of feet improved. Don't need to keep them covered. Still get some pain but much happier as feet are more comfortable”* ID2721F56
	Waiting for foot surgery	3 (1.9)	*“Waiting for foot surgery”* ID592F62
	Foot surgery not recommended	2 (1.3)	“*Had a triple fusion, ankle replacement, fractured bone repaired. Surgery didn't work if I have further surgery I will lose my leg.”* ID22492F64
	Foot surgery not related to RA	8 (5.1)	“*Surgery for ankle was not because of RA but car accident as a child.”* ID22982F45

*More than one response disclose

In general the free text response data support the findings of Study 1 (one to one interviews) and did not reveal any new issues relating to foot problems in RA. They reinforce the view that foot problems in RA can be multi-factorial: follow a fluctuating clinical pattern and impact on many aspects of patients' lives. However, a small number of responders indicated that their current foot problems were not related to RA. Further, some of the responders who had accessed orthopaedics had undergone surgical procedures which were not related to the consequences of RA.

5.6 Discussion

A total of 2335 patients with RA were identified as registered for follow up rheumatology care at both hospital sites (NBT and UHB) corroborating the initial patient population estimate of 2000. Of these 1003 (43%) were registered with a GP within Bristol Community Health boundaries compared to the 1500 forecasted during the study design. Changes in boundaries of community NHS clinical services are likely to account for the discrepancy between estimated and actual target population numbers for the geographical area. In the interim period between planning, designing the study and conduct of the survey, Bristol Primary Care Trust (the organisation providing NHS community health services), which was the basis on which the community size was being estimated, split to form South Gloucestershire Primary Care Trust and Bristol Community Health. Nonetheless the total number of questionnaires posted (n=739) was similar to original approximations (as outlined in 5.3.3)

This study achieved an overall response rate of 56%, similar to other postal surveys of patients with RA conducted in the UK (Neame and Hammond, 2005; Otter *et al,* 2010). Responders and non-responders were similar in relation to: hospital site, gender; age, and social deprivation (local). Responders to the questionnaire therefore approximate a representative sample of all RA patients in Bristol, and provide the first opportunity to assess a population not biased by selection procedures. The general and RA characteristics of responders were similar to previous postal survey studies undertaken in other parts of the UK (Blackburn *et al,* 1994; Goodacre *et al,* 2007; Firth *et al,* 2008; Sanderson *et al,* 2010) and so the findings of the study are likely to reflect the characteristics of patients with RA in the UK.

Patients with RA can experience additional health conditions (co-morbidities) and in the representative patient sample included here two thirds of responders reported additional health conditions. It is possible that even this high frequency of self-reported co-morbidities is an under estimate of the actual prevalence, as data were collected by an open ended question (see Appendix F2 question A5). Nonetheless, two thirds of patients had co-morbidities, a finding which has implications for the broader practice of rheumatology, as well as the provision of foot care.

An annual review of patients' feet is recommended in national guidelines (Luqmani *et al,* 2006). However, conduct of foot examinations in clinical practice can be variable. Some authors suggest that because the foot is omitted from standard measures of disease activity such as the DAS28 (van der Heijde *et al,* 1993), foot problems may be ignored (van der Leeden *et al,* 2010; Wechalekar *et al,* 2012). The majority of responders in this study recalled having undergone a foot examination, although only a quarter reported to have had a foot examination in the preceding twelve months. The accuracy of patients recalling the time when foot examinations were conducted requires consideration. Recall bias and accuracy of self-report if an event or exposure of interest occurred is recognised as a challenge in epidemiology studies (Coughlin, 1990). Further, it is also possible that some patients may not have accessed health care in relation to their RA in the previous year. However, almost all of the study responders were taking arthritis medications, many of whom would require regular contact with health care professionals for example haematological monitoring of arthritis medications. In Bristol, such monitoring is usually conducted in primary care by patients' GPs as well as hospital outpatient review. Nonetheless this study suggests that patients perceive the conduct of foot examinations to be variable and potentially inadequate.

This study has shown that patients with RA experience a wide range of foot problems and a large majority of responders reported one or more current foot problems. The nature of these problems was captured in detail, following careful construction of the questionnaire. Comparisons with other authors reporting the prevalence of foot problems in postal surveys is hampered by discordance of descriptors of foot problems and likely bias in the study sample. For example Otter *et al* (2010) included participants attending rheumatology out-patient clinics and members of an RA patient support group. The authors report the prevalence of foot problems in relation to articular features (pain, joint swelling) and extra-articular features (numbness). In contrast Firth *et al* (2008) report the prevalence of foot ulceration (self-report) in a survey of all patients registered for follow up medical care at one rheumatology department. The proportion of patients reporting foot problems in this study is slightly lower than in previous publications. Nonetheless these figures are only slightly lower and the prevalence of foot pain, numbness and ulceration reported in this study were broadly similar to earlier reports.

This study provides novel data on the range of self-care and self-management strategies adopted by patients with RA to manage their foot problems. It is not known if these strategies were self-initiated or suggested by clinicians. Work conducted by Hjlem *et al* (2002) investigating health behaviour in patients with diabetes and foot ulceration concluded women were more likely to participate in self-care of their feet. In contrast men tended to seek professional care, rely on family members and were more passive in self-care. Self-care and self-management strategies adopted by responders in this study were similar for both men and women. Health behaviours of patients with RA in relation to self-care and self-management of foot problems has not been fully explored.

Foot problems can have a substantial impact on patients' personal lives. The development of the FIS (Helliwell *et al*, 2005) has provided a useful tool to help measure the impact of foot problems. To the best of the researcher's knowledge, this is the first study to utilise the FIS in a postal survey. Overall, FIS scores were lower than previous studies (Turner *et al,* 2008; Hooper *et al*, 2012; Siddle *et al,* 2011), but as discussed above are likely to be a true representation of the overall position. However, the findings of Study 1 indicated that not all important issues of the impact of foot problems are captured in the FIS. These findings are supported by some patients reporting in the questionnaire that their foot problems were very important, severe and that they were not coping well with. Further a third reported that their foot problems were impacting on their ability to work. Work related disability in patients with RA has been widely described. This study therefore provides new data in relation to the impact of foot problems in relation to work related disability. Additional questions capturing impact (e.g. ability to cope with foot problems) included in the questionnaire correlated only modestly with FIS_{IF} scores and the FIS_{AP} scores, thus indicating they provided information not included in the FIS_{IF} and the FIS_{AP} scales. The use of the FIS as an outcome tool in routine clinical practice may be hampered by the length of the questionnaire. The development of a shorter PROM to measure the impact of foot problems was not an aim of this thesis, indeed the questionnaire became longer. Nevertheless this might usefully be addressed in future research.

Almost two thirds of the study sample had accessed one or more foot care services. The number of patients who had accessed foot care was higher than anticipated. This may be accounted for by the broader definition of access to foot care (AFC) used in this study (in particular, including the independent sector). Of the patients who had accessed podiatry in this study, over half had accessed independent sector care. Access to both NHS and independent sector podiatry has not been previously been reported. The frequency of access to self-funded (independent sector) foot care was an unexpected result. Reasons for accessing independent sector foot care require further exploration. This will be considered in Study 3 (Chapter 6).

In spite of the higher than expected access rates, many patients reporting foot problems, some very severe, had not accessed foot care services. In multivariate analyses age, gender and disease duration were independently associated with access to foot care, but not strongly. As expected, age and disease duration independently increased the odds of AFC but only by 2% and 4% per year, respectively. The strongest independent predictor of AFC was female gender. This is not an unexpected result as it has been thought that foot problems may be more prevalent in women (Dunn *et al,* 2004), and access and utilisation of health care has been widely thought to be higher in women (Hulka and Wheat, 1985; Bertakis *et al,* 2000; Courtenay, 2000). This study supports the notion that women access foot health care more than men.

While there was a trend for women to access all three foot care services more than men, there were some noticeable differences in referral routes to podiatry and orthopaedics. More women accessed podiatry via self-referral and more men had been referred by clinicians. When clinicians did the referring either to podiatry or orthopaedics, it was more likely to be from hospital for women and from the GP surgery for men. Further, the proportions of patients accessing foot care and initiating discussions about feet were similar for both males and females. These results suggest that both male and female patients discussed their foot problems in clinical consultations. Of the AFC group 60% reported to have discussed foot problems with hospital base clinicians (rheumatologist and/or rheumatology specialist nurse). The proportion for the NAFC group reporting to have talked about foot problems with hospital based clinicians was 53%. These data do raise the question of why hospital based clinicians do not refer more patients for foot care. Of the patients who had not accessed podiatry, over half indicated that they would like to have been referred, a similar finding being reported by Martin and Giffiths (2006).

This study has identified broad characteristics of which patients are likely to access foot care. Nonetheless both health care professionals and planners of health care need to consider the difference between statistical significance and clinical significance (importance). Whilst knowing which patients are likely to access foot care is beneficial, these characteristics (e.g. age, gender) may not reflect clinical need. Indeed being female, older with long disease duration may increase the chance of access to foot care but these factors do not capture the nature or severity of foot problems in patients with RA. These data alone are therefore unlikely to influence commissioners and planners of health care to review provision of foot care for patients with RA. There is currently no local integrated pathway (ICP) to foot care services for patients with RA and foot problems. This could be considered for development by both health care professionals and commissioners of health services locally. The development of an ICP encompassing hospital and community based services is a potential option. Integrated care pathways for patients with diabetes and foot disease are recommended (NICE NC19) and well established locally. The development and implementation of an ICP for the management of foot problems in RA could then facilitate opportunities for more efficient universal patient centred foot care, thus ensuring patients receive the appropriate care when there is clinical need.

A range of care interventions was reported. The frequency of prescribed footwear and foot surgery were similar to earlier reports (Otter *et al*, 2010). A fifth of patients who had accessed foot care indicated they had received treatment for calluses and corns. The clinical effectiveness of sharp callus debridement has been questioned (Davys *et al*, 2005; Siddle *et al,* 2013). Only a quarter of patients reported receiving any foot health care education. Additionally, despite having accessed care, the majority of patients reported current foot problems and substantial impact. This study has therefore highlighted that despite accessing foot care, many patients' foot problems continued. These data therefore raise questions regarding the quality of foot care received. Data were not collected in this study in relation to severity of foot problems prior to or after foot care was accessed. Therefore it is not possible from this study to confirm or refute the clinical benefits of the foot care received by patients. The clinical effectiveness and patient-perceived benefits of foot care will be explored in Study 3 and presented in Chapter 6.

This study has also highlighted in several ways that foot problems are important issues for many patients. Firstly, when discussions relating to feet were conducted, the majority were reportedly initiated by the patient. Secondly, foot problems clearly impact on many aspects of patients’ lives, such as affecting ability to work. Thirdly, patients reported using a wide range of self-care and self-management strategies to manage their foot problems and foot health needs. Patients clearly wanted to do something about their feet, but reservations remain about the appropriateness of their actions as some of the strategies utilised by patients may be detrimental, particularly for patients with impaired tissue viability (for example topical keratolytics). The important question of whether patient self-report of the presence of current foot problems is reliable will be addressed in Study 3 (Chapter 6).

Overall, this study has provided new data in relation to: (1) providing a description of the general and RA characteristics of a random sample of patients with RA; (2) the prevalence of additional health problems in a large sample of patients with RA; (3) the prevalence and impact of current foot problems; (4) description of the self-care and self-management strategies patients adopt to care for their foot problems and foot health needs.

5.7 Limitations and strengths

Early in the data collection and analysis of the survey it became clear that it would have been beneficial to collect some information about when foot care services were accessed or if patients were under follow-up foot care. Further, the perceived effectiveness and benefits (patient perspective) of foot surgery (orthopaedic surgery) were captured, but patients’ perspectives of the effectiveness of orthotics and podiatry care were omitted. It was decided to address these issues in Study 3.

This study is based on self-report. Some form of validation of patients’ self report is required to provide confidence in the overall conclusions, but this has not been reported in the literature. One form of validation might be through checking clinical records (for example additional morbidity). However, patients accessed any or all of hospital, community and independent sector foot care services. Validation of the self-report with such diverse clinical records was unachievable within the time scale of this work, and may even be unfeasible. As part of this thesis, Study 3 (Chapter 6) includes validation of the self-report of current foot problems, together with an independent clinical assessment of the current state of patients' feet and their foot care needs.

Research ethics approval was provided to retain anonymised data in relation to non–responders. However, permission was only granted to retain information about general characteristics of non-responders (gender, hospital site and local social deprivation). Data relating to the prevalence, impact and care of foot problems in non-responders is not known. It is therefore not possible to quantify the proportion of non-responders who had experienced foot problems or accessed foot care or not since being diagnosed with RA. The potential for non-responder bias is therefore acknowledged. Nevertheless the study sample (responders) for Study 2 was large, reflected the distribution of gender hospital site and social deprivation of the target population, and almost all responders had foot problems at some time and reported substantial impact. Therefore even taking into account the possibility that some non-responders may not experience the topic of interest in this thesis (prevalence, impact and care of foot problems in RA), this study demonstrates that foot problems are widely prevalent in a random sample of the population.

There are several strengths in this study. Firstly, the population was a random sample of all patients registered for rheumatology care at two hospital sites, and all resident within a fixed geographical area. Orthotics and orthopaedic services are provided at both hospital sites whereas NHS podiatry is provided by one community service. Patients within the community service boundaries formed the study population as all these patients had access to all three foot care services. It is possible that a very small number of patients with RA might not be registered for care at either hospital site (for example receiving care only in the independent sector). However, the provision of rheumatology services in Bristol is similar to other areas of England (Kirwan *et al,* 2003). It is possible the findings of this study (Study 2) may reflect circumstances in other urban areas although a more up to date national survey of foot care service provision may be warranted as a separate activity.

This study was also strengthened by the large sample size, and to supply sufficient patients for Study 3, which follows. Including a responder analysis made it possible to check for differences between responders and non-responders in relation to:

hospital site, gender, age or social deprivation. The differences were in reality very small, indicating that, in contrast to previous publications, the responder sample was a good representation of the whole target population of adult patients with RA. Additionally, the characteristics of responders in relation to: age, gender, disease duration, arthritis medications and disability levels were consistent with those reported in previous postal surveys conducted in other areas of the UK.

The value including the patient perspective in the pre-survey work in Study 1, and in the design and content of the survey itself has been demonstrated. This is evidenced by the fact that almost all returned surveys were admissible (minimal missing data), showing that patients found the survey items easy to understand and complete. Also, analysis of free text response data support the model of developed in Study 1 in relation to descriptors of foot problems, the impact of foot problems and decisions to access foot care.

5.8 Summary

This study reports the prevalence of a range of foot problems in a large random sample of all patients with RA, within a fixed geographical area. Data generated from a representative sample of all RA patients in Bristol support the impression that foot problems in RA are common and can be complex and multiple in presentation. Additionally foot problems can impact on many aspects of patients’ lives including their ability to work. This study has also demonstrated that foot problems are important issues for patients. Furthermore, many patients reported that their foot problems were: severe; important; and that they were not coping well with them. Additionally, discussions occurring during clinical consultations often included foot problems that were generated by the patients. This work also indicates that patients perceive the time interval of the conduct of foot examinations in clinical (rheumatology) consultations to be variable. Finally, although two thirds of the responders had accessed foot care, many patients reported current foot problems. This may be a reflection of the nature of foot problems in patients with RA to be complex, variable and follow a fluctuating clinical course. It also raises issues regarding the quality of care received.

This work was presented at the BSR /BHPR and the College of Podiatrist annual meetings 2014 and has been published in abstract format (Wilson *et al,* 2014; Appendix J2).

The findings of Study 2 are based on self-report. The accuracy of self-report in surveys requires consideration. In order to address this issue, independent clinical consultations with patients including a foot examination were arranged. The opportunity was taken to explore the reasons why some patients accessed or did not access foot care when the services were available, and the benefits of foot care from the patient perspective. This is Study 3, presented in Chapter 6.

The impact, frequency and care of foot problems in people with rheumatoid arthritis

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A thesis submitted in partial fulfilment of the requirements of the University of the West of England, Bristol for the degree of Doctor of Philosophy

Faculty of Health and Applied Sciences University of the West of England

January 2016

Word count: 87678

Volume 2

Chapter 6: Study 3 – Validation of self-report

The accuracy of the description of the prevalence and impact of foot problems in patients with RA captured in Study 2 depends on the validity of patient self-report. Therefore, Study 3 collected validation data from patients who had taken part in Study 2, using a detailed clinical consultation questionnaire and an independent clinical foot examination. Study 3 also provided a detailed clinical description of current foot problems, information regarding foot care received and patient's reasons for accessing foot care or not.

Although self-report of access to health care has been suggested as a valid estimate of health care utilisation (Reijneveld and Stronks, 2001), surveys can be prone to participation and response bias. In Study 2, respondents were quite representative of the target population as a whole for three items that might have been important for responder bias: hospital site, gender and area level social deprivation. However, bias could have occurred because of positive or negative experiences of the topic of investigation, recall bias and/or because of systematic difference between participants who had or had not experienced the topic of interest. A further consideration for the accuracy of survey studies is in relation to the accuracy of self-report. In order to address potential biases in Study 2, a third study was conducted on a selected set of responders from Study 2. Patients invited to participate in Study 3 had either accessed foot care (AFC) or not accessed foot care (NAFC). Prior to the conduct of Study 2, it was considered inevitable that disease duration could be a strong influence on the likelihood of accessing foot care as patients with longer disease duration would be more likely to develop foot problems and subsequently have accessed foot care at some time during their disease trajectory. Therefore, a matching exercise was undertaken for Study 3 to obtain AFC and NAFC patient groups of similar disease duration.

Study 3 provided the opportunity to investigate the accuracy of the self-report of foot problems by comparisons with foot problems observed in a clinical examination, hence validating the reports in Study 2. Data collection for Study 3 was conducted through a clinical assessment including a foot examination which captured a detailed clinical description of the nature and frequency of foot problems (articular features, extra-articular features, cutaneous lesion and structural deformity), assessment of function (detailed regional musculoskeletal assessment) and footwear adequacy. The direct clinical interview also explored further the reasons patients gave for accessing or not accessing foot care, and the benefits of care received from their perspective.

6.1 Aims of Study 3

1. Provide a detailed clinical description of current foot problems.
2. Validate self-report of current foot problems (or lack of foot problems) with clinical assessment and observation at a single time point.
3. Discover patients' reasons for accessing or not accessing foot care.
4. Discover patients' perceptions of the benefit of foot care received.

This study addresses aims 5 and 9 of the overall thesis aims as described in Chapter 3 section 3.4.1. It also aims to describe current foot problems by clinical assessment and benefits of foot care received from the patient perspective.

6.2 Methods

6.2.1 Study design

Patients invited to participate in Study 3 were selected from responders to Study 2. The primary aim of the Study 3 was to clinically validate the self-report of foot problems in order to estimate the actual (as opposed to the reported) prevalence of foot problems in patients with RA. It was acknowledged that earlier foot care consultations may have influenced the clinical accuracy of the report of current foot problems. Receiving a clinical diagnosis of a foot problem (e.g. presence of a nodule) may influence patient's ability to identify and report foot problems. As one area of interest was to determine foot problem prevalence and to investigate the accuracy of self-report of foot problems in RA, it was decided to sample all patients.

The influence of disease duration was considered *a priori* as the longer patients had been diagnosed with RA the more likely they were to have had opportunity to develop foot problems at some time during their disease trajectory. It is possible to conclude that age may have a similar association with the chance of developing foot problems. However, it was postulated during the study design process that age and disease duration would be inextricably linked. Indeed analyses of determinants of foot care conducted in Study 2 support this assumption as being correct. Therefore, a matching exercise was undertaken so that each AFC participant was 'matched' with a NAFC participant who had a similar duration of disease. The purpose of matching was not for pair-wise statistical analyses, but rather to obtain accurate information on prevalence of foot problems by investigating the accuracy of the self-report of current foot problems obtained in the AFC and NAFC patient groups with similar disease duration. Recruitment to Study 3 aimed to recruit similar numbers of patients in groups.

6.2.2 Identifying the patient population

A selected set of patients from within those responding to Study 2 (postal survey) were invited to participate in Study 3 (clinical assessment). The study recruited patients who reported on Study 2 questionnaires to have accessed foot care and not accessed foot care. The study inclusion criteria were: responder to Study 2 (postal survey) and able to attend for a clinical assessment.

Information about Study 2 responders was entered into a database including: patients' demographic data (name, gender, home address including post codes), disease duration (as reported in Study 2), date participated in Study 2 (date questionnaire returned), Study 2 identifiers and classification as AFC or NAFC. The Study 3 database was stored on a university computer and was password protected.

Recruitment for Study 3 occurred in batches and commenced as responses to Study 2 accumulated. Recruitment to both studies was then conducted simultaneously. When approximately 25 questionnaires (Study 2) had been returned, responders were added to the Study 3 eligible patient list. Patients study identifier, reported disease duration and if they had accessed foot care or not were entered into the Study 3 database for the matching process. The first patient on the eligible patient list who was AFC and had returned their questionnaire less than 2 months previously was 'matched' for disease duration with a patient from the NAFC list who had returned their questionnaire less than 2 months previously. Matching for disease duration was defined as: disease duration <5 years – matched to equal disease duration in years: disease duration 6 to 10 years - matched to within 1 year; disease duration 11 to 20 years – matched to within 2 years: and if disease duration was >21 years – matched within 5 years. These definitions were derived following discussions between the researcher and her academic supervisor (JK). If a match for disease duration was not achievable within batches, patients were carried forward and matching was conducted across subsequent batches. Additionally if a patient did not accept the invitation or did not attend for the clinical assessment, a further matching patient was identified and invited to participate from within the same batch of returned questionnaires. If this was not possible, a further patient was selected and invited to participate in subsequent batches. Selection of patients was conducted by the researcher and academic supervisor (JK) together to ensure quality of the research process. Identification and selection of patients continued until equal numbers of patients in both the AFC group and the NAFC were obtained. An interval of approximately 8 weeks between return of the postal survey and attending for the clinical assessment was considered the minimum time achievable between responding to Study 2 and participating (attending) in Study 3, in order for Study 2 data to be still relevant.

6.2.3. Data collection

6.2.3.1 Case record form

Items for inclusion in the case record form were initially determined by data generated in Study 1 (one-to-one interviews) and the final design of Study 2 (postal survey). Additional items were included following a review of the literature on regional assessment of the musculoskeletal system (Doherty *et al*, 1992) and best practice guidelines for the assessment of the foot in RA (Helliwell *et al,* 2007; Podiatry Rheumatology Care Association, 2008). A review of the literature in relation to validated scales measuring footwear suitability (Menz and Sherrington, 2000), impact of foot problems in RA (FIS, Helliwell *et al*, 2005) and general disability (HAQ) suggested further items. The inclusion of items, the ordering of the conduct of the clinical examination and phraseology of clinical assessment questions was finalised after discussions with two academic supervisors (JK and JW), the independent podiatrist (see 6.2.3.2) and trialling of the assessment form. The final version of the case record form (clinical assessment form / questionnaire) was agreed with all members of the research team (academic supervisors and PRPs), see Appendix H2.

Box 6.1 presents the content, source and rationale for the items included in the clinical assessment form. The content of Page 1 (age, gender, disease duration, arthritis medications, co-morbidities and postcodes) and HAQ (Section C) were required to describe the demographics and clinical characteristics of the study participants (patients).

The content of Section A was essential to capture a detailed clinical description of current foot problems (clinical examination and self-report), footwear suitability, musculoskeletal abnormalities and functional disability. These data were also required to investigate the accuracy of the self-report of foot problems that patients reported in Study 2.

The contents of Section B were designed to further understand patients’ reasons for accessing or not accessing foot care and perceived benefits of care received. Study 1 had shown that these were variable and complex and appeared to influence patients’ decisions to continue or cease accessing foot care.

Section C captured the impact of foot problems using a validated questionnaire (FIS) and the additional measures derived from Study 1 (e.g. ability to cope with foot problems) and included in Study 2.

The independent podiatrist obtained written informed consent from all patients. All case record forms were completed and no data were imputed from patients’ responses in Study 2 (survey). The podiatrist asked patients to report if they had current foot problems as listed in question A2 and to complete a HAQ and FIS prior to the clinical assessment.

Box 6.1 Content, source and rational of items included in clinical assessment form

Section:	**Item Included**	**Source**	**Rationale**
Page 1:	Patient's name		Was decided independent podiatrist was to address patients by name to maintain clinical professionalism
	Patient demographics age and gender		Data required for description of sample
	Clinical data	Disease duration, arthritis medications and co-morbidities	Data required for description of sample. Was decided to include co-morbidity data as some conditions have foot problems as clinical features e.g. diabetes
	Social deprivation	Obtained from postcodes	Data required for description of sample
	Date of research appointment		Recruitment for Study 3, aimed for conduct of clinical assessment and foot examination to be within approximately 2 months of completing postal survey (Study 2)
Section: A	Regional musculoskeletal assessment (A1)	GALS screen (Doherty *et al,* 1992)	Data required for description of musculoskeletal abnormalities and functional disability of sample (Study objective 1)
	Self-report of foot problems (A2)	Study 1 interviews (section 4.4.2.1) and Study 2 postal survey (section 5.2.3)	Data required to validate self-report with clinical observation (Study objective 4)
	Assessment of foot and ankle (A3, A4, A5, A7 & A8)	Best practice professional guidelines and expert clinical opinion (Podiatry Rheumatology Care Association, 2008; Helliwell *et al,* 2007)	Best practice assessment guidelines, to provide description of sample (Study objective 1)
	Clinical observation of foot problems (A6 & A9)		Data required for description of observed foot problems in sample (Study objective 1)
	Foot pathologies requiring intervention		Data required for clinical governance and ethics

	Box 6.1 continued		
Section	**Item Included**	**Source**	**Rationale**
	Footwear worn (A11)	Validated scale (Menz and Sherrington, 2000)	Standard questionnaire to measure footwear suitability
Section: B	Foot care services accessed (B1, B2 &B3)		Data required capturing foot care services accessed
	Foot care received (B1, B2 & B3)		Data required capturing description of foot care interventions received in sample (Study objective 3)
	Reasons for accessing foot care services (B1, B2)		Data required for patients'' reasons for accessing foot care (Study objective 3)
	Reasons for not accessing foot care services (B1, B2 & B3)		Data required for patients' reasons for not accessing foot care (Study objective 3)
	Use of devices issued by foot care services (B2)	Study 1 interviews (Section 4.4.3.1.4 & 4.4.3.15)	Data required for patients' reasons for not using devices issued (Study objective 4)
	Additional comments (B3)		Opportunity for patients to disclose any important issues relating to foot problems not covered in CRF
Section: C	Personal importance of foot problems (C1)	Study 1 interviews (Sections 4.4.2.4.1 & 4.4.3.3.4)	Additional impact of foot problems not capture by FIS
	Ability to cope with foot problems (C2)	Study 1interviews (Sections 4.4.3.2.3 & 4.4.3.3.1)	Additional impact of foot problems not captured by FIS
	Severity (magnitude) of foot problems (C3)	Study 1 interviews (Sections 4.4.3.2.2 & 4.4.3.3.4)	Additional impact of foot problems not captured by FIS.
	Member of patient support group	PRP	Data required describing sample.
	Foot Impact Scale (FIS)	Validated Scale (Helliwell *et al,* 2005)	Standard questionnaire to measure current impact of foot problems in RA
	Health Assessment Questionnaire (HAQ)	Validated scale (Fries *et al,* 1980, Kirwan and Reeback, 1986) Gold standard scale of disability in RA.	Standard questionnaire to measure current disability

6.2.3.2 Independent clinician

To avoid any bias that might be introduced by the researcher conducting the clinical assessment and foot examinations, an independent podiatrist (WB) was the observer who conducted all the clinical assessments and foot examinations. This observer had over 20 years of experience as an NHS clinical lead podiatrist in diabetes, care of the elderly and falls prevention. The observer was trained by the researcher and academic supervisors (JK and JW) in regional musculoskeletal assessment (Gait, Arms, Leg and Spine screen (GALS), tender swollen joint counts and passive range of motion of foot joints) and in the completion of a standardised case record form (CRF) for data collection (Appendix H2). The observer also received Good Clinical Practice training. Prior to the conduct of the clinical assessment and foot examination the observer had no knowledge of which group (AFC or NAFC) a patient belonged to. Before data were collected from a patient about previous access to foot care, the observer assessed whether the patient had foot problems that required immediate intervention. Each patient thought to require immediate foot care was informed of the observer's clinical recommendations at the end of the research session.

6.2.3.3 Clinical examination

Assessment of patients' general musculoskeletal and locomotor system was conducted using the GALS screen (Doherty *et al,* 1992). Box 6.2 presents a summary of the GALS screen conducted. The observer recorded the normality or abnormality for appearance and movement of each component of the GALS screen. Abnormal results (e.g. presence of pes planus) were recorded by free text data on the CRF, to provide a detailed clinical description of regional functional impairment.

Box 6.2 Conduct of GALS screen

Inspection	Conduct	Observation / examination
Gait	Weight bearing	Movement smoothness and symmetry
		Normal heel strike / toe off
		Ability to turn normally
Observation from behind	Standing	Spinal alignment normal / scoliosis (abnormal lateral curvature)
		Iliac crest alignment
		Rear foot alignment (calcaneous inverted / everted)
Observation from behind	Standing	Shoulder symmetry
		Elbow extension
		Knee (presence of swelling / deformity)
		Foot arch profile (high arch (pes cavus), low arch profile (pes planus)
Observation from the side	Standing	Spinal alignment (presence of kyphosis (increased thoracic convex curvature) / lordosis (increased lumbar concave curvature)
		Knees flexed (knee unable to extend to 0º / hyperextend >10º extension)
Spine	Standing	Lumbar flexion (patient asked to touch their toes)
		Cervical flexion (patient asked to tilt head to bring ears to their shoulders)
Arms	Standing	Abduction / external rotation of shoulders (patient asked to place hands behind their head)
Hands	Sitting on edge of examination couch	Pronation (patient asked to move hands so palms are facing down) / supination (patient asked to move hands so palms are facing upwards)
		Presence of swelling / deformity in hands
		Power grip (patient asked to grip observer's fingers)
		Precision grip (patient asked to touch each finger in turn with thumb)
		Metacarpal (MCP) joint squeeze test (lateral compression of MCP joints to detect for synovitis)
Legs	Patient lying prone on examination couch	Assessment of passive hip internal / external range of motion with patients knee flexed
		Knees extended, boarders of patella palpated for tenderness / swelling)
		Metatarsophalangeal (MTP) joint squeeze test (lateral compression of MTP joints to detect for synovitis)

Foot examinations were conducted in accordance with published guidelines and expert clinical opinion (Helliwell *et al,* 2007; Podiatry Rheumatology Care Association, 2008). Box 6.3 presents the conduct of assessing for disease activity in the feet (e.g. joint swelling) and foot impairment (e.g. structural deformity). Foot joints examined were:

ankle, talo-calcaneo joint (subtalar), talo–navicular; calcaneo-cuboid (mid tarsal joint), metatarsophalangeal joints (MTPs) and interphalangeal joints (IPJs). Joint range of motion (ROM) was assessed pragmatically by visualisation (not through quantified measurement). Due to the complexity in assessing planes of motion, subtalar joints and midtarsal joints were examined as single mortise joints. Detection of cutaenous lesions (e.g. callus formation) and extra-articular features (e.g. nail infarcts) was conducted by observation. Presence of nodules and bursae were detected by physical examination.

Box 6.3 Protocol for assessing feet for disease activity and impairment

Clinical features	Examination	Conduct / definition / classification
Disease activity	Joint swelling	Examination of joint margins - four finger technique (Scott and Houssien, 1996)
	Joint tenderness	Presence of joint pain at rest on movement or direct pressure on joint using four finger technique (Scott and Houssien, 1996)
	Forefoot synovitis	Lateral squeeze test MTP joints
Foot impairment	Ankle ROM	Knee extended, subtalar joint held in neutral *Full ROM*: ≥20º dorsiflexion, ≥50 º plantar flexion *Limited ROM*: <20º dorsiflexion and/or <50 º plantar flexion *Rigid:* No dorsiflexion or plantar flexion
	Subtalar ROM	Knee extended, lower third of leg stabilised, calcaneus held, subtalar joint moved through ROM *Full ROM*: ≥20º inversion, ≥10º eversion *Limited ROM:* <20º inversion <10º eversion *Rigid:* No inversion or eversion
	Midtarsal ROM	Knee extended, subtalar joint in neutral, joint ROM examined at base of metatarsals. Normal ROM variable in the literature, joint examination for any ROM versus rigid (Oatis,1998)
	1st MTP ROM	Knee extended, first metatarsal shaft stabilized, proximal phalanx of 1st toe moved through plantar flexion and dorsiflexion *Full ROM*: ≥70º dorsiflexion, ≥45º plantar flexion *Limited ROM:* < 70º dorsiflexion, <45º plantar flexion *Rigid:* No dorsiflexion or plantar flexion
	Hallux valgus	*Stage 1*: lateral displacement of the 1st toe *Stage 2*: 1st toe displaced and in contact with 2nd toe *Stage 3:* complete dislocation of 1st MTP with 1st toe over riding or under riding lesser toes
	5Th MTP exostosis	Prominence of the lateral aspect of the 5th MTP
	Hammer / claw toes	Fixed deformity at proximal interphalangeal joint and/or distal interphalangeal joint
	MTP subluxation (dislocation)	MTP joint prominence on plantar aspect of foot with clinical evidence of fibro-fat pad atrophy

Assessment of peripheral vascular status was conducted by palpation of pedal pulses (posterior tibial artery and dorsalis pedis artery) and clinical examination (e.g. poor tissue perfusion). Assessment of peripheral neurological status was achieved through self-report (e.g. tingling) and response to light touch (protective sensation). Reduced protective sensation was assessed using a 10g Semmes Weinstein monofilament (Baileys Instruments Manchester UK). A 10g monofilament was applied perpendicular to the skin for approximately 1.5 seconds applying a bulking force of 10g of pressure. Patients were asked to respond “yes” if they perceived the test. A total of 6 sites were tested on both feet twice (plantar aspect of the hallux and plantar aspects of the MTP joints). A score of ≤11 positive sites was defined as a participant (patient) having reduced protective sensation in a foot (Wilson and Kirwan, 2006).

An assessment of participants’ footwear was conducted using a modified version of the Footwear Assessment Form (FAF) (Menz and Sherrington, 2000). The tool was developed in Australia to assess footwear suitability in relation to falls risks in older people. Minor modifications of the FAF to reflect differences in footwear classifications and styles of UK footwear (e.g. thongs / jandals to flip flops) and inclusion of additional styles (e.g. Lady Jane shoe (low heeled ladies shoe with a strap / T bar) were introduced following discussions between the researcher and observer. Although the FAF is an objective clinical assessment of the suitability of current footwear defined as “good”, “average” or “poor” (Silvester *et al,* 2010), there is potential for misclassification of the suitability of footwear (Dufour *et al,* 2009). For example “athletic shoe” is a broad term including sport and fashion athletic shoes. Fashion athletic shoes have minimal shock absorbing and anti-pronatory features. It was therefore possible that a study participant who was wearing a fashion athletic shoe may have their footwear misclassified as “good”. Data in relation to type of footwear worn by patients was collected for descriptive purposes only not for association with presence of current foot problems. Subsequently, patients’ footwear suitability was based on the observer’s clinical opinion. Classification of footwear type and suitability is presented in Box 6.4. The modified version is presented in question A11 in the CRF Appendix H2.

Box 6.4 Footwear type, definition and suitability

Footwear type	**Definition**	**Suitability**
Athletic shoe	Footwear primarily aimed for partaking in sporting activities	Good
Lady Jane	A ladies low shoe with a strap across the dorsal mid foot	Good
Oxford shoe	Men’s formal closed in shoe with laces	Good
Prescribed footwear	Hospital issued footwear not commercially available	Good
Walking shoe	Light comfortable shoe suitable for regular wear and extensive walking	Good
Boot	Type of footwear covering the foot and ankle which can also extend to the lower leg.	Average
Backless slipper	A backless low shoe which can be “slipped on and off” the foot easily, mainly worn indoors	Poor
Court shoe	A shoe with a low cut front without a fastening. Can also be referred to as a “pump”	Poor
High heel	Ladies footwear in which the heel of the foot is considerably higher than the height of the toes	Poor
Flip flop	Flat backless footwear attached to the foot by a thong between the first and second toes	Poor
Mule	Backless shoe with or without enclosed toe box	Poor
Moccasin	A flat soft leather slipper with a continuous sole extending and sewn to the leather upper	Poor
Sandal	Open footwear attached to the foot by a strap or thong	Poor
Slipper	A low shoe which can be “slipped on and off” the foot easily, mainly worn indoors	Poor
Ugg Boots	Boots with suede uppers and fleece liners	Poor
No footwear worn	Bare foot, stockings only or socks only	Poor

6.2.3.4 Foot care received

Data in relation to podiatric and orthopaedic care received and perceived benefits of care received were recorded verbatim by the observer. In relation to orthotic interventions received such as pressure relief (e.g. insoles) and prescribed footwear, data were collected by self-report and clinical observation. The observer recorded the classification of devices received on the CRF according to the definitions in Box 6.5.

Box 6.5 Orthotic devices classification and definitions

Device	Definition
Insole	Any device placed in the shoe to support or cushion the foot
Pre-moulded orthotic	Mass produced orthoses / insoles designed and contoured to the foot
Functional	Designed and contoured to the foot to alter foot function and joint alignment e.g. addition of rear foot posting
Total contact inlay	Full length orthotic made form a cast of a patients' foot (bespoke device)
NA	Not applicable as device not issued
Stock footwear	"Off the shelf" hospital issued footwear with a standard last (360 model of the foot), available in variety of widths
Modular footwear	Footwear manufactured with slight adjustments to standard last
Bespoke	Custom made footwear for an individual patient including a bespoke last

6.2.4 Scoring the scales

The HAQ, FIS and additional measures of impact (severity, ability to cope with and importance) were measured again at the clinical assessment visit and were scored as described in Chapter 5.

6.2.5 Social deprivation

Local social deprivation was captured using the Index of Multiple Deprivation (IMD) 2007 as described in Chapter 5 section 5.2.5. The IMD scores were computed from patients' postcodes in Study 2 and these scores were utilised in Study 3

6.3 Study procedures

Approval was obtained from Central Bristol Medical Research Ethics Committee (reference 101/SW/0327) and the University of the West of England Research Ethics Committee (reference HLS/12/01/12). Research and development approval was obtained from both hospital sites (NBT and UHB). Additional research and development approval was obtained from Bristol Community Health (BCH) as two Community Health Centres were utilised to conduct some of the research appointments for the clinical assessment and foot examination. The use of BCH facilities was required as an additional site due to limited clinical room availability at one hospital site during major redevelopment works.

An invitation to participate in Study 3 was posted to the patient's home address. The invitation packs included an invitation letter (signed by the researcher), patient information sheet (PIS), reply slip agreeing to be contacted by the researcher and a return FREEPOST envelope. The invitation packs were the same for both hospital sites apart from the invitation letter and PIS, which were on individual department headed notepaper. In order to reduce bias (as discussed in Chapter 5) contact details on the invitation packs introduced the researcher as a clinical doctoral research fellow, not as a podiatrist. If no response was received after three weeks a reminder was sent. All patients who returned the reply slip and agreed to be contacted were telephoned by the researcher and provided with more information about the study. Patients agreeing to participate in Study 3 were then invited to attend a clinical assessment including a foot examination with the observer at a choice of three NHS sites (one hospital site and two community health centres). Patients were invited in batches to aid administration, including facilitation the conduct of the research appointments, which would last 30 minutes. Informed written consent was obtained immediately prior to data collection by the independent podiatrist who also completed and returned case record forms (CRFs) to the researcher who entered all data in the study data base.

6.4 Analysis plan and sample size

6.4.1 Statistical analyses

Analyses were conducted using SPSS 19.0 (SPSS Inc. Chicago. Illinois). Each CRF was checked for completeness by the researcher. Accuracy checking of data entry was checked by duplicate entry of a random sample of 10% CRFs and by inspecting frequency distributions and minimum and maximum values as previously described. Descriptive statistics were used for: general characteristics (hospital site, age gender, and social deprivation); RA characteristics (disease duration, arthritis medications, and disability), regional musculoskeletal assessment, presence of foot problems (self-report, clinical examination), footwear suitability, impact of foot problems and foot care services accessed. Normally distributed continuous data were expressed as means and standard deviations (SD) or 95% confidence intervals (CI). Skewed continuous data were expressed as medians and inter quartile range (IQR). For categorical data, proportions were calculated and expressed as percentages. Comparisons of general characteristics, RA characteristics, presence of foot problems between the AFC group and the NAFC group were conducted using descriptive and inferential statistics. Independent samples t-tests were computed for continuous (normally distributed) variables. The Mann-Whitney U test was used for continuous variables, not normally distributed and Chi-square tests for categorical variables. P values were considered statistically significant if they were less than 0.05.

To explore the accuracy of self-report of foot problems, comparisons were computed between the level of agreement of current foot problems by self-report and clinical examination (e.g. hallux valgus reported and hallux valgus observed). Contained in Appendix H2 are the current and previous foot problems which patients were asked to report. Responses to each question were recorded as binary variables (yes / no). Definitions and classifications of current foot problems observed are presented in Box 6.6. The presence of foot problems observed was computed as binary variables (e.g. ≥ 1 stage hallux valguses - yes / no). The self-report and clinical observation binary variables were calculated as proportions and expressed as percentages.

Box 6.6 Comparisons of current foot problems by self-report and clinical assessment

Current foot problem reported	**Current foot problem definition observed on examination**
Pain	Unable to define as pain is a subjective experience and unable to quantify by examination
Stiffness	Unable to define as no clinical measurement available
Numbness	Reduced protective sensation – scoring <11 either foot
Swelling	≥ 1 joint swelling
Bunions	Presence of hallux valgus stage ≥ 1
Callus (hard skin)	Presence of callus - thickening of the epidermis on a weight bearing / pressure area / bony prominence
Corns	Small conical shaped callus on a weight bearing / pressure area / bony prominence
Blisters	Collection of fluid below the epidermis
Ulcers	Presence of a full thickness wound (exposing dermis or deeper tissues (e.g. bone) on or below the level of the malleoli
Thickened toe nails	Presence of onychauxic (thickening of nail plate) / onycogryphosis (thickening of nail plate with deformity) / onycomycosis (fungal involvement of nail plate with thickening)
Infection	Presence of bacterial / fungal infection involving epidermis and/or soft tissues
In-grown toe nails	Involution of nail plate (curvature of nail plate sulci / boarders) / convolution of nail plate (increased curvature of nail plate sulci / boarders) onycocryptosis (presence of spike of nail)
Misshapen toes	Fixed flexion deformity at ≥ 1 interphalangeal joint
Nodules (bumps)	Nodules - presence of a small palpable subcutaneous mass
Fallen arches	Presence of pes planus – flattening loss of normal medial longitudinal arch

The Kappa statistic was used to calculate the overall percentage of agreement. The Kappa statistic indicates the proportion of agreement between two observers accounting for proportion of chance agreement. Interpretation of Kappa values are presented in Table 6.1 (Landis and Koch, 1977).

Table 6.1 Interpretation of Kappa

Kappa	**Agreement**
< 0	Less than chance agreement
0.01-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement

However, the Kappa statistic does not give an indication explaining levels of disagreement and can also be influenced by frequency. Thus it may not reflect level of agreement for rare events (e.g. foot ulceration). Additionally Sims and Wright (2005) recommend the use of the Kappa with caution when measuring levels of agreement between variables measured on different scales (e.g. self-report of numbness and clinically detected reduced protective sensation).

The accuracy of self-report was therefore further analysed in relation to sensitivity and specificity: 1) “true positives” (patient reports foot problem and foot problem observed); 2) “false positives” (patient reports foot problem but no foot problem observed): 3) “true negatives” (patient does not report foot problem and foot problem not observed); 4) “false negatives” (patient does not report foot problem but foot problems is observed). Accuracy of self-report was computed comparing proportions of agreement with clinical examination for each of the classifications of sensitivity and specificity stated above.

6.4.2 Free text analyses

Data in relation to arthritis medications, additional morbidity and foot care received were collected by free text response and recorded verbatim by the observer. Consensus on the classification and categorisation of the free text responses was reached following discussion between the researcher, academic supervisor (JK) and observer. A coding frame was derived and entered into SPSS for quantitative analyses.

Content analyses (CA) were conducted on patients’ free text responses to: description of foot care received, perceived benefits of care, reasons for accessing or not accessing foot care and reasons for not utilising orthotic devices issued. The observer’s clinical opinions of current foot problems requiring intervention were also analysed using CA. A full description of the rationale and the conduct of CA is presented and discussed in Chapter 5. Free text data were transcribed verbatim into the study data base. Data relating to similar points were grouped together in codes and codes were subsequently merged to form comment categories to produce a coding frame. The free text data were entered as string variables in SPSS along with the coding frame and treated for variables as quantitative analyses.

6.4.3 Sample size

The sample size estimate for Study 3 was based on the expectation that there might be 5-6 main determinants of access to foot care, identified by multivariate analysis conducted in Study 2. Therefore Study 3 would require approximately 10 participants for each variable (Belle, 2008) requiring 60 patients in each group (accessed foot care, AFC and not accessed foot care, NAFC). It was estimated that between 350 – 500 responders in Study 2 would be appropriate to achieve a final sample size of 120 for Study 3.

6.4.4 Patient research partner involvement

Collaboration with the patient research partners (PRPs) continued during the planning of the study design and conduct of the data collection (clinical assessment and foot examination). Both PRPs provided valuable comments regarding the overall approach to the study and actively participated in the researcher’s supervisory meetings.

6.5 Results

Data collection commenced in June 2012 and was completed in April 2013.

6.5.1 Participation rates and characteristics of participants and non-participants

Of the 413 patients who responded to the postal survey, 235 were invited to participate in Study 3 (Figure 6.1) and 143 (60.9%) accepted the invitation. Of these, 110 (76.9%) attended the research appointment for clinical assessment and foot examination, an overall participation rate of 46.8%.

Figure 6.1 Flow diagram of recruitment Study 3

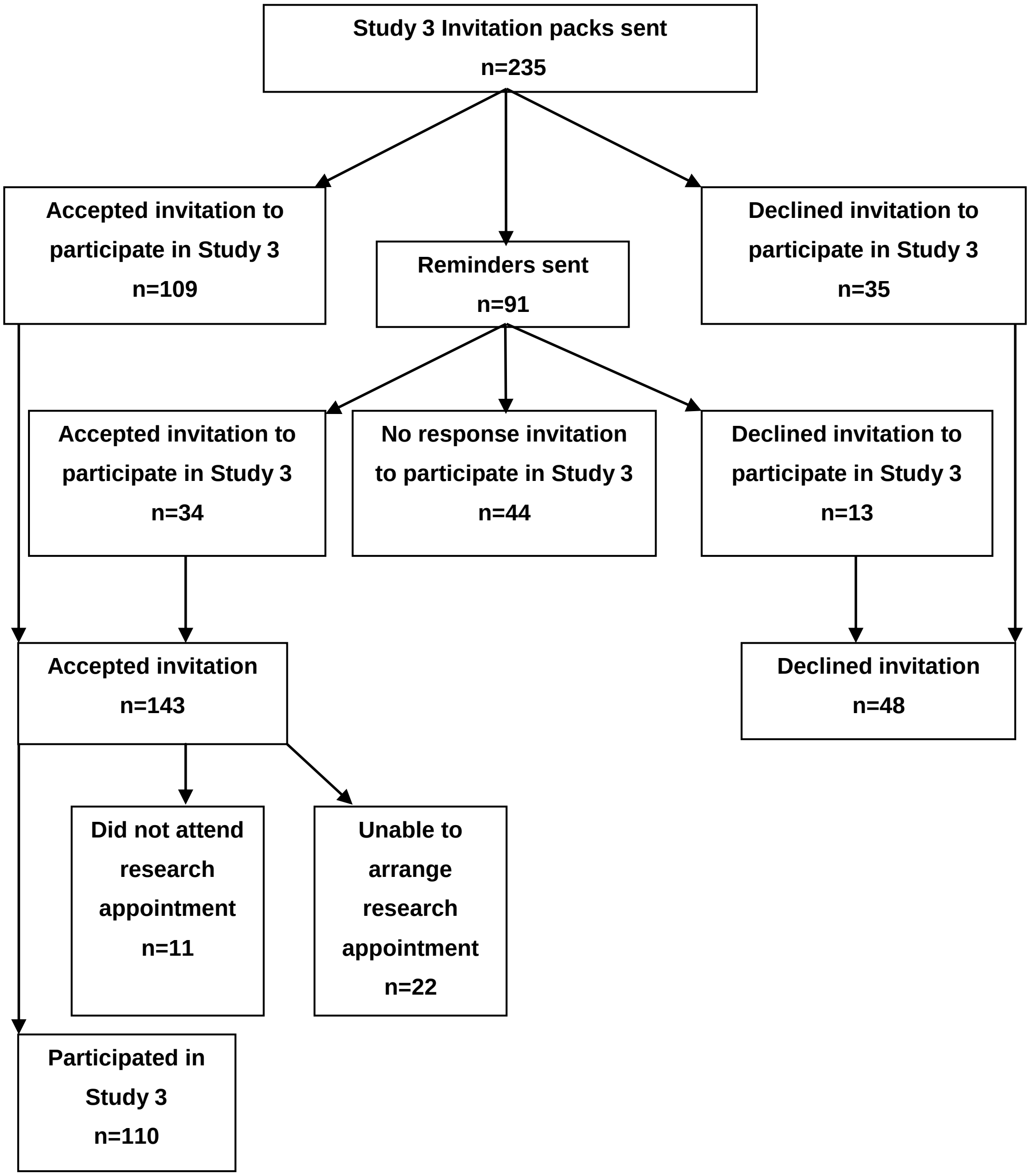


Table 6.2 compares the general characteristics (hospital site, gender, age, and social deprivation) and clinical characteristics (disease duration, arthritis medications, disability and additional morbidity) of patients who attended (participants) and those who did not attend (non-participants). Overall the proportions were broadly similar for all general and clinical characteristic variables between patients invited to participate, participants and non-participants. Almost all participants and non-participants (as reported in Study 2) were taking arthritis medications (98.2% versus 93.6%). Small variation was detected between the proportions of participants and non-participants taking biologics, glucocorticoids and NSAIDs. Additionally the difference in means in age (years) between participants and non-participants was nearly 2 years. The proportion of patients attending who resided in socially deprived areas was very similar to the proportion invited (and the proportion in the target population as shown in Chapter 5).

Table 6.2 Participation general and clinical characteristics

Variable		**Total selected n=235 (%)**	**Participants n=110 (%)**	**Non-participants n=125 (%)**
Hospital site UHB (%)		135 (57.5)	66 (60.0)	69 (55.2)
Female (%)		172 (73.2)	77 (70.0)	95 (76.0)
Age years mean (SD)		62.2 (12.6)	63.1 (11.2)	61.4 (13.7)
Local social deprivation	Category 1 (least deprived)	58 (24.7)	27 (24.5)	31 (24.8)
	Category 2	87 (37.0)	46 (41.8)	41 (32.8)
	Category 3	59 (25.1)	22 (20.0)	37 (29.6)
	Category 4	19 (8.1)	9 (8.2)	10 (8.0)
	Category 5 (most deprived)	12 (5.1)	6 (5.5)	6 (4.8)
Disease duration years median (IQR)		9 (5-15)	8.5 (5-13)	10 (5-13)
Arthritis medications (%)	NSAIDs	97 (41.3)	36 (28.8)	61 (55.5)
	DMARDs	196 (83.4)	103 (82.4)	93 (84.5)
	Glucocorticoids	70 (29.8)	42 (33.6)	28 (25.5)
	Biologics	43 (18.3)	15 (12.0)	28 (26.4)
HAQ median (IQR)		1.5 (0.750-2.00)	1.25 (0.375-2.00)	1.562 (0.75-1.968)
Morbidity (%)	No co-morbidity	85 (36.2)	31 (28.2)	54 (43.2)
	1 co-morbidities	99 (42.1)	43 (39.1)	56 (44.8)
	>1 co-morbidities	50 (21.3)	36 (32.7)	28 (22.4)

6.5.1.1 Identifying study sample controlled for disease duration

The one to one matching process implied that there would be equal numbers of those who had accessed foot care (AFC) and those who had not accessed foot care (NAFC). In the event, of the 110 patients, 65 (59%) had accessed one or more foot care service. This variation in the numbers in each group was due to difficulties in organising research appointments. Patients were also selected to provide a balance of disease duration between the AFC group and the NAFC groups. The median

(IQR) disease duration in the AFC group was 8 years (6 to 15). The median disease duration in the NAFC group was 7 years (4 to 12). The difference in medians of 1 year shows that a balance for disease duration was achieved.

6.5.1.2 Demographic and clinical characteristics

Table 6.3 presents comparisons of clinical and demographic characteristics of the study participants by AFC group and NAFC group. Overall the proportions were similar for the AFC group and the NAFC group in relation to hospital site, categories of local social deprivation and arthritis medications. Additionally a wide range of current disability was reported by the study patients. The number of patients reporting no current disability was small (n=10, 9%). The median HAQ scores were similar for both the AFC group and the NAFC group (1.375 versus 1.125).

Table 6.3 Demographic and clinical characteristics

Variable		**Total selected participants n=110 (%)**	**AFC n=65 (%)**	**NAFC n=45 (%)**
Hospital site UHB (%)		66 (60)	39 (60)	27 (60)
Female (%)		77 (70)	48 (74)	29 (64)
Age years mean (SD)		63.8 (11)	65.4 (11)	61.6 (11)
Local social deprivation	Category 1	27 (25)	15 (23)	12 (27)
	Category 2	46 (42)	27 (42)	19 (42)
	Category 3	22 (20)	13 (20)	9 (20)
	Category 4 and 5	15 (14)	10 (15)	5 (11)
RA medications (%)	NSAIDs	61 (56)	37 (57)	24 (53)
	DMARDs	93 (85)	54 (83)	39 (87)
	Glucocorticoids	28 (26)	13 (20)	15 (33)
	Biologics	29 (26)	15 (23)	14 (31)
	None	3 (3)	3 (5)	0 (0)
HAQ median (IQR)		1.25 (0.375-2.00)	1.375 (0.375-2.00)	1.125 (0.375-1.75)
Morbidity (%)	No co-morbidity	31 (28)	17 (26)	14 (31)
	1 co-morbidities	46 (42)	24 (37)	22 (49)
	>1 co-morbidities	33 (30)	24 (37)	9 (20)

Of the AFC group (n=65), 48 (74%) were female compared to 29 (64%) in the NAFC group (n=45). There was no statistically significant difference (x^2 = 1.12, df=1, p=0.29). The mean age of patients was 63.8 years (SD=11.2, min 38, max 88). The mean age for the AFC group was 65.4 years (SD=11.0, min 40, max 88) and for the NAFC group was 61.6 years (SD=11.2, min 38, max 81) which was not statistically significant (t=-1.77, df=108, p=0.08). Of the 110 patients, 79 (72%) reported other medical conditions (co-morbidities). The proportions of patients reporting additional morbidity were similar for both groups. The classification and categorisation of additional health problems reported by both groups is available in Appendix I supplementary data.

6.5.1.3 Arthritis support group membership

Almost all patients reported that they were not members of an arthritis support group (n=108, 98%). Of the two patients who did report to being members of a support group, both had accessed foot care.

6.5.1.4 Overview of patient and RA characteristics

Overall, no difference was detected between the AFC and the NAFC group in relation to general demographic characteristics (hospital site, gender, age and socio-economic status). Further, the RA characteristics were similar for both groups in terms of: disease duration; classification and categorisation of arthritis medications and disability (HAQ).

6.5.2 Foot related characteristics and impact

6.5.2.1 Foot problems self-report

Table 6.4 presents the frequencies of current foot problems reported on the day of attendance for clinical examination. All patients reported one or more current foot problems. The frequencies were similar between the AFC group and the NAFC group for the majority of foot problem categories. However, there were differences between the groups for current articular features and extra-articular features. Of the AFC group, two thirds reported one or more articular features and one or more extra-articular features (currently) in their feet (n=45, 69% and n=32, 70%, respectively). The similar numbers for the NAFC group were 28 (43%) and 14 (30%). This was not a statistically significant difference (x^2 = 0.59, df=1, p=0.44).

Table 6.4 Foot problems self-report

Foot problem category	Foot problems	Foot problems now AFC n=65 (%)	Foot problems now NAFC n=45 (%)
Articular features	Pain	25 (39)	19 (42)
	Stiffness	31 (48))	21 (53)
	Swelling	19 (29)	12 (27)
	Any articular feature	**45 (69)**	**28 (43)**
Cutaneous lesions	Blisters	3 (5)	2 (4)
	Callus	38 (59)	24 (53)
	Corns	10 (9)	3 (7)
	In-grown toe nails	11 (17)	6 (13)
	Thickened Toe nails	35 (54)	28 (62)
	Ulcers	0 (0)	0 (0)
	Any cutaneous lesions	**54 (83)**	**39 (87)**
Structural deformity	Bunions	22 (34)	16 (36)
	Fallen arches	21 (33)	7 (16)
	Misshaped toes	44 (68)	27 (60)
	Any structural deformity	**50 (77)**	**30 (67)**
Extra-articular features	Nodules	15 (23)	10 (22)
	Numbness	24 (37)	6 (13)
	Any extra-articular feature	**32 (70)**	**14 (31)**
Other	Infection	4 (6)	4 (9)
Any foot problems		**65 (100)**	**45 (100)**

6.5.2.2 Impact of foot problems (Section C)

Data were collected in relation to the impact of current foot problems at the time of the research appointment. All patients fully completed both sub-scales of the FIS ($\mathrm{FIS}_{\mathrm{IF}}$ and $\mathrm{FIS}_{\mathrm{AP}}$). There was a wide range of $\mathrm{FIS}_{\mathrm{IF}}$ scores in both groups (Figure 6.2) with similar distributions. The median (IQR) $\mathrm{FIS}_{\mathrm{IF}}$ scale score for the patients was 9 (5 to 13). The median (IQR) $\mathrm{FIS}_{\mathrm{IF}}$ scale score for the AFC group was 9 (6 to 13). The median (IQR) $\mathrm{FIS}_{\mathrm{IF}}$ scale score for the NAFC group was 8 (2 to 13). The difference in medians of 3 between the groups was not statistically significant (U=1281, p=0.27). Of the AFC group, 9 (14%) scored > 16 on the $\mathrm{FIS}_{\mathrm{IF}}$ scale. For the NAFC group 4 scored >16 (9%).

Figure 6.2 Frequency distribution of FIS$_{IF}$ scores

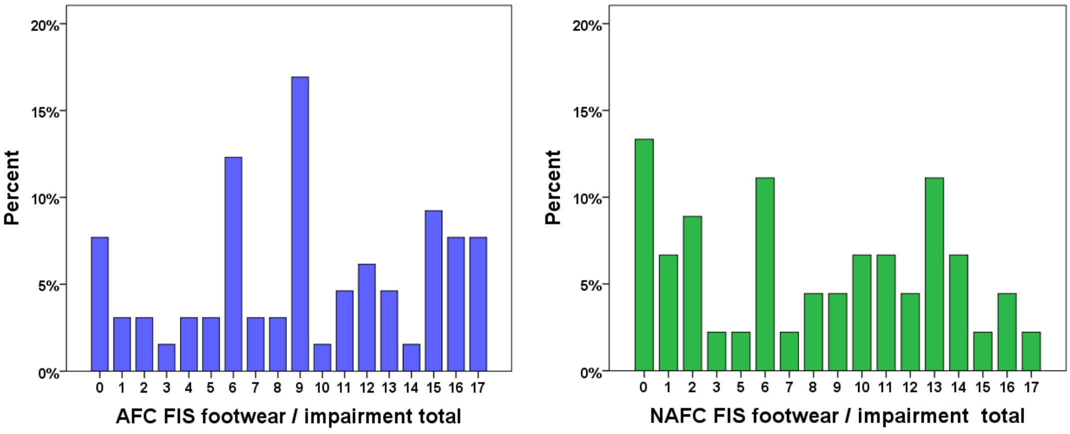
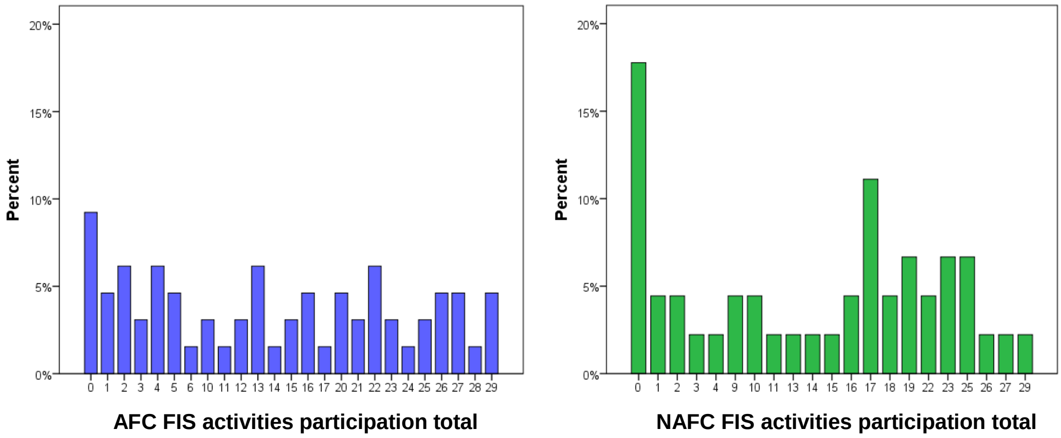


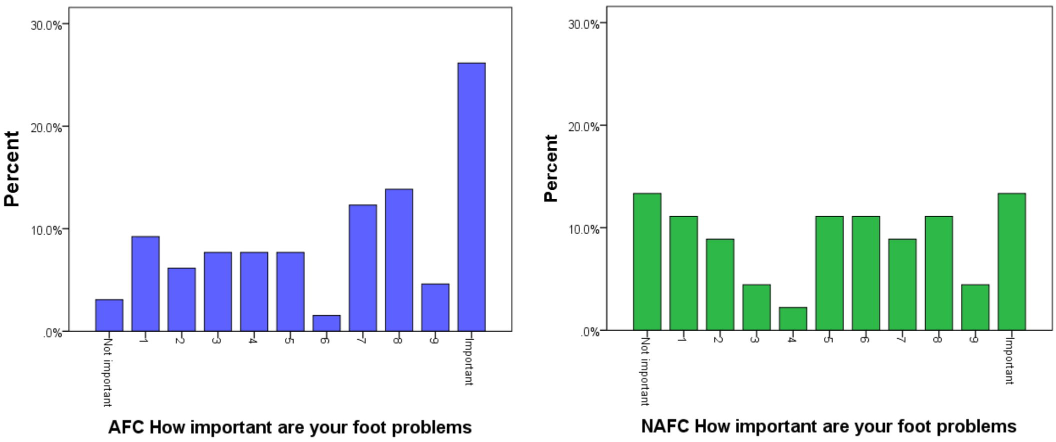
Figure 6.3 shows the distribution of FIS$_{AP}$ scale scores for the AFC and NAFC groups. There was a wide range of scores in both groups with similar distributions. The median (IQR) FIS$_{AP}$ scale score for patients was 15 (3 to 22). The median (IQR) FIS$_{AP}$ score for the AFC group was 13 (4 to 22) and for the NAFC group was 16 (2 to 22). This was not a statistically significant difference (u=1397, p=0.69). Of the AFC group, two patients scored >30 on the FIS$_{AP}$ scale. The highest FIS$_{AP}$ score in the NAFC group was 29.

Figure 6.3 Frequency distribution of FIS$_{AP}$ scores



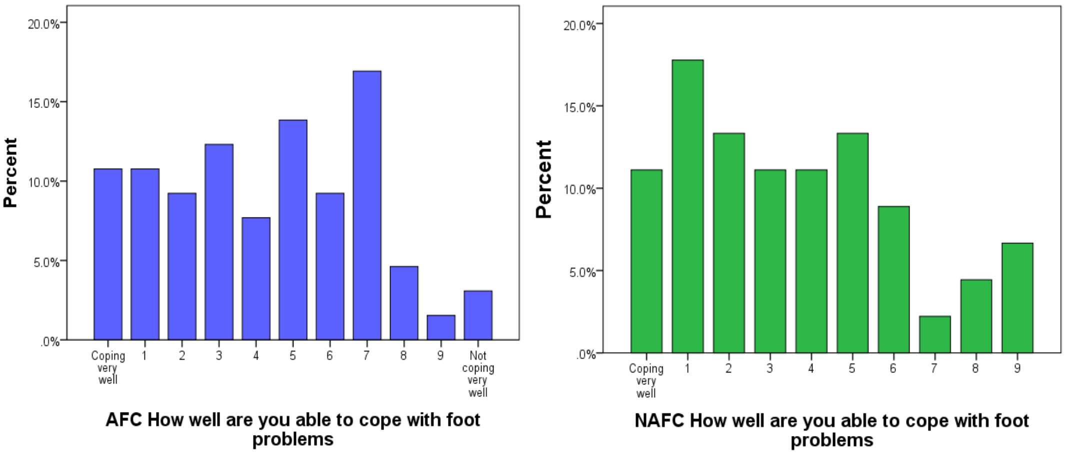
The median (IQR) importance of foot problems score for the patients was 6 (3 to 9). The median (IQR) importance score for the AFC group was 7 (3 to 10) and for the NAFC group was 5 (2 to 8). This was not a statistically significant difference (U=1164, p=0.67). Of the AFC group, 17 (26%) considered their foot problems to be very important (scoring 10), compared to 6 (13%) in the NAFC group. This result indicates that despite reporting foot problems to be very important, some patients had not accessed foot care. Figure 6.4 presents the distribution of importance scores for the AFC and the NAFC groups.

Figure 6.4 Importance of foot problem scores



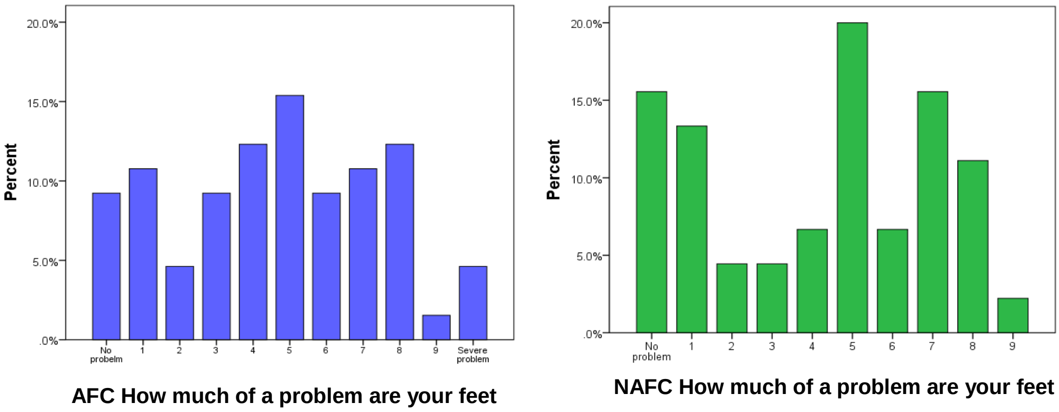
The median (IQR) of patients ability to cope with foot problems score was 4 (2 to 6). The median (IQR) ability to cope with foot problems score for the AFC group was 4 (2 to 6) and for the NAFC group was 3 (1 to 5), which was not a statistically significant difference (U=1303, p=0.33). Figure 6.5 shows the distributions of ability to cope with foot problems scores in both groups. Of the AFC, 7 (11%) reported to be coping very well with their foot problems (scoring 0). The number of the NAFC group reported to be coping well with their foot problems was 5 (11%). Of the ACF group, 7 (11%) reported not coping well with their foot problems (>8) as did 11% of the NAFC group (n=5). This result indicates that despite some patients reporting difficulty coping with their foot problems, they had not accessed foot care.

Figure 6.5 Ability to cope with foot problems scores



The median (IQR) magnitude (severity) of foot problems score for the patients was 5 (2 to 7). The median (IQR) score for the AFC group was 5 (3 to 7) as was the NAFC group (1 to 7). The proportion of patients reporting no severity (scoring 0) was higher in the NAFC group (n=7, 16% versus n= 6, 9%). Of the AFC group, 3 (5%) reported severe current foot problems (scoring 10).This result indicates despite accessing foot care a small number of patients were still experiencing severe foot problems. Figure 6.6 illustrates the distribution of magnitude scores.

Figure 6.6 Magnitude of foot problems distribution scores



6.5.2.3 Overview of foot related characteristics and impact

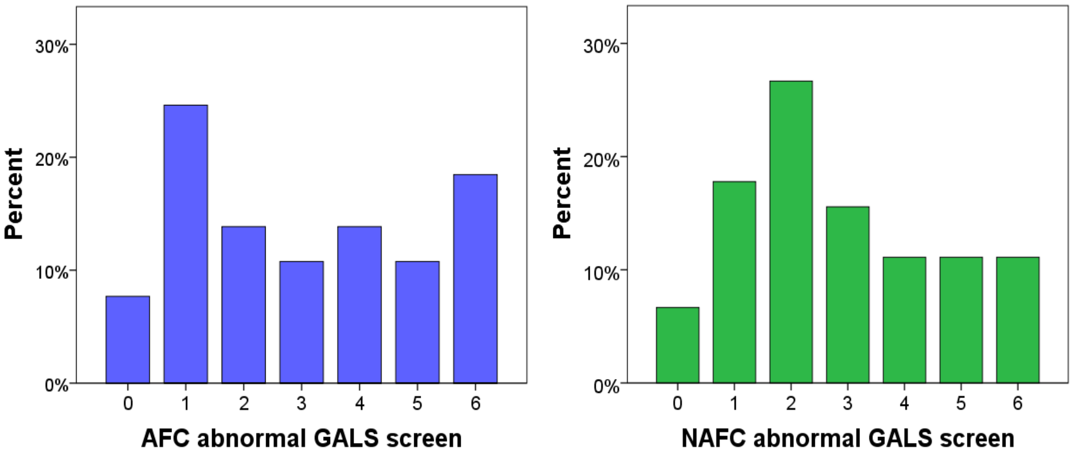
All patients reported one or more current foot problems. The majority of the AFC group reported 1 or more: articular feature; cutaneous lesion; structural deformity and/or extra-articular feature. These results imply that despite accessing foot care, foot problems continued. Overall, a wide range of impact scores (FIS_{IF}, FIS_{AP}, importance of foot problems, ability to cope with foot problems and severity of foot problems) were reported by both the AFC group and the NAFC group, demonstrating that foot problems were impacting on many aspects of patients' personal lives. In relation to comparisons of impact scores between the AFC group and the NAFC group, no statistically significant differences were detected. Some patients had not accessed foot care despite reporting substantial impact in terms of foot problems. For other patients, even though foot care had been accessed, some reported that their foot problems were severe.

6.5.3 Clinical observation (Section A)

6.5.3.1 Musculoskeletal system assessment

Figure 6.7 presents the frequencies of the gait, arms, legs and spine - screen (GALS) abnormalities observed. The majority of patients were observed to have one or more musculoskeletal abnormality and/or restricted function. The frequency distribution of GALS abnormalities were broadly similar for both groups.

Figure 6.7 Frequencies of GALS abnormalities



The frequencies (proportions) of abnormalities for the components of the GALS screen are presented in Table 6. 5. A Chi-square test amalgamating scores 6 (AFC n=6, 9%; NAFC n=4, 9%) and 7 (AFC n=6, 9%; NAFC n=1, 2%) GALS abnormalities achieving minimum cell count of 5 was not significant statistically (x^2=5.55, df=6, p=0.48). A greater proportion of patients in the NAFC group were observed to have abnormal gait appearance compared with the AFC group (36% versus 28%). Of the AFC group, 36 (55%) had an abnormal GALS leg screen. The frequency for an abnormal legs screen for the NAFC group was identical (n=23, 55%). These results show that almost all patients had restriction of function. Further, the proportions of functional restriction were similar for the AFC group and NAFC groups.

Table 6.5 GALS screen

GALS screen abnormality	AFC (n=65) number of patients in this category (%)	NAFC (n=45) number of patients in this category (%)
Gait appearance	31 (28)	16 (36)
Arms appearance	9 (8)	6 (13)
Arms movement	12 (19)	9 (20)
Any arm abnormality	48 (74)	37 (82)
Legs appearance	29 (45)	19 (42)
Legs movement	31 (28)	15 (33)
Any legs abnormality	36 (55)	23 (55)
Spine appearance	18 (28)	12 (27)
Spine movement	17 (26)	11 (24)
Any spine abnormality	23 (35)	16 (36)

6.5.3.2 Frequencies of foot problems by clinical observation

Almost all patients had one or more foot problems (n=104, 95%): 62 (95%) of the AFC group and 42 (93%) of the NAFC group. Table 6.6 presents the frequencies of clinically observed foot problems.

Table 6.6 Frequencies of observed foot problems

Foot problem category	Foot problems	AFC (n=65) number of patients in this category (%)	NAFC (n=45) number of patients in this category (%)
Extra-articular features	Bursa	7 (11)	6 (13)
	Nodules	1 (2)	2 (4)
	Any extra-articular feature	8 (12)	8 (18)
Cutaneous lesions	Blisters	2 (3)	0 (0)
	Callus	35 (53)	23 (51)
	Corns	7 (11)	6 (13)
	In-grown toe nails	12 (19)	4 (9)
	Thickened toe nails	30 (46)	19 (42)
	Onycomycosis	8 (12)	5 (11)
	Any cutaneous lesions	**49 (75)**	**32 (71)**
Structural deformity	Classic daylight	8 (12)	6 (13)
	Hallux valgus	23 (35)	13 (29)
	Retracted / clawed toes	32 (49)	22 (49)
	Pes planus	18 (28)	10 (22)
	Subluxed MTPs	38 (59)	22 (49)
	5th MTP exostosis	10 (15)	10 (22)
	Any structural deformity	**54 (84)**	**35 (78)**
Any foot problems		**62 (95)**	**42 (93)**

The majority of the patients had one or more cutaneous lesions (n=81, 74%). The frequencies of cutaneous lesions categories were similar for both the AFC group and the NAFC group. Of the AFC group about one half (n=35, 54%) were observed to have callosities. Of these: 16 (46%) had callus formation at one or more metatarsophalangeal joint (MTP), 5 (14%) digital (toes) callus and 11 (31%) at more than one site (MTP, toes or heels). The equivalent numbers for the NAFC group were: 23 (51%) any callus formation, 14 (61%) MTP callus, 4 (17%) digital callus and more than one site 5 (22%). The frequencies of thickened toe nails and onycomycotic nails were similar for both groups. In contrast the frequency of ingrown toe nails was higher in the AFC group (19% versus 9%).

Of the 110 patients, 89 (81%) had one or more structural foot deformities. The frequencies of structural deformity categories were similar for both the AFC group and the NAFC group with the exception of frequencies of one or more subluxed MTPs and 5th MTP exostoses (n=38, 59% versus n=18, 49% and n=16, 15% versus n=10, 22%, respectively). A wide range of the number of subluxed MTPs and toe deformities (retracted / clawed) were observed in both the AFC group and the NAFC group. A third of the AFC group was observed to have hallux valgus (HV) (n=23, 35%). Of these, 16 (70%) had HV bilaterally. The frequency of bilateral HV was lower in the NAFC group (n=5, 11%).

No patients had current foot ulceration. However, 9 (8%) reported foot ulceration at some time since being diagnosed with RA. Of these 9, 7 (78%) had accessed foot care. No patients had or reported an episode of systemic or skin vasculitis (digital infarcts, petechiae, palpable pura) and no bacterial infections were observed during the clinical examination. Data were not collected on recalled (self-report) previous episodes of bacterial foot infections.

6.5.3.3 Footwear characteristics

The classification of footwear suitability is presented in Table 6.7. No patients were wearing or reported their preferred footwear to be high heels (heel considerably higher than forefoot sole) or slippers. However, 13 (12%) of patients' shoes had a heel height between 2.6cm and 5.0cm. Of these, 9 (69%) had footwear with a wedged sole (heel continuous with the sole). Of the remainder, four patients were wearing court shoes and one mule style shoes. Overall, nearly half were wearing "good" (appropriate / suitable) footwear (n=49, 44%). However, the frequency of preferred usual footwear classified as "good" was higher than the observation of good footwear worn. The discrepancies between the frequencies occurred due to: personal choice in terms of seasonal variation (n=12, 11%), employment regulations (n=2, 2%), fluctuating symptoms (n=1, 1%) and ease of removal for foot examination (n=1, 1%). A small number (n=3, 3%) said their choice of "poor" footwear was due to inability to tie shoe laces or buckles due to reduced function (e.g. reduced hand dexterity).

Table 6.7 Observed and preferred footwear type

Footwear suitability	Footwear type	AFC (n=65) number of patients in this category (%)	NAFC (n=45) number of patients in this category (%)	Preferred footwear* AFC (n=65) number of patients in this category (%)	Preferred footwear* NAFC (n=45) number of patients in this category (%)
Good	Athletic shoe	11 (17)	8 (18)	12 (19)	8 (18)
	Oxford shoe	1 (2)	0 (0)	1 (2)	1 (2)
	Prescribed footwear	1 (2)	0 (0)	2 (3)	0 (0)
	Walking shoe	18 (28)	9 (20)	22 (34)	14 (31)
	Any good footwear	**31 (48)**	**17 (38)**	**37 (57)**	**23 (51)**
Average	Boot	10 (15)	8 (18)	9 (14)	7 (16)
	Any average footwear	10 (15)	8 (18)	9 (14)	7 (16)
Poor	Court shoe	2 (3)	5 (9)	3 (5)	4 (9)
	Flip flop	0 (0)	2 (4)	1 (2)	1 (2)
	Mule	1 (2)	2 (4)	1 (2)	2 (4)
	Moccasin	10 (15)	8 (18)	5 (8)	6 (13)
	Sandal	10 (15)	3 (7)	6 (9)	2 (4)
	Ugg Boots	1 (2)	0 (0)	1 (2)	0 (0)
	Any poor footwear	**24 (37)**	**20 (44)**	**17 (26)**	**15 (33)**

*self-report general preferred footwear

Of the AFC group, 31 (48%) were classified as wearing good footwear compared 17 (38%) of the NAFC group. However, a third the AFC (n=24, 37%) group were assessed to be wearing poor footwear. Data were not collected in relation to receiving footwear education at the time that foot care was accessed.

Table 6.8 shows footwear construction characteristics. The majority of footwear had some form of fixation (for example laces) to facilitate individual adjustment of the shoes (n=87, 79%). Moderate heel counter stiffness (facilitate rear foot motion >45 degrees) was observed in the shoes of 65 (59%) patients. The majority (n=84, 76%) of footwear facilitated normal 1st MTP ROM (sole flexion point at level of 1st MTP). Further, the majority of footwear had satisfactory tread pattern (textured) and sole hardness (firm) in relation to reducing slips / falls risk and shock absorbing properties (n=94, 86% and n=86, 78%, respectively). Comparisons of the frequencies of footwear construct characteristics were on the whole similar for both patient groups. Of the 23 patients with no shoe fixation, half were in the AFC group 11 (48%).

Table 6.8 Footwear construction characteristics

Footwear variable		**AFC (n=65) Number of patients in this category (%)**	**NAFC(n=45) Number of patients in this category (%)**
Heel height	0-2.5 cm	58 (89)	39 (87)
	2.6-5.0cm	7 (11)	6 (13)
Fixation	None	11 (17)	12 (27)
	Laces	14 (22)	17 (38)
	Straps/Buckles	15 (23)	4 (9)
	Velcro	4 (6)	0 (0)
	Other (Elastic gusset)	21 (32)	12 (27)
Heel counter stiffness	Not available	15 (23)	10 (22)
	<45 degrees	36 (55)	29 (64)
	>45 degrees	14 (22)	6 (13)
Longitudinal sole rigidity	<45 degrees	22 (34)	16 (36)
	>45 degrees	43 (66)	29 (64)
Sole flexion point	At level of 1st MTP	48 (74)	36 (80)
	Before 1st MTP	15 (23)	8 (18)
	No flexion	2 (3)	1 (2)
Tread wear pattern	Textured	56 (86)	38 (84)
	Smooth	9 (14)	7 (16)
	Not worn	32 (49)	27 (60)
	Partly worn	30 (46)	16 (36)
	Fully worn	3 (5)	2 (4)
Sole hardness	Soft	10 (15)	5 (11)
	Firm	53 (82)	33 (73)
	Hard	2 (3)	7 (16)

6.5.3.4 Overview of clinical observation

Almost all of the patients had one or more current foot problems and more than half had callosities, thickened toe nails, retracted / clawed toes and one or more subluxed MTP joints. Extra-articular features (nodules, bursa) occurred but less frequently than cutaneous lesions and structural deformity. Overall, the frequencies of observed foot problems were similar for both the AFC group and the NAFC group. These results reinforce previous reports that foot involvement is common in RA and multi-factorial in clinical presentation.

Overall, only half of the patients were wearing “good” footwear. Further, a third of the AFC group were wearing “poor” footwear. Some patients’ reported they varied their choice of footwear to account for: seasonal variation (e.g. sandals in summer shoes in winter), fluctuating foot symptoms and or paid employment regulations (e.g. safety boots). A small number of patients elected to wear slip on shoes for convenience of removal when attending the research appointment, limited dexterity (unable to tie laces) and/or restricted mobility.

6.5.4 Clinical assessment (Section A)

6.5.4.1 Tender joint count

A range of tender joint count scores was observed in both groups. The number of patients with no tender foot joints was similar for the AFC group and the NAFC group (n=13, 20% versus n=12, 27%). A small number of patients scored a maximum tender joint count of 28 (AFC n=1 versus NAFC n=1). The median (IQR) tender joint count (feet) for all patients was 5.5 (1 to13). In the AFC group, the median (IQR) tender joint count was 5 (1 to 13) and for the NAFC group was 6 (0 to 10), which was not significantly different (U=1382.5, p=0.62).

6.5.4.2 Swollen joint count

The median (IQR) swollen joint count (feet) for patients was 2 (0 to 8).The median (IQR) swollen joint counts for the AFC group and the NAFC group were similar (2 (0-8), 2 (0-7), respectively). A third (n=39, 36%) of the patients had no swollen joints. Of the AFC group, 20 (31%) had no swollen joints. Of the NAFC group, 19 (42%) had no swollen joints.

6.5.4.3 Foot joints range of motion

The highest frequency for reduced range (passive) of motion (ROM - limited / rigid) was detected in assessment of the 1st MTP joints. Table 6.9 presents the frequencies ROM of foot joint assessments. The proportions of the AFC group with reduced ROM at the ankle joint and subtalar joints (either side) in the AFC group, was 45% (n=29) and 32% (n=21), respectively. The same numbers for the NAFC group were 22% (10) versus 13 (n=6). These were statistically significant differences (x^2 =5.83 df=1 p=0.02 and x^2=5.17 df=1 p=0.02, respectively). Of the AFC, group 13 (20%) had reduced ROM at the mid tarsal joint and 58 (89%) reduced ROM at either 1st MTP joint. The same numbers for the NAFC group were 4 (9%) and 37 (82%), respectively, which were not significant differences (x^2 = 2.51 df =1 p=0.11 and (x^2 = 1.13 df=1 p=0.29). The highest frequency for reduced PROM (limited / rigid) was detected in assessment of the 1st MTP joints. Overall, the frequencies for full PROM of all joints were higher in the NAFC group.

Table 6.9 Frequencies of ROM joint assessment

Joint ROM		**AFC (n=65) Frequency (%)**	**NAFC (n=45) Frequency (%)**
Ankle joint	Full ROM bilateral	36 (55)	35 (78)
	Reduced ROM unilateral	3 (5)	1 (2)
	Reduced ROM bilateral*	26 (40)	9 (20)
Subtalar joint	Full ROM bilateral	44 (68)	39 (87)
	Reduced ROM unilateral	5 (8)	1 (2)
	Reduced ROM bilateral	16 (25)	5 (11)
Midtarsal joint	Full ROM bilateral	52 (80)	41 (91)
	Reduced ROM unilateral	4 (6)	0 (0)
	Reduced ROM bilateral	9 (14)	4 (9)
1st MTP	Full ROM bilateral	7 (11)	8 (18)
	Reduced ROM unilateral*	8 (12)	1 (2)
	Reduced ROM bilateral	**50 (77)**	**36 (80)**

*Reduced ROM (limited / rigid)

6.5.4.4 Metatarsophalangeal joint squeeze test

Over half of the patients (n=63, 57%) were metatarsophalangeal (MTP) squeeze positive and 48 (44%) squeeze test positive bilaterally. Table 6.10 illustrates the frequencies of unilateral and bilateral MTP positive squeeze test frequencies. A significant difference was detected between the AFC group and the NAFC group in relation to frequencies of MTP squeeze test positive results (x^2= 6.02, df=2, p=0.05). This result indicates that the AFC group was more likely to have foot problems in relation to the MTP area.

Table 6.10 MTP squeeze test positive frequencies

	AFC (n=65) Frequency (%)	**NAFC (n=45) Frequency (%)**
MTP squeeze test positive unilateral	5 (8)	10 (22)
MTP squeeze test positive bilateral	33 (51)	15 (33)

6.5.4.5 Vascular assessment

The majority of patients had palpable pedal pulses bilaterally (Table 6.11) but 4 had no palpable pedal pulses (dorsalis pedis or posterior tibial). Of these, one patient had severe lower leg and foot odema. For the remainder (n=3), the independent podiatrist concluded that these patients’ vascular status did not require further investigation.

Table 6.11 Frequencies of bilateral palpable foot pulses

	AFC (n=65) Frequency (%)	NAFC (n=45) Frequency (%)
Dorsalis pedis non-palpable	4 (6)	4 (9)
Dorsalis pedis palpable	60 (92)	40 (89)
Posterior tibial non-palpable	9 (14)	2 (4)
Posterior tibial palpable	55 (85)	43 (96)

6.5.4.6 Neurological assessment

Reduced protective sensation was detected in the feet of 21 (19%) patients, of whom 14 had accessed foot care. Of the 5 patients with diabetes, one had reduced protective sensation. This patient had accessed foot care. Data regarding other clinical features of neurological symptoms were collected by self-report. The majority of patients reported one or more current neurological symptoms in their feet (n=99, 90%). Table 6.12 presents the number of current neurological symptoms. The report of one or more neurological symptoms was similar for the AFC and NAFC groups.

Table 6.12 Frequencies of neurological foot symptoms

Neurological foot symptoms	AFC (n=65) Frequency (%)	NAFC (n=45) Frequency (%)
No neurological symptoms	5 (8)	6 (13)
1 neurological symptom	8 (12)	6 (13)
2 neurological symptoms	15 (23)	10 (22)
3 neurological symptoms	10 (15)	9 (20)
4 neurological symptoms	11 (17)	10 (22)
≥5 neurological symptoms	16 (25)	4 (8)
Any neurological symptoms	**60 (92)**	**39 (88)**

A wide range of categories of neurological symptoms was reported by patients (Table 6.13). The frequencies of all neurological symptom descriptors were similar for both the AFC group and the NAFC group with the exception of sharp sensation and numbness (n=39, 60% versus n=19, 42%, n=31, 48% versus n=12, 27%, respectively). However, sharp sensation and dull ache can also be descriptions of somatic pain (activation of pain receptors in the skin or musculoskeletal tissues). These data indicate that neurological foot symptoms appear to be common in patients with RA.

Table 6.13 Categories of neurological foot symptoms

Neurological foot symptoms	AFC (n=65) number of patients in this category Frequency (%)	NAFC (n=45) number of patients in this category Frequency (%)
Sharp	39 (60)	19 (42)
Burning	38 (59)	20 (44)
Dull ache	44 (69)	30 (67)
Numbness	31 (48)	12 (27)
Tingling	32 (49)	21 (47)
Other	12 (19)	11 (24)
No neurological symptoms	5 (8)	6 (13)

6.5.4.7 Overview of clinical examination

The presence of inflammation in the feet was common as two thirds of the patients had swollen joints and approximately half were metatarsal squeeze test positive. Overall many patients had reduced range of motion (ROM) at one or more foot joint and the majority had reduced 1st MTP ROM (bilaterally), supporting previous reports that 1st MTP dysfunction is common in patients with RA. Almost all of the patients had an adequate peripheral vascular supply to the feet. A fifth of the patients were concluded to have reduced protective sensation (light touch). However, the majority reported to have one or more current neurological symptoms involving the feet.

6.5.5 Foot problems requiring intervention

Of the 110 patients, 45 (41%) were considered to require foot care. Of the AFC group nearly half were concluded to require foot care (n=30, 46%) compared to a third in the NAFC (n=15, 33%). The frequencies of foot care treatment categories required are shown in Table 6.14. There was a tendency for patients in the AFC group to require more complex care (> 1 treatment category). However, this was not significant (amalgamating 2 and 3 treatment categories required to achieve minimum cell count of 5 (x^2=2.22, df=2, p=0.33).

Table 6.14 Frequencies of treatment categories

Categories of foot problems requiring intervention	AFC (n=65) number of patients in this category Number (%)	NAFC (n=45) number of patients in this category Number (%)
No treatment required	35 (54)	30 (67)
1 treatment category	19 (29)	11 (24)
2 treatment categories	10 (15)	4 (9)
3 treatment categories	1 (2)	0 (0)

Table 6.15 presents the independent podiatrist's clinical conclusions for recommending assess to foot care. Interventions required were similar for both groups (corn /callus reduction x^2=1.49, df=1, p=0.22; treatment for toe nail pathologies x^2=0.117, df=1, p=0.74; tissue viability x^2=0.95, df=1, p=0.33;

biomechanical / insoles / orthotics/ x^2=0.95, df=1, p=0.33; and self-care x^2=0.7, df=1, p=0.4). Nonetheless, these results indicate that despite having accessed foot care two thirds of patients' foot health care needs continued particularly in relation to cutaneous lesions (e.g. callus and toe nail pathologies). Data were not collected in relation to if any of the AFC group intended to continue to access and/or if they had a foot care appointment pending. However, these data show that a third of the NAFC group would benefit from receiving foot care.

Table 6.15 Foot problems requiring intervention by group*

Foot problems requiring intervention	AFC (n=65) number of patients in this category (%)	NAFC (n=45) number of patients in this category (%)
Callus / corn reduction	11 (17)	7 (16)
Treatment for toe nail pathologies	23 (35)	11 (24)
Tissue viability	4 (6)	1 (2)
Biomechanical / insoles / orthotics	4 (6)	1 (2)
Self care	1 (2)	0 (0)
Total interventions required	43 (66)	20 (44)

*More than one intervention required

Of the 45 patients assessed as requiring foot care, 24 (53%) (11 AFC, 13 NAFC) were considered to require immediate intervention and were provided with an NHS podiatry self-referral form. The independent podiatrist arranged an urgent referral for one patient (NAFC) to the community podiatry service for care as they were classified as high risk (impaired tissue viability and neuropathy). These data further indicate that despite accessing foot care some patients' foot health care needs were not being addressed in the current system.

Additionally three patients with persistent articular foot problems (pain, stiffness and swelling) were advised by the independent podiatrist to contact the rheumatology specialist nurse via their telephone helpline for advice. Another two patients were recommended to arrange a consultation with their GP regarding peripheral micro vascular problems (chilblains / erythema pernio) for one and for assessment of an area of eczema on the dorsal aspect of one foot for the other.

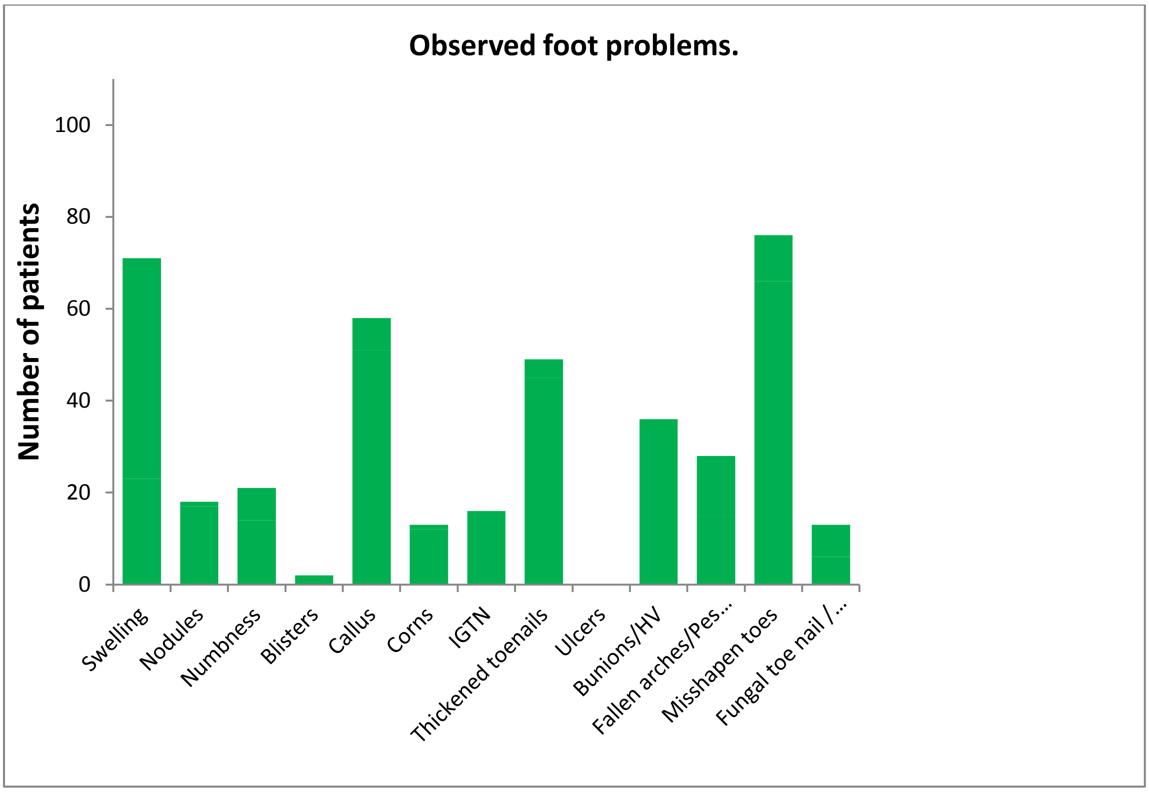
6.5.5.1 Overview of foot problems requiring intervention

One third of the NAFC group and nearly half of the AFC group were considered to require additional foot care. The most frequent interventions required (by both groups) were for reduction of corns and/or calluses and treatment of toe nail pathologies. However, there was a tendency for the AFC group to require more complex care. Half of those requiring additional care were felt to have immediate foot health care needs; therefore the research podiatrist provided a self-referral form to the local NHS podiatry service. A greater number of the NAFC group required immediate foot care compared with the AFC group (n=13, 29% versus n=11, 17%). Further, one of the NAFC group was assessed to be high risk (peripheral vascular disease and neurological symptoms) in terms of their foot health. Thus, despite having accessed foot care, many patients' foot health care needs continued

6.5.6 Validation of self-report foot problems with clinical examination observation

Validation of self-report was examined for the overall study sample and not according to AFC versus NAFC. Variables selected for analyses are presented in Box 6.6. The time differential between data collection by self-report and clinical examination was approximately 10 minutes. Figure 6.8 illustrates the frequencies (prevalence) of current foot problems observed on examination.

Figure 6.8 Frequency of current foot problems observed



The highest frequencies of foot problems observed were: misshapen toes (clawed / retracted) 76 (69%), swelling (one or more swollen joints) 71 (65%) and callus 58 (53%). The observed frequencies of hallux valgus; pes planus and nodules were 36 (33%), 28 (26%) and 18 (16%), respectively. Of the 78 patients who had nail problems, 13 had onycomycosis (fungal infection involving the nail plate). No patients had ulceration, bacterial infection or fungal, infection involving the skin. These data provide a description of: articular features (e.g. swelling), extra-articluar features (e.g. numbness), cutaneous lesions (e.g. callus) and structural deformity (e.g. hallux valgus) currently present in nested set of patients from a random sample of patients with RA in Bristol.

6.5.6.1 Comparisons of self-report and clinical observation of foot problems

Table 6.16 presents the level of agreement between self-report of current foot problems with clinical observation. Overall, excellent levels of agreement (kappa >0.81) were detected for the presence of: corns (kappa=0.91), in-grown toe nails (kappa=0.89) and bunions / hallux valgus (kappa=0.96). In relation to the presence of: nodules, calluses, and misshapen toes levels of agreement were substantial (kappa= 0.6-0.80). The kappa coefficients for agreement on the presence of:

blisters; thickened toe nails; and infection / onycomycosis were moderate (kappa=0.41-0.60). Levels of agreement between self-report and clinical observation for the presence of numbness and fallen arches / pes planus were fair (kappa=0.12-0.4) and less than chance agreement for swelling (kappa<0.01). No patient reported the presence of current foot ulceration and none were observed by the independent podiatrist. Levels of agreement between the self-report and clinical observation for the presence of foot pain and stiffness were not able to be calculated, as these clinical features resist accurate clinical assessment.

Table 6.16 Comparisons of current foot problems self-report and clinical observation

Foot problem category	Foot problems	Foot problems now self-report Frequency (%)	Foot problems observed Frequency (%)	Agreement self-report and observation Frequency (%)	Kappa (k level of agreement)
Articular features	Pain	44 (40.0)	[1]	[1]	†
	Stiffness	52 (47.3)	[1]	[1]	†
	Swelling	31 (28.2)	71 (64.5)	55 (49.1)	0.097**
Extra-articular features	Nodules (bumps)	25 (22.7)	18 (16.4)	101 (91.8)	0.724**
	Numbness	30 (27.3)	21 (19.1)	87 (79.1)	0.418**
Cutaneous lesions	Blisters	5 (4.5)	2 (1.8)	107 (97.3)	0.560**
	Callus	62 (56.4)	58 (52.7)	92 (83.6)	0.670**
	Corns	13 (11.8)	13 (11.8)	108 (98.2)	0.913**
	In-grown toe nails	17 (15.5)	16 (14.5)	107 (97.3)	0.893**
	Thickened Toe nails	63 (57.3)	49 (44.5)	88 (80.0)	0.606**
	Ulcers	0 (0)	0 (0)	110 (100)	†
Structural deformity	Bunions / hallux valgus	38 (34.5)	36 (32.7)	108 (98.2)	0.959**
	Fallen arches	28 (25.5)	28 (25.5)	84 (76.4)	0.377**
	Misshaped toes	72 (65.5)	76 (69.1)	94 (85.5)	0.670**
Other	Infection / onycomycosis	8 (7.3)	13 (11.8)	101 (91.8)	0.529**

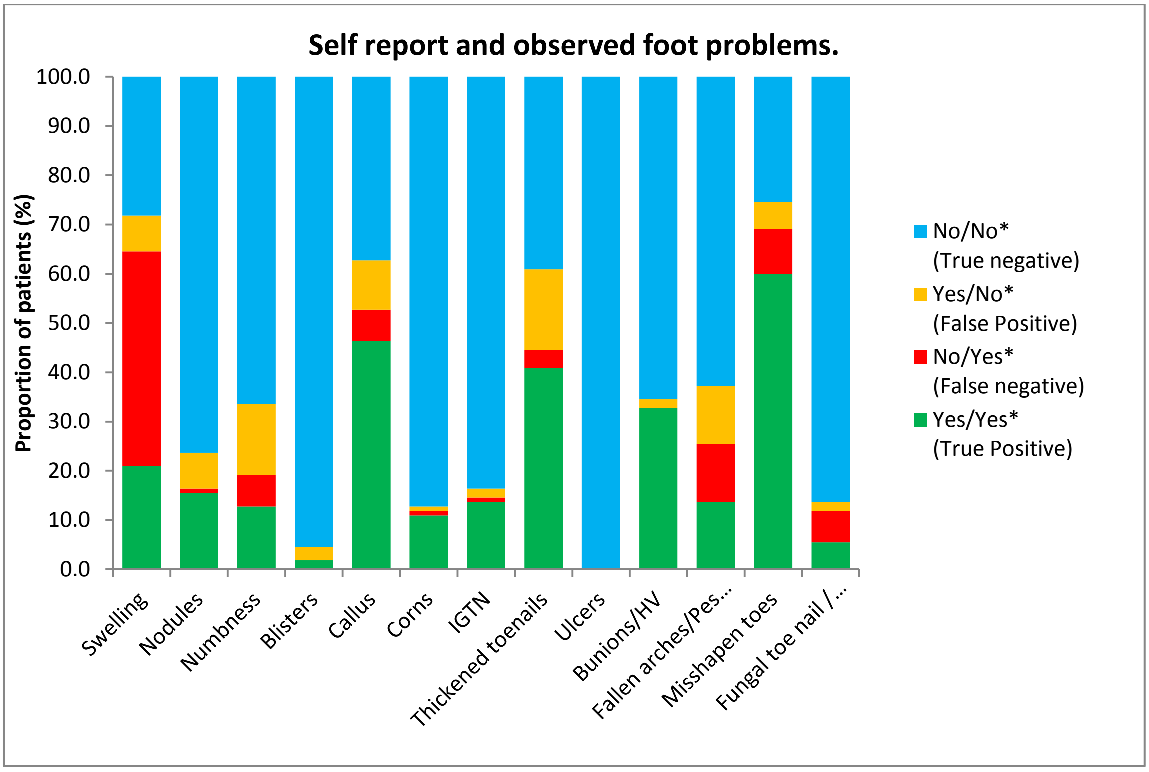
[1] Unable to quantify through clinical examination / observation
† Unable to calculate k
**p<0.005

The kappa value is a statistical measure of levels of agreement and does not take into account the clinical importance of false negative reporting (e.g. failure of patients to report bacterial infections). Further, the kappa value is also influenced by prevalence (proportion of sample with outcome of interest) therefore it is possible that the statistical validity of self-report in relation to clinical significance of rare events may therefore be misleading. Levels of agreement between self-report and clinical observations of the presence of foot problems in terms of false negative results (failure of patients to report a foot problem when foot problem observed) are therefore required.

6.5.6.2 Comparisons of false negative self-report with clinical observation.

Comparisons of current foot problems by self-report and clinical observation are illustrated in Figure 6.9 in terms of proportions in level of agreement. The frequency of false negatives was 0% for the presence of hallux valgus and blisters. Further, the frequency of false negatives for level of agreement of: nodules; callus; corns; ingrown-toe nails, thickened toe nails and misshapen toes were < 14%.These results show that if patients report any of these foot problems, their report is likely to be correct due to few false negatives.

Figure 6.9 Comparisons of current foot problems self-report and observation



*Self-report/observation

Of the patients, 13 were observed to have onycomycosis involving one or more toe nails. Of these, 7 (54%) failed to self-report the presence of fungal infections involving toe nails. Thus the presence of onycomycosis by self-reports is not reliable. Variation in levels of agreement was most notable for swelling. Of the 71 (65%) of patients observed (clinical examination) to have joint swelling (one or more swollen foot joint), 48 (68%) failed to self-report the presence of swelling. Of the 21 (19%) patients classified as having reduced sensation, the proportion of false negatives was 33% (n=7). This result indicates that some patients were unaware of reduced sensation in their feet; therefore the self-report of numbness is not reliable. Of the 28 patients observed to have pes planus, 13 (46%) failed to self-report having fallen arches.

6.5.6.3 Overview comparisons of foot problems self-report and observation

Given these results, the self-report of: nodules; callus, corns, ingrown-toe nails, thickened toe nails, hallux valgus and misshapen toes appears to be reliable. This suggests self-report can be utilised with a high degree of confidence. Although levels of agreement were moderate for the presence of infection, half of the patients who had onycomycosis did not report the presence of infection. It is possible that these patients did not perceive or recognise fungal nail dystrophy as an infection. However, levels of agreement for more complex foot problems (e.g. pes planus) were only fair and patients substantially under-reported features of disease activity (e.g. joint swelling). Additionally, disparity was detected between self-report and positive clinical findings of numbness (reduced protective sensation / light touch). The wording of the questions in relation to presence of fallen arches, numbness and swelling may have been ambiguous to some patients and questions relating to the self-report of these foot problems may need refinement. Overall these data indicate that self-report of many foot problems in RA is reliable. Therefore these data are considered to be a legitimate description of the nature and prevalence of current foot problems in a selected sample of patients with RA. However, for more complex foot problems (e.g. pes planus), and for important clinical observations such as joint swelling, numbness and fungal infections, false negatives may mislead and direct assessment of the feet is required.

6.5.7 Accessed foot care services (Section B)

Of the 65 patients who reported they had accessed foot care, 33 (51%) had accessed two or more services (Table 6.17).

Table 6.17 Number of different foot care services accessed

Foot care services accessed	AFC =65 Frequency (%)
1 Foot care service	32 (49)
2 Foot care services	19 (30)
≥ 3 Foot care services	14 (22)

6.5.7.1 Access to separate foot care services

Of the AFC group (n=65): 26 (40%) had accessed NHS podiatry, 27 (42%) independent podiatry, 44 (68%) orthotics and 17 (26%) orthopaedics. A small number of the AFC group had accessed all foot care services (n=2, 3%). Of the 26 patients who had accessed podiatry, 7 (27%) had accessed both NHS and independent podiatry services. Data were not collected on the number of occasions each participant accessed the different foot care services

Table 6.18 presents the frequency of foot care services accessed by category of referral route. A range of referral routes to NHS podiatry was detected with a third of patients accessing the service by self-referral (n=8, 31%). Of the 27 patients, who accessed independent podiatry, almost all (n=25, 93%) had done so through self-referral. However, a small number of patients reported that accessing independent podiatry was influenced by GP recommendation (n=2, 7%). Of the 44 who had accessed orthotics, 42 (96%) had been referred by hospital based clinicians. In contrast of the 17 who had accessed orthopaedics, 11 (65%) reported they were referred by their GP. These data indicate that hospital based clinicians are more likely to refer patients to orthotics (hospital based) than podiatry (primary care based). This implies hospital clinicians consider devices (insoles / foot orthoses and/or prescribed footwear) as key foot care interventions. However, one third of patients (34%) required immediate intervention for cutaenous lesions (calluses / corns and/or nail pathologies) and only the minority (5%) required review for foot devices.

Table 6.18 Foot care services accessed and referral route categories overall

Referral route	NHS Podiatry (n=26) Frequency (%)	Independent podiatry (n=27) Frequency (%)	Orthotics (n=44) Frequency (%)	Orthopaedics (n=17) Frequency (%)
Self	8 (31)	25 (93)	0 (0)	0 (0)
GP	12 (46)	2 (7)	0 (0)	11 (65)
Hospital	5 (19)	0 (0)	42 (96)	5 (29)
Physiotherapist	2 (8)	0 (0)	1 (2)	0 (0)
Other	1 (4)	0 (0)	1 (2)	1 (6)

***** 2 patients accessed NHS podiatry by more than one referral route

6.5.7.2 Comparisons of patient characteristics according to foot care services accessed

Table 6.19 presents the patient characteristics (gender, age, social deprivation, hospital site, disease duration and disability) in relation to each foot care service accessed. Overall the characteristics of patients who had accessed each service were broadly similar.

Table 6.19 Comparisons of patients' characteristics in relation to foot care services accessed

Variable	Podiatry NHS (n=26) Frequency (%)	Independent podiatry (n=27) Frequency (%)	Orthotics (n=44) Frequency (%)	Orthopaedics (n=17) Frequency (%)
Female	19 (73)	20 (74)	34 (77)	12 (71)
Mean age (years) (SD)	66 (12.9)	68.1 (11.2)	63 (11.9)	66.6 (10.5)
Local social deprivation categories 4 and 5	3 (12)	5 (19)	5 (11)	5 (29)
UHB (%)	17 (65)	18 (67)	24 (55)	11 (65)
Median Disease duration years (range)	10.5 (min 1, max 51)	8 (min 1, max 51)	8.5 (min, max 51)	10 (min 6, max 30)
Median HAQ (range)	1.625 (min 0, max 2.500)	1.250 (min 0, max 2.250)	1.500 (min 0, max 2.250)	1.500 (min 0, max 2.750)

6.5.7.3 Overview of access to foot care services

Of the 65 patients who had accessed foot care services, half had accessed more than one service. The most frequently accessed service was orthotics. The number of patients who had accessed all four foot care services was small but a third of patients who had accessed NHS podiatry reported they had also accessed independent sector podiatry.

A range of referral routes were reported by patients who accessed NHS podiatry. In contrast, almost all patients who accessed orthotics had been referred by hospital based clinicians. Conversely, access to orthopaedics was reported to be generated by similar proportions of GP and hospital based clinicians. These results reflect local access criteria to NHS provided foot care services. However, there was a tendency for hospital based clinicians to be more likely to refer patients to hospital based foot care services (e.g. orthotics) rather than NHS primary care services (e.g. podiatry).

The mean patient age and median disease duration were similar for all services accessed. There was a tendency for a higher proportion of UHB patients to access NHS podiatry, independent podiatry and orthopaedics. However, data were not collected in relation to the time at which foot care services were accessed. Thus comparisons of patient characteristics at point of access are unknown. Patient characteristics as determinants of access to foot care therefore need to be considered with caution.

6.5.8 Description of reasons for accessing or not accessing foot care, and care received (Section B)

Patients' reasons for accessing and not accessing foot care and their description of care received were recorded verbatim as textual data by the observer. These responses to open ended questions produced "quasi-qualitative data" which were subsequently analysed by content analysis.

6.5.8.1 Reasons for accessing foot care

A wide range of reasons was given for accessing NHS podiatry and independent sector podiatry (Table 6.20). However, a small number of patients were unsure why they had been referred (n=2, 8%). Of the independent podiatry group (n=27), over half reported reasons related to treatment for corns and or / calluses and inability to self-care (e.g. cut toe nails) (n=17, 63%). Additionally, 6 (22%) patients reported their reason for accessing private care had been influenced by: convenience; continuity of care provided by the same clinician; and dissatisfaction of care provided by the NHS podiatric service (e.g. refusal to cut toe nails).

> *"NHS wouldn't cut my toe nails. Age concern would because I've got RA."*
> ID4239F72

Table 6.20 Reasons for access to NHS and independent podiatry

Reason for access	**Podiatry NHS (n=26) Frequency (%)**	**Podiatry independent (n=27) Frequency (%)**
Biomechanical assessment	2 (8)	0 (0)
Corn / callus	2 (8)	11 (41)
Unable to cut toe nails	7 (27)	6 (22)
Ingrown toe nails	6 (23)	1 (4)
Infection	1 (4)	0 (0)
Pain	4 (15)	2 (7)
Referred by clinician	3 (12)	2 (7)
Ulceration	1 (4)	0 (0)
Convenience / continuity of care / negative experience of NHS	0 (0)	6 (22)

*More than one reason provided

Data were not collected on the reasons for accessing orthotics and orthopaedics as local access to these foot care services are restricted to clinician-generated referrals only. It was therefore considered that accessing orthotics and orthopaedics would have occurred if further assessment for care (intervention) was required as a result of clinical consultations rather than patients perceiving the need for intervention.

6.5.8.2 Reasons for not accessing foot care

Patients who had not accessed NHS podiatry, independent podiatry and/or orthotics were asked their reasons for not accessing each service (Table 6.21). Of the 84 who had not accessed NHS podiatry care, 58 (69%) perceived access to NHS podiatry to be unnecessary (e.g. feet not a problem). However, for 25 (30%) access to NHS podiatry was hindered by their perceptions (e.g. lack of knowledge how to access NHS podiatry). Two (2%) were currently considering accessing NHS podiatry as they were unable to self-care (cut toe nails).

Table 6.21 Reasons for not accessing NHS podiatry care (n=84, 76%)*

Reason category	Reason	Frequency (%)	Qualitative data
Access perceived unnecessary by patients	Feet not a problem	50 (60)	*"Don't feel I need to [see a podiatrist.]"* ID3827F67
	Foot care supported by family	2 (2)	*"My son always does them [referring to foot care] and the feet are the best bit of my body."* ID3012M76
	Accessed independent care	6 (7)	"*Have always had private [podiatry] care."* ID158F76
Access hindered by patients' perception	Lack of knowledge how to access NHS podiatry care	11 (13)	*"Didn't know you could get it [podiatry] on the NHS unless you had bad problems, like diabetes."* ID23039F81
	Feet ignored by patients and clinicians	3 (4)	"*No one in rheumatology suggested it. Surgical podiatrist is referring me to NHS podiatry so I don't have to pay."* ID23919F65
	MDT will refer if needed	10 (12)	*Always come to the doctor about my foot pain. He's never suggested I go anywhere."* ID21558M63
	Unwilling to ask for additional care	1 (1)	*"I'm ashamed to ask [for podiatry] I think I'm enough of a burden to them [referring to NHS]."* ID23566F72
Appointment pending	Been referred	1 (1)	*"They [hospital clinician] have referred me to a podiatrist - not been seen yet."* ID5070F38
Considering access	Thinking about it	2 (2)	*Thinking about it [accessing NHS podiatry]. Can't manage toe nails because of hands."* ID4674F69

*More than one reason provided

Of the 83 patients who had not accessed independent podiatry, the majority (n=77, 93%) felt it to be unnecessary (Table 6.22), 10 (13%) because they were under the care of the NHS podiatry service. A small number (7) indicated limited personal financial resources as barriers to access independent podiatry care.

Table 6.22 Reasons for not accessing independent podiatry (n=83, 76%)*

Reason category	Reason	Frequency (%)	Qualitative data
Access perceived unnecessary by patients	No need	64 (77)	*“Never had a problem for a podiatrist to deal with.”* ID1427F66
	Foot care supported by family	3 (4)	*“Don't need to my husband or granddaughter cut my toe nails.”* ID22177F58
	Accessed NHS care	10 (12)	“*See NHS podiatrist so no need to.”* ID2048F58
Access hindered by patients’ perception	Limited awareness of treatment options	1 (1)	“*When I had foot problems just thought it was the RA and nothing could be done.”* ID22356M64
	Limited knowledge of access	1 (1)	“*Lack of time and a job to get to see one [independent podiatrist].”* ID2767F52
	MDT will refer if needed	2 (2)	“*No one [referring to MDT] recommended I saw one [independent podiatrist].”* ID3012F59
	Previous negative experiences	2 (2)	*Tried a few years ago but it was very expensive [independent podiatry] and didn’t help [referring to foot pain].”* ID3266F72
Financial cost	Can’t afford it	7 (8)	“*Would like to get them [feet] tidied up but can't afford to go privately.”* ID677F57
Considering access	Thinking about it	1 (1)	*“Feet are alright at the moment, would go [independent podiatry] if nails were bad.”* ID2112F69

*More than one reason provided

Table 6.23 presents the reasons given by 66 patients who had not accessed orthotics. One third felt access to the service to be unnecessary as their feet were not a problem and they were able to self-source footwear and/or insoles. The majority gave reasons for not accessing care which were related to limited knowledge of orthotic treatment options, and clinicians not referring patients for care. The aesthetics of prescribed footwear was mentioned by one patient as a barrier to accessing orthotics.

> *“Don't want to wear those shoes,”* ID20648F74

Table 6.23 Reasons for not accessing orthotics (n=66, 60%)*

Reason category	Reason	Frequency (%)	Qualitative data
Access perceived unnecessary by patients	Feet not a problem	11 (17)	*"Don't need to see them [orthotics]"* ID3620F70
	Can get shoes	8 (12)	*"Been able to manage with shoes"* ID350F74
	Self-sourced insoles	3 (5)	*"I buy my own gel insoles which work really well"* ID1427F66
Access hindered by patients' perception	Limited awareness of treatment options	5 (8)	*"Don't know who they are or what they do [referring to othtotics"* ID3827F67
	Feet ignored by patients and clinicians	33 (50)	*"They said I wouldn't like the shoes, so I didn't peruse it"* ID4239M72
Appointment pending	Been referred	1 (2)	*"Been referred but not had appointment yet"* ID1512F40
Podiatry review	See podiatrist first	1 (2)	*"They [rheumatology clinicians] want me to see the podiatrist first"* ID5070F38

*More than one reason disclosed

6.5.8.3 Foot care received

Of those patients who had accessed NHS podiatry (n=26), the majority (n=20, 77%) had received treatment for cutaneous lesions (toe nail care and reduction of corns or calluses) (Table 6.24). No patient reported having received any foot orthoses or insoles from the podiatry service. Of the two patients (8%) who were referred to another health professional, both had been reviewed in a multidisciplinary rheumatology foot clinic, which includes a podiatrist. Both had been referred to orthotics for foot orthoses and one to NHS community podiatry for treatment for toe nail problems; both reported to have appointments which were pending.

Table 6.24 categories of care received from NHS and independent podiatry

Foot care received	NHS podiatry (n=26) Frequency (%)*	Independent podiatry (n=27) Frequency (%)
Assessment only	6 (23)	1 (4)
Biomechanical assessment	6 (23)	4 (15)
Cutanous lesions	20 (77)	22 (81)
Referred to another health professional	2 (8)	0 (0)
Tissue viability	2 (8)	0 (0)

* 6 (23.1%) patients accessed NHS podiatry reported to have received more than one foot care category

Of those patients accessing independent podiatry (n=27), 22 (81%) reported having received treatment for cutaneous lesions (toe nail care and/or reduction of corns and/or calluses). The number of the independent podiatry group issued with foot devices (insoles or foot orthoses) was small (n=2, 7%).

Of those patients in the orthotics group (n=44), the majority (n=42, 96%) had been issued with insoles (non-contoured devices) or moulded foot orthoses (contoured devices to foot). Of these, only 15 (36%) were currently using the devices. A variety of reasons were given for not using the foot devices, ranging from difficulty accommodating the devices in footwear to resolution of foot problems (Table 6.25). Of the 11 patients issued with prescribed footwear, only 3 patients continued to wear their prescribed footwear and only one patient wore the prescribed footwear to the research appointment (see Table 6.7). Reasons for not using prescribed footwear included negative perceptions of appearance and poor fit.

Table 6.25 Reasons for not using devices issued (n=27, 64%)*

Orthotic device category	**Reason**	**Frequency (%)**	**Qualitative data**
Insoles/ foot orthoses (n=27)	Difficulty accommodating devices in footwear	14 (60)	*"Couldn't wear shoes that would accommodate insoles"* ID221F39
	Not comfortable	2 (7)	*"They [insoles] were not very comfortable"* ID1164F60
	Not effective	6 (22)	"*I used to wear them [insoles] all the time but they don't make much difference now."* ID22982F45
	Devices for prescribed footwear, not wearing prescribed footwear	2 (7)	"*They[insoles] were for prescribed shoes - not wearing prescribed shoes*." ID22982F45
	Did not receive devices supplied	2 (7)	*"They [orthotist] made me a temporary insole but not followed up. Was in so much pain I didn't follow it up."* 21026F64
	Foot problems resolved	1 (4)	"*My feet are much better, so don't need them [insoles]."* ID4550F69
Prescribed footwear (n=8)	Negative perceptions of appearance	6 (75)	*"They [prescribed footwear] look so big, didn't like the look of them."* ID3767F79
	Poor fit	2 (25)	*"Too big, couldn't wear them [prescribed shoes] and couldn't be bothered to go back and argue about shoes."* ID2767F32

*More than one reason disclosed

A total of 17 patients had been referred to orthopaedics for assessment of their foot problems. Of these, 6 did not have any surgical intervention. Of the 11 patients who did undergo foot surgery, the majority had surgery involving the forefoot (n=10). A variety of forefoot surgery was described: correction of toe deformities (n=4); hallux valgus surgery (n=3); surgery involving MTP joints (n=3). Surgery of the ankle joint was reported by one patient.

6.5.8.4 Patients' experiences of foot care received

Of those patients in the NHS podiatry (n=26), the majority reported benefits (n=19, 73%).

> *“Very helpful [referring to NHS podiatry care], once you get past the receptionist”* ID2048F58

Podiatric care not improving foot problems was reported by a few patients (n=2) who felt they had received care by clinicians with limited experience and had difficulty with timely access to care when their feet were symptomatic.

> *“Nice [referring to podiatrists] but inexperienced and always someone different. Couldn’t get the appointments when I needed them.”* ID23064F54

Two patients who had been discharged from the service to self-care reported that they were unable to self-care due to reduced function and disability. A minority of the NHS podiatry group been assessed and no treatment provided (n=2) and one found the treatment received painful.

> *“It helped [podiatric care] but they said I couldn’t come again because I can manage [foot care] but I can’t.”* ID23713.1F51

The majority of independent podiatry group (n=27) reported that the care they received was beneficial (n=24). However, some patients (n=3) reported that their foot problems persisted despite and questioned the financial value of the care received.

> *“Cost £220 [independent foot care] and it didn’t work. Would not recommend it.”* ID 21737F69

Data were not collected on patients’ experience and benefits of interventions provided by orthotics services. However, while almost the entire orthotics group had been issued with insoles or foot orthoses, only a third continued to use the devices issued. Further, of the patients issued with prescribed footwear only a quarter currently wore the footwear provided. These results suggest foot orthoses (insoles) were often not beneficial and positive experiences from the patient perspective were the lowest of any of the foot care services.

Of the 11 patients who had undergone foot surgery, 6 reported that they found surgical intervention beneficial.

> “*They look much better [feet] and they feel much better. Glad I had it [hallux valgus surgery] done.”* 23831F61

In contrast, negative experiences and lack of improvement in symptoms after surgical intervention reported by 5 patients and as a consequence 2 patients were reluctant to consider further orthopaedic intervention.

> *“It was a wonderful place [referring to hospital site] but don't think I would do it again [surgery]. It's not benefited me much. My toes are now numb and I can walk much less since the surgery”* 20690F77

6.5.8.5 Additional comments

All patients were asked if they would like to make any additional comments relating to their feet and 74 (68%) did so (Table 6.26). The most frequent additional comments category was foot symptoms with some patients describing their foot symptoms fluctuating. Further foot symptoms were important issues particularly in relation to ability to work. The use of self-care and self-management strategies (e.g. hot / cold therapies) was reported by a small number of patients (n=8). Despite foot problems being important issues for some patients, a range of barriers to accessing foot care were reported (n=11), including they felt their feet had been ignored in clinical consultations. Further, a small number considered that their foot problems were very important and planned to discuss their foot health care needs with clinicians (n=5). Foot problems not being an issue or of low priority was expressed by a small number (n=7).

Table 6.26 Additional comments

Do you have anything else you want to tell me about your feet? Frequency (n=74: 67%) *			
Comment category	**Comment label**	**Frequency (%)**	**Qualitative data**
Foot symptoms	Feet first	10 (14)	*"In the beginning feet very painful but not anymore."* ID23617F52
	Pain	7 (9)	*"Feet just hurt don't want to put them on the ground. It's like your feet have been beaten with metal rods."* ID22589M61
	Swelling / stiffness	3 (4)	*"Feet swell at the end of the day. Have a bath in the morning to ease the stiffness in the feet and at end of day to ease the swelling."* ID218181F51
	Cutaneous lesions	7 (9)	*"Callus has been there for years - think it's to do with standing for long periods on hard floors at work"* ID23304M47
	Deformity	3 (4)	*"Feet are quite deformed and recurring ulcer L 4th toe"* ID2048F58
	Fluctuations	18 (24)	*"Today is a good day some days they [feet] are so bad I can't walk"* ID21575M46
	Feet and flare	1 (1)	*"Feels like I'm walking on pebbles. They [feet] are problem if I have a flare."* ID23977M54
	Feet a priority	3 (4)	*"My hands and feet are my biggest problem."* ID4550F69
Impact of foot symptoms	Ability to work	3 (4)	*"I'm an HGV driver can't do more than an hour [driving] because of my legs and feet."* ID10012M64
	Footwear	7 (9)	*"Problems with footwear had to wear slippers to work."* ID21866F53
	Activities	4 (5)	*"The feet are not as bad as my hands and shoulders but I really suffer if I do anything in the form of activity and they [feet] make me slow."* ID23963M56
Self-care and self-management	Hot / cold therapies	2 (3)	*"Used to the pain in my feet. It's usually bad in the morning I put ice packs on them [feet] every day"* ID3266F72
	Pacing and planning	1 (1)	*"Have to try and pace myself to avoid having pain. If I stand for too long or do too much on my feet that's when they get very painful."* ID23064F54
	Self-source insoles pads	4 (5)	*"I buy pads from the catalogue. I buy things that will make my feet more comfortable even tried tubegrip"* ID3021F59
	Weight loss	1 (1)	*"Lost a bit of weight which has helped swelling in the ankles."* ID23831F61
Foot problems a priority	Will discuss feet	5 (7)	*"Getting shoes is difficult thinking about getting some made privately. Will talk to consultant to see if I can get shoes through NHS."* ID23989M71
Access to foot care hindered by patients perception	Do not want hospital shoes	1 (1)	*"Have been offered prescribed footwear twice. It's difficult to get shoes but not keen to have prescribed shoes. Surgical podiatrist said they wouldn't help."* ID23919F65
	Limited knowledge of foot care	1 (1)	*"If only I had known orthotics could provided safety boots then I would not have had surgery done."* ID2887M75
	Feet ignored by clinicians and patients	5 (7)	*"They [rheumatologists] don't check our feet so it's difficult to know what help available and when to ask for it."* ID2149F55
	Concerned about intervention	2 (3)	*"I need the bunion done at some point but I've heard the op is very painful."* ID2339M62
	Negative experiences	2 (3)	*"It was like walking on pebbles which is when I saw the orthotist but didn't get on with insoles."* ID1852F73

Table 6.26 continued

Comment category	Comment label	Frequency (%)	Qualitative data
Access to foot care perceived unnecessary by patients	Feet not a problem	7 (9)	*"I don't have any problems with my feet my hands are the worst."* ID1148M64
Foot surgery	Been referred	3 (4)	*"Waiting to see surgeon about feet."* ID1148M64
	Surgery not related to RA	2 (3)	*"Had bunion surgery before RA."* ID350F74
	Positive experience	3 (4)	*"It's mostly in my hands and feet and wanted to take part [in the study] as foot surgery has helped so much and wanted to let you know."* ID1559F40
	Surgery not performed	3 (4)	*"Assessed for bunion surgery but couldn't be done due to poor circulation"* ID165F72

6.5.8.6 Overview of access to foot care services and care received

A wide range of reasons for accessing NHS podiatry was provided; the majority were for current foot symptoms requiring further assessment and treatment. In contrast the most frequently reported reasons for accessing independent podiatry was for reduction of corns, calluses and toe nails. Further, some patients reported they had accessed independent care for convenience (flexibility of appointments) and/or they had had previous negative experiences of NHS care.

The majority of patients who had not accessed podiatry care (NHS or independent) did not consider their foot problems required podiatric intervention. A small number of patients who were unable to self-care and self-manage (foot problems) reported their foot health needs were met by family members; therefore access to care was not required. In contrast the most frequent category for not accessing orthotics was due to access hindered by patients' perceptions. These reasons ranged from negative perceptions of prescribed footwear, limited knowledge of service and treatment options and feet being ignored in clinical practice.

Overall, the majority of patients who had accessed NHS and independent podiatry care found the treatment they received to be beneficial. The majority of patients who had accessed NHS podiatric care reported they had received care for cutaneous lesions. None had been issued with insoles or foot orthoses. A similar frequency of care received was described by the independent podiatry group, although a small number had received insoles or foot orthoses as part of their care. Only half of the patients who had undergone foot surgery considered their foot problems had improved. Almost all of the patients who had accessed orthotics had been issued with insoles or foot orthoses. However, only a third continued to use the devices. Further, of the patients who had been issued with prescribed footwear (hospital issued shoes) the majority had discontinued to wear the footwear provided. The number of patients choosing to discontinue using the devices or footwear issued suggests relatively less benefit and /or more disaffection from orthotics.

Analysis of open response questions and free text data support the findings from Study 1 (one to one interviews) and Study 2 (postal survey); that foot problems are common in patients with RA and impact on many aspects of their lives. Further, access to foot care is variable and despite accessing care many patients' reported current foot problems.

6.6 Discussion

The participants for this study were selected from a sample of patients (responders to Study 2). Responders to Study 2, source sample for study 3 were representative of the local population of patients with RA. Approximately equal numbers of those who had accessed foot care (AFC) and had not accessed foot care (NAFC) were included, and the two groups had similar disease durations. The issue of disease duration was considered important for several reasons. The pharmacological management of RA has evolved in recent years with the introduction of new treatment paradigms (e.g. biologics therapies) and now aims to achieve the lowest disease activity and ideally remission of the disease process as early as possible (e.g. Smolen *et al,* 2010). It is possible that patients who were diagnosed before the introduction of modern treatment paradigms (i.e. those with longer disease duration) would be more likely to develop disease features in the feet compared with patients with shorter disease duration. It was therefore postulated that, not only due to the cumulative effects of the disease, but also because of these changes in management, patients with longer disease duration would be at increased risk of developing foot problems. Analyses were not performed to investigate the association of disease duration and presence of foot problems. Overall, the proportions of patients observed to have one or more: extra-articular features, cutaneous lesions and structural deformity were similar for both the AFC group and the NAFC group.

Of the 235 patients invited to participate in the study, 110 attended - an overall participation rate of 47%. There were no systematic differences between those patients who were invited and those who attended in relation to the general characteristics (hospital sites, age, gender and local deprivation) and RA characteristics (disease duration, mean age diagnosed with RA and current disability). This suggests the findings can be related to the whole sample of those who were invited, and in turn may represent a true sample of the overall RA patient population.

As with the survey results (Study 2), almost all reported taking one or more arthritis medications and nearly two thirds reported additional morbidity. Additionally, as with Study 2 results, no important differences were detected between the AFC and NAFC groups in relation to hospital sites, age, gender or local deprivation. Furthermore the clinical characteristics (arthritis medications and general disability) of both groups were broadly similar. The findings of this study will therefore be discussed in general for the study sample. The exceptions will be in discussing: patients' reasons for accessing or not accessing foot care, description of care received and patients' perceptions of the benefits of foot care received.

In comparisons with earlier (probably non-representative) studies reporting foot problems in patients with RA, there were differences in general characteristics (e.g. age and gender) and clinical characteristics (e.g. disease duration and arthritis medications) of the patients. For example, the mean age of Study 3 participants was higher than earlier reports whereas the proportion of women was lower (Rojas-Villaraga *et al*, 2009; Bowen *et al*, 2010; Baan *et al*, 2011). However, disease duration and classification and categorisation of arthritis medications reported by the study patients were broadly similar to earlier studies (Rojas-Villaraga *et al,* 2009; Rome *et al*, 2009; Borman *et al*, 2012). Variation in general and clinical characteristics of participants recruited from heterogeneous samples is not unexpected.

All patients reported one or more current foot problems, the majority reported presence of cutaneous lesions (e.g. calluses) and/or structural deformity (e.g. bunions). The report of articular features (e.g. foot pain) and extra-articular features (e.g. nodules) involving the feet was less frequent. There is a dearth of observational studies checking data in relation to the accuracy of the self-report of foot problems in patients with RA and data reported in earlier (probably non-representative) studies on the frequency of foot problems by clinical assessment (direct clinical examination, clinical observation and/or using imaging techniques) did not include patient self-report. This was probably because self-report was not required for the purpose of the study. Rojas-Villarraga *et al* (2009) investigated the impact of foot problems on quality of life, disease activity and general disability using validated measures (e.g. HAQ). The authors report pain on forefoot movement was strongly associated with disease activity and general disability. As the self-report of foot problems has not been validated or developed as a PROM, it would seem appropriate for the report not to consider self-report as an approach for data collection. Further, if the self-report of a clinical feature does not address the fundamental aims of a study, the omission of this approach to data collection would seem reasonable. Borman *et al* (2012) did collect and present data from patient completed questionnaires and clinical assessment. However, the questionnaire used by Borman *et al* captured self-report but on a limited number of foot problem categories (e.g. pain, stiffness and numbness). In the present study we used Study 1 and Study 2 and contributions from our PRPs to ensure we covered a full range of self-report foot problem categories.

A majority of patients (74%) was observed to have one or more cutaneous lesions (calluses, corns and/or toe nail pathologies) and a similar proportion (82%) was observed to have one or more structural foot deformity (hallux valgus, toe deformities, pes planus, subluxed MTPs and/or 5th MTP exostosis). None of the patients had current foot ulceration but 8% reported a previous episode of foot ulceration at some time since being diagnosed with RA. The prevalence of foot ulceration in RA has been reported to be 9.7% (Firth *et al,* 2008) but the sample of patients in the present study, while providing evidence that foot ulceration can be a clinical feature of RA, suggests it is not very wide spread at any particular point in time. The proportions of patients with calluses, hallux valgus and lesser toe deformities were 53%, 33%, and 49% respectively. Rome *et al* (2009) report the findings of a clinical audit of 100 patients with RA. Of the audit participants, 63% were observed to have calluses, 64% hallux valgus and 86% lesser toe deformities. Similar data are reported by Rojas-Villarraga *et al* (2009) for calluses and hallux valgus. It is likely that the sampling strategy (“convenience” sampling) adopted by these authors accounts for the higher proportion of foot abnormalities reported.

A range of neurological symptoms was reported by patients and a fifth had reduced protective sensation on examination. Peripheral sensory impairment can lead to painless trauma which can lead to serious clinical outcomes for some patients such as development of ulceration and potentially lower limb amputations. Reduced sensation may not be recognised by patients and self-report for this was unreliable.

Screening for sensory deficit is widely implemented in podiatric practice in the UK. Mild sensory impairment has been described as a clinical feature in patients with RA (Wilson and Kirwan, 2006). The proportion of patients with reduced sensation in Study 3 was lower than a previous study conducted by Wilson and Kirwan (2006), but this earlier study was hospital-based, utilised a "convenience" sampling strategy and was conducted prior to the introduction of new arthritis medications (e.g. biologic therapies).

Only half of the patients were wearing good footwear, which was self-sourced commercial/retail footwear. Patients with RA wearing inadequate (poor) footwear has been observed in earlier works (Williams and Bowden, 2004; Rome *et al,* 2009). Adequate footwear is an important factor in optimal foot health particularly for patients with diabetes (Boulton and Jude, 2004; Cavanagh, 2004; Maciejewski *et al*, 2004). The evidence to support the benefits of footwear for patients with RA has predominately focused on prescribed footwear (hospital issued) with the exception of a small study conducted by Hennessy, Burns and Penkala (2007). A link between wearing poor footwear and direct negative consequences for patients with RA seems sensible but has not been unequivocally established (Riskowski, Dufour and Hannan, 2011b). This study indicates that many patients' current footwear was poor but neither the reasons why patients chose to wear inadequate (poor) footwear nor any association of footwear with foot problems were investigated in this study. These issues could be investigated in future work.

A wide range of pathological changes due to RA were assessed in this study. A general assessment of patients' musculoskeletal system was performed using the GALS screen (Doherty *et al,* 1992). Almost all patients had one or more GALS screen abnormality, as would be expected in a sample of patients with RA. The GALS screen has been proposed to be a valid tool for identifying patients with symptoms of RA and recommended as a clinical screening tool in primary care (Plant *et al,* 1993). Three quarters of patients had one or more tender joints in their feet, two thirds had one or more swollen joints and over half were MTP squeeze test positive. The clinical significance of a positive MTP squeeze as an indication of disease activity is not clear cut (Scott, 2002; Wiesinger *et al*, 2013) but nevertheless these data indicate that many patients had clinical indications of inflammation in their feet at the time of the clinical assessment.

The classification and categorisation of foot problems in previous observational studies has tended to concentrate on structural deformity (e.g. toe deformities) and presence of cutaneous lesions (e.g. callus). The present study reports a wider range of features including cutaenous lesions (e.g. callus), articular features (e.g. structural deformity, lesser toe deformities), extra-articluar features (e.g. nodules), presence of inflammation by clinical examination (e.g. tender joint counts), joint mobility (ROM) and neurovascular status (e.g. protective sensation). There is also a broad description of the patients in relation to general characteristics (hospital site, age, gender, local deprivation and additional morbidity) and RA characteristics (disease duration, mean age RA diagnosed, arthritis medications and current disability). The findings of this study support the literature that foot problems in RA are common and can be multi-factorial in clinical presentation. However, severity and frequency of foot problems reported in this study are slightly less than in previous reports. It seems reasonable to suggest that this study reports the most comprehensive description of the general demographic characteristics, clinical characteristics and current foot problems in patients with RA to date.

Data in relation to the prevalence of foot problems in RA can be obtained through self-report by patients and clinical assessment by health professionals. For example Otter *et al* (2010) present prevalence data of foot problems obtained through a postal questionnaire of patients with RA. In contrast several observational studies report the prevalence of foot problems through clinical assessment (e.g. Borman *et al,* 2012). However, levels of agreement between these two approaches have not been established in RA. This study therefore facilitated the opportunity to investigate the levels of agreement between the self-report of foot problems and clinical assessment. The self-report of foot problems were recorded in response to the question “Since you were diagnosed with RA, do you have any of the following problems with your feet?”

High agreement occurred for most foot problems. However, agreement for numbness and pes planus was only fair and only chance agreement was detected for joint swelling using the Kappa value as a statistical measurement of inter-rater agreement. However, the Kappa value can be influenced by frequencies and therefore may not reflect levels of agreement for less common problems. Additionally the Kappa value does not give an indication of false negative reporting; that is patients failing to report a foot problem detected by clinical assessment. Investigation of levels of agreement for true positives, true negatives, false negatives and false positives indicated that the self-report of many foot problems is reliable (e.g. bunions reported and hallux valgus observed). However, a third of patients who had reduced sensation did not report numbness. A similar situation was detected for pes planus where half did not report fallen arches. It is possible that some patients may have had a low medial longitudinal arch profile before being diagnosed with RA and therefore did not identify this as a foot problem since being diagnosed with RA. The most surprising result was for joint swelling in the feet. The clinician observed joint swelling in more than 65% of patients but only a third of these patients reported joint swelling. It is possible that patients did not interpret the question “Do you have swelling in your feet?” as the question was intended (“Do you have joint swelling in your feet?”). Hewlett *et al* (1995) reach similar conclusions regarding patients’ ability to recognise joint swelling. Overall these data demonstrate that the self-report of most foot problems is reliable and can therefore be used with a high degree of confidence. However, a direct examination is required for numbness, pes planus and most importantly for joint swelling, and the observed prevalence reported in Study 3 should be taken as the correct value rather than the self-report prevalence in Study 2.

In relation to foot care accessed, the general characteristics (age, gender, hospital site, social deprivation) and RA characteristics (disease duration, disability) were similar for all foot care services (orthotics, orthopaedics and podiatry). Additionally, over half of the patients had accessed more than one foot care service. The service most frequently accessed was podiatry. The proportions of patients who had accessed NHS and independent sector podiatry were similar. A range of reasons was given for accessing independent sector podiatry including negative experiences of NHS podiatry services. The fact that patients may choose independent sector podiatry due to negative past experiences and dissatisfaction of NHS podiatry services has been reported previously (White and Mulley, 1989). Andersen’s model for health care utilisation (Andersen, 1985) includes the influence of patient (consumer) satisfaction with care received and influences further interaction and use of health care. Previous experiences of foot care also emerged in Study 1 as an important contributing factor to the decision to access further care.

Over half the patients who had accessed care did so for cutaneous lesions. The clinical effectiveness of sharp callus debridement in the RA foot has received attention (Davys *et al,* 2005). A combined approach to the management of painful callosities (e.g. self-care and foot orthoses) is proposed by Siddle *et al* (2013). The findings of this study indicate that patients consider the presence of callus to be an important health care need as this was the most frequent reason given for accessing podiatry services. Further, many considered treatment for cutaneous lesions to be so personally important that they self-funded care.

There is evidence supporting the clinical benefits of foot orthoses for patients with RA (e.g. Woodburn, Barker and Helliwell, 2003). Of the podiatry group (NHS and independent sector), no patients reported to have received foot orthoses. The researcher’s clinical experience is that there is currently a dearth of orthotics/insoles available to the local NHS podiatry service. This may explain the low rates of orthotics/insoles issued. There may be a disincentive for independent sector practitioners to prescribe foot devices because of additional financial costs to patients. The majority of patients (96%) who had accessed orthotics received foot orthoses but only a third were using the devices issued. Reasons for cessation were varied such as difficulty accommodating the devices in footwear and not being effective. In order for the therapeutic benefits of insoles/orthotics to be achieved, patients need to be able to accommodate the devices in their footwear. As many patients were wearing “poor” footwear, it is possible that prescribing insoles/orthotics would not be achievable or appropriate unless footwear suitability was also addressed. However, this cannot be confirmed by these data as access to foot care clinical records were not available.

Overall, the majority who had accessed podiatry services reported to be satisfied with the care they received. In contrast, half of those who had undergone foot surgery reported to be dissatisfied with the outcomes of surgical intervention. The perceived benefits of foot surgery in RA differ between patients and the surgeons (Backhouse *et al,* 2012). The patients’ experiences of care received by orthotics services were not explored directly in this study. However, the proportion of patients who had stopped using their devices and orthoses was very high. Reasons for not wearing the prescribed footwear issued included poor fit and aesthetical unacceptable by the patients. Similar findings relating to poor usage of prescribed footwear have been reported previously (Williams and Meacher, 2001; Williams, Rome and Nester, 2007; de Boer *et al*, 2009). Further work in relation to clinical practice and prescribing of orthoses, devices and footwear seems advisable.

The majority of patients who had not accessed foot care perceived it to be unnecessary (e.g. feet not a problem). This is not unreasonable as, for example, asymptomatic stage 1 hallux valgus which can be accommodated in footwear is not likely be clinically significant and therefore no treatment would be indicated. However, some patients' reasons for not accessing care included access hindered by their perception (e.g. lack of knowledge of how to access NHS podiatry). Additionally some patients considered if their foot problem warranted specialist care, then their rheumatology clinicians would have initiated a referral. The aesthetics of prescribed footwear was the most common reason for not accessing orthotics.

While this study had demonstrated that the self-report of most foot problems can be utilised with a high degree of confidence, knowing the prevalence of foot problems alone will not necessarily provide an indication of clinical significance. Two fifths of patients were assessed as requiring further foot care, of which half had immediate foot care needs. These clinical conclusions were lower compared to an earlier report by Williams and Bowen (2004) but this earlier work was a service evaluation, not specific for RA. This was a worrying finding. Further, some patients requiring further care said they were currently under regular podiatry care, raising issues regarding the quality of care received. However, it is not possible to examine this more deeply in the present study as data relating to the clinical presentation of foot problems at the time when foot care was accessed are not available. These data demonstrate that many patients had foot problems that were not being addressed. The most common reason for intervention (observer's recommendation) was for the treatment of cutaneous lesions.

6.7 Strengths and limitations

This study has provided novel data: 1) a detailed clinical description of current prevalence of foot problems in a selected sub-set from a random sample of patients with RA; 2) evidence that self-report of most common foot problems is reliable and can be ustilised with a high degree of confidence; 3) a clear indication that a direct examination of patients feet is required to detect for numbness, pes planus and most importantly for joint swelling; 4) the number of patients with immediate foot care needs was high; 5) patient satisfaction and perceived benefits with care received differs between foot care services.

The independent podiatrist conducting the clinical assessment in this study had extensive clinical experience specialising in diabetes, care of the elderly and also general podiatric practice. Following training provided by an academic podiatrist (JW), Professor of Rheumatic Diseases (JK) and the researcher, the independent podiatrist was confident in conducting a detailed regional musculoskeletal and foot examination. This podiatrist had no previous connection with rheumatology foot care services and was not subsequently part of such services. She was therefore able to remain an independent observer impartial in the study outcomes and their implications for rheumatology care.

That the study did not use techniques such as imaging (x-ray, MRI and or ultrasound) to identify foot problems may be considered a limitation. However, the overall aim of this study was to identify current foot problems by clinical examination, not to inform clinical care (e.g. decision to refer for surgery). For this purpose, exposing patients to additional diagnostic imaging was therefore unnecessary (and consequently unethical) and would incur unnecessary financial costs.

Data were not collected in this study in relation to further exploration of foot problems affecting patients' ability to work. In retrospect and because foot problems were interfering with patients' ability to work turned out to be an important issue for some patients in Study 2, it may have been useful to have done this. However, recruitment for Study 2 (postal survey) and Study 3 were conducted simultaneously. Analysis of the data generated by Study 2 was only conducted once recruitment to Study 3 had been completed and thus the high proportion of patients reporting that their foot problems were affecting their ability to work was therefore an unexpected result and could not have been anticipated *a priori*. Nonetheless analysis of the free text data further supports the notion that foot problems impact on many aspects of patients' lives, including ability to work.

The matching process for disease duration meant that there was no automatic expectation that the study sample would reflect the general RA patient population. However, as it transpired the general patient characteristics (age, gender, hospital site and deprivation scores) were similar to the Study 2 responder sample. Moreover, the RA characteristics (disease duration, arthritis medications and current disability) of patients in Study 3 were similar to responders to Study 2. This is because none of these data distinguished the AFC and NAFC groups in any important way. Consequently the observations made on the state of patients' feet may be generalised to the whole RA patient population. This study has demonstrated that the self-report of most common foot problems is accurate and so the self-report of these in Study 2 would be valid in any case.

The broad range of clinical assessments conducted in this study is an additional strength and the data presented provides the most comprehensive description of current foot problems in a selected sample of patients with RA to date. The clinical assessments lasted approximately 30 minutes which included obtaining informed written consent, the collection of patient demographic data, conducting foot examinations, exploring patients' reasons for accessing or not accessing care, description of foot care received and completion of standardised outcome measures (FIS and HAQ). The conduct of the direct examination of patients' feet took approximately 10 minutes to complete. It is therefore likely that the conduct of the foot assessment described in this study can be achieved in routine clinical practice, particularly in podiatry and orthotics clinical consultations.

A further strength of this study was the independent podiatrist's extensive clinical experience in managing podiatric high risk patients. This therefore ensured both clinical governance and research ethics were maintained. Data have been presented regarding the categories of foot problems requiring intervention. All patients who were considered to require additional foot care were advised by the independent podiatrist of her clinical conclusions. Further, those patients who required immediate foot care were provided with information on how to access the local NHS podiatry service.

6.8 Summary

This chapter strengthens the existing literature showing that foot problems are common in patients with RA and here for the first time the prevalence in the whole population can be inferred from the representative nature of the study sample. All of the patients had one or more current foot problems. Nearly half of the participants were considered by the independent podiatrist to require foot care. Further this study demonstrates self-report of most foot problems can be utilised with a high degree of confidence. Nonetheless this study also supports the need for some aspects of foot pathology to be assessed by examination, particularly in relation for signs of inflammation involving the foot joints. This study also provides valuable insight into patients' reasons for accessing or not accessing foot care. As expected, some patients had not accessed foot care as they did not consider they had any problems which would warrant accessing care. Of the patients who had accessed foot care, the most common reasons were for treatment of cutaneous lesions (e.g. calluses) and inability to self-care their foot health needs (e.g. cut their toe nails).

The perceived benefits (patient perspective) of care received differed in relation to individual services accessed. The proportion of patients who had been issued with foot orthoses was high. However, the majority had ceased using the devices issued. Difficulty accommodating devices in footwear was the most frequent reason for cessation. Clinicians need to consider the accommodate features of patients footwear when prescribing foot orthoses. For the clinical benefits of foot orthoses to be achieved, patients need to be able use devices issued.

This chapter completes the investigation of the prevalence, impact and care of foot problems in people with RA. Almost all patients have foot problems, some of substantial importance, and many patients had accessed foot care. However, many of those who had done so had continuing foot care problems, some requiring immediate attention. An abstract of Study 3 has been presented as an oral presentation at the EULAR meeting 2015 (Wilson *et al,* 2015) and a copy can be found in Appendix J3.

The findings of the three studies taken together are considered and their implications for clinical practice, organisation and delivery of foot care services and areas for further research are explored further in Chapter 7.

Chapter 7: Discussion

The results of each of the three interlinked studies presented in this thesis were discussed at the end of each relevant chapter. The findings of all three studies taken together as one body of work are now addressed. The evaluations and interpretations of all three studies are drawn together, their combined contributions to the issues raised in the introduction are discussed, and the implications of the overall findings for clinical practice, health policy and further research considered.

7.1 How this work adds to previous reports of foot involvement in RA

The common occurrence of foot problems in patients with RA, caused by a combination of disease processes and altered foot mechanics, is supported by population-based studies (Grondal *et al,* 2008; Otter *et al,* 2010; Jurez *et al,* 2010) and observational studies (Michelson *et al,* 1994; Rome *et al,* 2009; Borman *et al,* 2012). Evidence for the benefits of non-pharmacological interventions such as foot orthoses and prescribed footwear is accumulating and national guidelines advocate examination of patients' feet and timely access to foot care (Luqmani *et al,* 2006; NICE CG79). However, surveys of rheumatology departments in the UK have found that access to dedicated foot care services for patients with RA is variable (Williams and Bowden, 2004; Redmond, Waxman and Helliwell, 2006). There are some important limitations to previous work on both the prevalence of foot problems and access to foot care services. These weaken their generalisability and comprehensiveness. Perhaps the most important limitation is the sampling strategies that have been used. The majority of these earlier studies were either based in hospital rheumatology departments, used patients specifically referred for foot evaluation, and/or or sampled patients attending foot care services of some kind. These selected populations may not represent the overall population of RA patients, and the studies risk overestimating the prevalence and extent of foot problems. Further, many studies reported only a limited classification or categorisation of foot problems and in some instances the reports were not RA specific. A study of patients representing the whole population was required in order to establish the true prevalence and nature of foot problems in RA, the impact they have on the lives of patients, and the extent to which patients in general access foot care services. The main aim of the work reported here was to undertake such a study.

A survey of a large randomly selected cohort of patients taken from all those in a known geographical area was required, reflecting access to both secondary (hospital based) and primary (community based) care foot care services. The target sample therefore was identified from patients with RA who were currently being clinically managed in secondary care but whom all had access to the same community based services. This was conducted in Study 2 and was a postal questionnaire survey. However, in order to capture the consequences and important issues of foot problems in RA from the patient perspective a preceding qualitative study was conducted. This was Study 1, a qualitative analysis of interviews with patients to inform the content of the questionnaire. As data collected in Study 2 would be based on self-report, a third investigation (Study 3) was conducted to investigate the reliability of the self-report of foot problems, and also to provide a detailed clinical description of current foot involvement in a selected sample of patients (responders to Study 2). Study 3 also provided an opportunity to further explore patients' reasons for accessing or not accessing foot care, and to provide a description of the foot care received. In order to compare patients who had or had not accessed foot care services, and because foot problems and the opportunity to access foot care might be strongly linked to disease duration, participants (patients) were matched to ensure a similar distribution of disease duration in both patient groups.

7.2 Thesis aims:

1. Measure the prevalence of self-reported foot problems in RA by examining a large sample of patients in a postal survey.
2. Quantify the nature and types of foot problems experienced by patients.
3. Measure the impact of current foot problems.
4. Identify the proportion of patients who have accessed foot care services.
5. Discover patients' reasons for accessing or not accessing foot care services.
6. Identify factors associated with accessing foot care.
7. Provide a description of the foot care patients have received.
8. Identify self-care and self-management strategies adopted by patients to manage foot problems.
9. Validate self-report of current foot problems (or lack of foot problems).

7.3 Influence of methodological considerations

Often it is not possible (practically or economically) to collect data from every individual in the population of interest. Studies therefore generally identify and select a sample of the population (Bowling, 2014). The transferability of the findings from population samples to the entire population of interest is widely discussed in the literature. Demographic and clinical characteristics are reported to influence response rates to health surveys (Hoeymans *et al,* 1998; Rupp *et al,* 2002; Turrell *et al,* 2003). If patients who participate in research studies are different to the general patient population the generalisability of findings may not reflect or be applicable to the wider patient group (Anderson and Mantel, 1983; Gluud, 2006). Common categories of bias in clinical research studies, which may result in researchers reaching incorrect conclusions about the topic of interest, include selection bias (how the participants were identified and sampled) and measurement bias (how the outcome / topic of interest was measured) (Krishna, Maithreyi, Surapaneni, 2010). Female gender, social deprivation, and clinical disease features are reported as determinants of which patients with RA are likely to participate in clinical research (Reisine, Fifield and Winkleman, 2000). The issues of selection bias and measurement bias were therefore identified and addressed in the methodological approaches for all three studies.

In Study 1, patients were purposively selected / sampled who had experienced foot problems at some time since developing RA and had accessed foot care or not. This sampling strategy was appropriate to explore patients' individual accounts and experiences of foot problems to inform the content of the postal questionnaire. Study 2 directly addressed the issues raised by Starr (2012), who proposed responders to surveys are a self-selected group, therefore recommends comparing characteristics of responders and non-responders. Overall no significant difference was detected in Study 2 between the target population (patients invited to participate) and the study sample in relation to hospital site, gender or age. The frequencies of social deprivation categories were very similar for responders and non-responders. Given these data, responders to Study 2 are considered to be a representative sample of all patients with RA in Bristol. Furthermore the general patient demographics (gender, age, social deprivation, hospital site) and clinical characteristics (disease duration, arthritis medications, disability, and additional morbidity) were similar for Study 2 responders and Study 3 participants.

One source of participation bias to be considered for all three studies is that patients with foot problems may have been more likely to participate in the studies as they were experiencing the overall topic of interest of this thesis (Sica, 2006). There is potential for this bias in Study 2 and Study 3, which is acknowledged, but given the characteristics of sample population, responders and participants any bias is likely to be small.

Firm conclusions and inferences from research studies can only technically be applied to the patients who participated in the study. It is not possible to conclude with confidence how applicable the prevalence of foot problems reported in this thesis reflects patients with RA in other urban areas of the UK or indeed patient populations internationally. However, the study sample for Study 2 seems to be a representative sample of patients with RA. This thesis therefore may guide the generalisability of epidemiology data from a single population to other defined RA populations or indeed the whole population.

An additional consideration is the influence of measurement bias. All foot examinations in Study 3 were performed by a single observer (podiatrist). To minimise the effect of observer bias the independent observer was trained in the conduct of the foot examination by the researcher and two of the academic supervisors. Additionally the independent podiatrist was fully aware of the study protocol and used a standardised case record form for all data collection which she autonomously trialled the case record form with patient volunteers before use. Furthermore she was unaware if a participant had accessed foot care or not until after the clinical assessments had been completed. All case record forms were fully completed with no missing data, indicating the independent podiatrist was familiar and competent with both the conduct of the foot examination and the data collection process. It is possible that because the participants were aware of the independent observers’ clinical background this may have influenced their behaviours and responses to the clinical interview questions (Monahan and Fisher, 2010). This potential observer effect is acknowledged.

The response rate of 56% in Study 2, although similar to response rates in other UK based surveys of patients with RA (Neame and Hammond, 2005; Otter *et al,* 2010), was lower than the anticipated rate of 70%. The estimated response rate was based on an earlier survey of patients with RA carried out in the same geographical region (Nicklin *et al,* 2010). However, recruitment for this earlier study was by face-to-face approach by the researcher in clinic. The accuracy of patient information (Study 2) was checked as one of the NHS hospital sites appeared to hold errors in relation to a small number of patients (e.g. patients' contact details). This was highlighted by the return of one questionnaire indicating the recipient no longer resided at the postal address. Any further errors in relation to patients contact details were identified by the researcher by cross checking the study data base with hospital data bases. This not only ensured patients' details were accurate but also added to the quality of the research process. Errors in patient contact details are therefore unlikely to have been associated with response rates.

A major strength of this thesis was the collaboration with patients at each stage of the research process. Patient (service user) involvement in clinical research is widely advocated (Hewlett. *et al,* 2006; de Wit *et al,* 2011). Patient involvement in this thesis was achieved firstly from valuable discussions with the initial thesis research advisory group (RAG). The RAG included members of the rheumatology clinical team and patients. Secondly, support from the patient research partners linked to all three studies. Patient involvement was therefore incorporated in all parts of the research process including the overall approach of the three studies, wording and content of items in the questionnaire, trialling of the questionnaire and interpretation of the overall findings of each of the studies. For example of the Study 2 questionnaires returned, only two were considered inadmissible due to large amounts of missing data. It was therefore considered that patients found the items in the questionnaire straightforward; supporting the benefits of including patients in the design and wording of the questionnaire.

Capturing the patient perspective in relation to foot problems in RA has received attention in recent years. However, previous works have tended to focus on specific areas of interest such as: experiences of prescribed footwear (e.g. Naidoo *et al,* 2011), factors influencing patients' decisions to access foot care (Blake, Mandy and Stew, 2013) and patients perceptions of foot problems being overlooked in clinical consultations (Williams and Graham, 2012). The primary aim of Study 1 (interviews) was to capture important issues of foot problems in RA from the patient perspective to inform the content of the postal questionnaire (Study 2). However, Study 1 also provided a rich description of the complex nature of foot problems in RA, consequences and importance of foot problems, factors influencing patient's decisions to access foot care or not, their experiences of accessing foot care, and beliefs regarding benefits of care received. The global nature of the consequences, impact and care of foot problems from the patient perspective has not been fully investigated in previous work.

7.4 Findings on the prevalence and impact of foot problems in patients with RA (aims 1-3 and 9)

Following a narrative review of the literature and from clinical experience it was expected *a priori* that foot problems were likely to be common in patients with RA. Additionally, Study 1 participants reported the occurrence of a wide range of foot problems since being diagnosed with RA. These included articular features (e.g. pain), cutaneous lesions (e.g. presence of callosities), structural deformity (e.g. bunions / hallux valgus), and extra-articular features (e.g. nodules), indicating that patients recognise many different foot problems. The patient comments also supported the literature reports that foot problems can be multiple and complex in clinical presentation and may follow a variable fluctuating clinical pattern.

7.4.1 Prevalence of foot problems by self-report

The vast majority of responders to the postal survey in Study 2 and all of the participants in the clinical assessment in Study 3 reported one or more current foot problems. The proportion of survey patients reporting current foot pain, numbness and ulceration were in keeping with previous work (Otter *et al,* 2010; Firth *et al,* 2008). However, the proportions of responders reporting current joint stiffness and joint swelling were higher than earlier reports. Otter *et al* (2010) reported the prevalence of joint swelling and joint stiffness as “never”, “sometimes” or “always”. The term “sometimes” may reflect current joint stiffness and joint swelling, therefore the proportions of responders reporting current joint stiffness and swelling cannot be deduced from the report. It is therefore possible that the data reported by Otter *et al,* may be an underestimation of the current prevalence of joint swelling and joint stiffness in the patient population. Nevertheless both Otter *et al* and Firth *et al* provide important data for the literature estimating the prevalence of foot pain, numbness, swelling, stiffness and ulceration in the feet of patients with RA. Additionally both studies were population based and although they were non-random samples both had relatively large sample sizes. Overall Study 2 demonstrates that foot problems are common in a random sample of the population. Furthermore, these findings provide novel data in relation to the broad range of categories of foot problems currently experienced by patients with RA. Based on the results Study 2, the prevalence of one or more current foot problems in patients with

RA by self report is estimated to be 91%. It is evident that the classification and categorisation of foot problems adopted in this thesis provides the most comprehensive estimation of the prevalence of foot problems in RA to date. However, the clinical significance and the proportion of patients requiring foot care cannot be extrapolated from these data, but rather require evidence from direct clinical examination.

7.4.2 Prevalence of foot problems by clinical exanimation

Study 3 included a foot examination by a trained podiatrist (observer). Feet were examined for pathological changes due to RA (e.g. joint swelling) and presence of common foot problems (e.g. foot deformities and cutaneous lesions). The majority of patients had one or more tender and/or swollen joints in the feet and nearly half were MTP squeeze test positive. Additionally over half had one or more subluxed MTP joints. An early arthritis cohort study conducted by van der Leeden *et al,* (2008) reported that 40% of the study participants had joint involvement of one or more MTP joints. In contrast by Borman *et al* (2012) reported similar findings to Michelson *et al* (1994), where foot problems in RA were more common in the rear foot than the forefoot (42% versus 28%). However, Borman *et al* report data collected by three examiners and interrater levels of agreement were not considered. Michelson *et al* (1994) reported data from a hospital based sample, which were collected prior to the development of the current pharmacological management of RA (e.g. introduction of biologic therapies). Nonetheless, despite recent advances in the pharmacological management of RA, data from Study 3 indicate many patients have clinical evidence of inflammatory features in their feet. This is a clinically important result as it provides an indication of the presence of current foot problems which are attributable to RA. Indeed Woodburn *et al* (2010) propose the care of foot problems in RA should parallel the medical management of RA, so that foot problems are detected and diagnosed early in order for care to be targeted. Similar conclusions are proposed for targeted treatment of extra-articular disease features involving the forefoot by Hooper *et al* (2012). The results from the clinical examination in Study 3 add strong support to the call for feet to be examined for timely and appropriate management of foot problems. Additionally the findings of Study 3 provide a detailed clinical description of the features (articular, extra-articular, cutaneous lesions and structural deformity) of current foot problems in this sample of patients with RA.

Peripheral sensory neuropathy is reported to occur in RA (Ferguson and Hollingsworth, 1993). A fifth of Study 3 patients were classified as having reduced peripheral sensation. The proportion of patients with reduced sensation was lower than a previously reported prevalence of 59% (Wilson and Kirwan, 2006). However, this earlier study was hospital based and used “convenience” sampling. The phathophysiology, clinical progression and indeed the clinical significance of reduced protective sensation in RA is unclear. The clinical progression and most importantly the clinical significance of sensory deficit in the feet of patients with RA warrants further study.

7.4.3 Validation of the self-report of foot problems

Self-report is a widely used method for gathering information regarding population characteristics, health status, and utilisation of health services (Bhandari and Wagner, 2006). However, there are limitations for data collected by self-report. For example responders may misinterpret questions, inaccurately recall past events and develop response acquiescence (Kimberlin and Winterstein, 2008). Nonetheless there is evidence supporting the reliability of self-report of health conditions (Siorda, 2013). Levels of agreement between self-report and clinical examination of foot problems have not previously been reported for RA and so an assessment in relation to the accuracy of the self-report of foot problems was required.

All 110 patients who participated in Study 3 completed a new questionnaire reporting current foot problems immediately prior to having their feet examined. As the observer recorded patients’ report of foot problems on the case record form she was therefore aware of their responses. However, she was unaware that comparisons were to be made investigating levels of agreement between self-report by patients and her clinical assessment. Further, the observer did not undertake any of the data entry, analyses and/or interpretation of the findings. As reported in detail in Chapter 6, overall high levels of agreement occurred for most foot problems. However levels of agreement for numbness and pes planus were only fair and (rather surprisingly) only chance agreement was detected for joint swelling. Analyses were conducted using the Kappa statistic. As discussed in Chapter 6 there can be limitations in interpreting the value of the Kappa statistic particularly in relation to situations were subjective observer interpretation is required, such as clinical examinations (Viera and Garrett, 2005). For example false negative reporting can have important clinical consequences for patients’ foot health. Patients’ failing to identify foot ulceration and/or soft tissue infection could lead to delays in both accessing care and receiving care. Therefore levels of agreement were also calculated in relation to comparisons of true positives (positive self-report and positive observation); false negatives (negative self report but positive observation); false positives (positive self-report but negative observation); and true negatives (negative self-report and negative observation) for the presence of current foot problems. Overall, the proportions of agreement for true negatives and true positives for the presence of: nodules, callus, corns, ingrown-toe nails, thickened toe nails; hallux valgus and misshapen toes were high. These results indicate that if patients report any of these foot problems, their report is reliable.

However, a third of the patients found to have reduced sensation on clinical examination (insensate to light touch) failed to report numbness in their feet. In diabetic foot disease, sensory neuropathy is a serious clinical feature which develops gradually and insidiously. Often patients are unaware of initial sensory deficit (e.g. Boulton, 2005). Screening for peripheral neuropathy (sensory deficit) in diabetic feet is recommended and well established in clinical practice (e.g. Perkins and Bril, 2003). Peripheral sensory deficit is a clinical feature of RA and the reliability of a clinical screening tool to detect reduced sensation in the feet has been demonstrated (Wilson and Kirwan, 2006). Sim *et al* (2014) comment that differentiating between general neurological symptoms and peripheral neuropathy can be challenging in patients with RA. The long term clinical significance of reduced foot sensation in RA has yet to be established, but the lack of reliable self-report identified in this thesis indicates that further investigations will need to employ direct clinical examination.

The prevalence of pes planus in RA has been estimated at 64% (Michelson *et al,* 1994) but in Study 2 only a fifth of responders reported to have fallen arches (the commonly used description of pes planus). In Study 3, a quarter of the patients examined had pes planus but half failed to report fallen arches. Allowing for this under-reporting suggests a prevalence of pes planus to be about 40%. Variation in the estimated prevalence of pes planus with earlier studies may be accounted for by sampling strategies. The study conducted by Michelson *et al* has limitations as discussed in 7.4.2. In contrast Study 2 was a population based sample of patients with RA in which the demographic characteristics of responders and non-responders were similar, indicating a high degree of representativeness. Pes planus can lead to alterations of gait, localized functional and structural changes (Turner *et al,* 2006). Additionally, pes planus can lead to other lower limb pathologies such as: Achilles tendinopathy and tibialis posterior tendinopathy, patello-femoral disorders and hip pain (Shibuya *et al,* 2014). Foot orthoses are recommended for the management of pes planus (Franco, 1987), although high quality evidence to support their effectiveness is limited (Banwell, Mackintosh and Thewlis, 2014). Nonetheless pes planus is an important feature of the foot in RA. For further research and timely clinical interventions to reduce the clinical consequences of pes planus patient self-report will be inadequate and direct examination of the feet is required.

The self-report of joint swelling in the feet was different between Study 2 and Study 3 (53% and 28%, respectively). Additionally Study 3 demonstrated that many patients who do have joint swelling did not report it on their questionnaire. Of the study 3 participants, two thirds were assessed to have one or more swollen joint in their feet. Of these patients only a third reported to have joint swelling. Random variation may account for the difference in self-report in Studies 2 and 3, but the very large discrepancy between the low self-report prevalence and the high prevalence of joint swelling on clinical examination means self-report of joint swelling cannot be relied on with confidence. Therefore direct observation / assessment is required to detect for the presence of foot joint swelling in a particular clinical or research situation. In relation to this it may be noted that omitting the feet in measures of disease status can result in patients being misclassified as in remission (van der Leeden, van Schaardenburg and Dekker*,* 2010).

Investigating levels of agreement of multiple assessors in conduct of the foot examinations performed in Study 3 was beyond the scope of this thesis. Interrater agreement in relation to the conduct of foot examinations has received attention. For example high levels of interrater agreement for assessing for peripheral neuropathy are reported (Rayman *et al,* 2011). However, a systematic review conducted by Wrobel and Armstrong (2008) conclude levels of agreement between multiple assessors of physical examinations of the foot is variable. Examining the level of agreement between multiple assessors conducting the clinical examination described in Study 3 could be the focus of future study.

7.4.4 Consequences of foot problems

There emerged from the interviews in Study 1 a description of consequences of foot problems on patients' lives that are not included in the Foot Impact scale (FIS). One such issue was how footwear influences the choice of which clothing to wear. Further, the importance of footwear was also interlinked with identity and body image particularly when attending social functions, and was not gender specific. Additionally less than half of the patients in Study 3 were wearing good or adequate footwear. Footwear is an important factor in maintaining foot health in general populations and patients with long term conditions, and affects the risk of falls in vulnerable groups (Williams, Rome and Nester, 2007; Menant *et al,* 2008; Koepsell *et al.* 2004). However, this thesis has indicated that sourcing adequate and appropriate footwear is a challenge for many patients with RA. Indeed nearly all of the Study 1 participants described difficulty at some time in sourcing commercially available footwear which would accommodate fluctuating foot problems and deformity and which were aesthetically acceptable. Patients with RA experiencing difficulty with high street footwear and the negative consequences of footwear in relation to body image and clothing choice has been reported relatively recently (Naidoo *et al,* 2011, Goodacre and Candy, 2011).

7.4.5 The impact of foot problems in RA

The ‘impact’ of a disease or condition has not always been the central outcome measure used in clinical care and clinical research of foot problems. In clinical practice, particularly podiatric practice there is a tendency to consider impact of foot problems in relation to subjective clinical assessment, severity and prevention to improve symptoms, maintain function and improve quality of life for patients (Woodburn and Helliwell, 1997). However, the evidence demonstrating that contact with a podiatrist reduces consequences and impact of foot problems is limited (Buckley *et al,* 2013). There have been calls for the assessment and delivery of care for people with long term conditions to be reconsidered (Bodenheimer, Wagner and Grumback, 2002a; Lewis and Dixon, 2004). The focus should be on the provision and delivery of care which is patient centred, to address both the individual’s clinical needs and personal priorities. A recent example of a revised model of care for people with long term conditions is the “House of Care” model (Coulter, Roberts and Dixon, 2013). The model recommends that care should be holistic, preventative and patient centred. In order for this to be achieved patients need to assume an active role in their care. The model also challenges the traditional approach to medical care in which the clinician is viewed as being responsible for clinical management. Instead the “House of Care” promotes a partnership approach to clinical consultations with the inclusion of the patient perspective. The importance of the patient perspective in the management of RA is well recognised particularly in relation to improving outcome measurement in rheumatology (Tugwell *et al,* 2007). Patient reported outcome measures (PROMs) are widely used in rheumatology clinical research and practice. Nonetheless disparity of view between clinicians and patients in relation to the consequences of RA has been reported (Scott, Smith and

Kingsley, 2005). There is a growing interest within the rheumatology community to consider the consequences and impact of RA from the patient perspective (Lempp, Scott, and Kingsley, 2006). Indeed Sanderson *et al* (2011) propose a concept of the personal impact of RA as comprising three overlapping aspects of a condition: 1) the severity of the symptoms or effects of the condition; 2) the importance these effects have for an individual; 3) and the individual’s ability to cope with the symptoms or effects (the ‘Impact Triad’). Foot health clinicians need to consider the value of the inclusion of individual patients’ priorities and the personal impact of foot problems during clinical consultations. Such dialogue could then provide the opportunity to devise treatment plans which are not only appropriate and timely but acceptable to the individual patient.

The importance of foot problems to patients with RA was highlighted in the Study 1 interviews where some patients considered their foot problems to be central. The impact of foot problems in RA has been recognised with the development of the Foot Impact Scale (FIS) (Hellwell *et al,* 2005). The FIS has not previously been used in a postal survey thus comparisons with results from Study 2 with previous work are not possible. However, the FIS has been used in an earlier observational study investigating forefoot related disability in RA (Hooper *et al,* 2012)*.* The FIS scores obtained in Study 3 (clinical assessment) were similar in numerical values reported by Hooper *et al*. However direct comparisons may be limited between values in measures of central tendency reported by Hooper *et al* and Study 3, mean versus mode. Nevertheless FIS scores in both Study 2 and Study 3 show that even in this very wide population sample the impact of foot problems was considerable.

Since the development of the FIS outcome measurement methodology has increasingly recognised the need to consult with appropriate stakeholders in developing measurement tools such as questionnaires (de Wit *et al,* 2011). An important outcome of Study 1 was the clear indication that the FIS does indeed include foot problems which impact on patients’ lives (such as difficulty with footwear; reduced participation in valued activities; and ability to walk), providing external validity to the content of the FIS. However, patients also reported that foot problems were impacting on other aspects of their lives, including psychological well-being and ability to work. Furthermore, Study 1 participants described these impacts as important, severe and difficult to cope with. These descriptions are additionally consistent with the Impact Triad proposed by Sanderson *et al* (2011). The present studies were not intended to further validate the FIS or to develop an enhanced scale to measure impact of foot problems in RA. However, the findings of Study 1 indicated that some very important issues relating to impact from the patient perspective are not captured by the FIS. Therefore additional measures of impact, concentrating on these issues, were included as items in the Study 2 questionnaire. Considerable impact was detected using these additional measures in Study 2, particularly work related disability. Of the Study 2 responders one third reported their foot problems were impacting on their ability to work. Work related disability is a recognised consequence of RA (Young *et al,* 2002). Foot problems impacting on patients' ability to work has not been previously reported, but the results presented in this thesis suggest that work disability due to foot problems could be an important contributing factor.

7.4.6 Discussing foot problems

An annual review of patients' feet is recommended in national guidelines (Luqmani *et al,* 2006; NICE CG79). However, these results of Study 1 and Study 2 indicate patients perceive foot examinations to be variable and raise issues of concordance of national guidelines in clinical practice. Indeed Otter *et al* (2010) report similar inconsistency in regular conduct of foot examinations.

7.4.7 Overview of the prevalence and impact of foot problems in patients with RA

The results of all three studies indicate that foot problems are not only common, but can be complex in clinical presentation. Further, data from Study 3 provide a detailed clinical description of patients' current foot function (joint range of motion), assessment of disease features (e.g. joint tenderness; vascular and neurological status) footwear suitability and confirms that, for patients as a whole, foot problems are a common feature of RA. Not only are they common, they are important for patients and impact on many aspects of their personal lives. However, foot problems can be overlooked in clinical practice as they are not included in many measures of disease status. Clinicians need to be mindful of foot problems and their important consequences for patients.

7.5 Foot care received and self-care / self-management strategies adopted by patients (aims 4-8)

7.5.1 Access to foot care services

Based on comments in the literature, experience from a rheumatology outpatient department, discussions within the research team (including with the patient research partners) and published findings on access to health care services in general, we anticipated that a small proportion of patients would have accessed foot care services and that such patients would be more likely to be women and from affluent (low deprivation) groups. The results of the Studies 2 and 3 showed that these expectations were in general incorrect.

Of the responders to Study 2, 70% reported they had accessed one or more foot care service. Access to foot care was defined in this thesis as accessed podiatry, orthotics and/or orthopaedics. This broad definition of access to foot care may have accounted for the higher than anticipated proportion of patients reporting to have accessed foot care. However, two thirds of responders reported they had accessed podiatry and orthotics and a third had accessed orthopaedics. The proportion of patients who had accessed podiatry was similar to an earlier postal survey of patients with RA (Otter *et al,* 2010). In contrast a longitudinal cohort study of patients with earlier RA, only 30% of study participants reported to have accessed podiatry and 4% orthopaedics (Backhouse *et al,* 2011). The mean age of participants at base line in Backhouse *et al* report was 55 years. The mean age of Study 2 responders and the accessed foot care group was 64 years and 65 years, respectively. The older age of responders to Study 2 is not an unexpected result as they were a sample of all patients with RA. In contrast the focus of Backhouse *et al,* study was patients with early RA. As the patients in Study 2 were older and had longer disease duration it is likely that they would have more opportunity to access foot care. Additionally as Study 2 responders were a population based random sample of all patients with RA, the proportions of patients who had accessed foot care is likely to be a more accurate estimation.

One reasonable conclusion of why some responders to Study 2 had not accessed foot care is they have not had a clinical need. Indeed the emergent sub-theme of “Access perceived unnecessary” was identified in Study 1. This finding is further supported through the analyses of the clinical interviews conducted in Study 3. However, many of the patients who had not accessed foot care reported that they would like to have been referred (Study 2). This was most notable for podiatry services. Of the 413 responders to Study 2, 204 had accessed podiatry. Of the patients who had not accessed podiatry, over one half indicated they would welcome a referral. Similar results are reported by Martin and Griffiths (2006). However, half of the patients in Study 2 who had accessed podiatry had sourced independent sector care (self-funded). This was an unexpected result. Data generated from Study 1 and from Study 3 therefore provides novel information regarding patients' reasons for accessing independent sector foot care. Flexibility of appointments, continuity of receiving care from the same clinician and dissatisfaction with NHS podiatry service providing routine foot care (nail care), were reasons given for accessing independent care. Similar findings were reported by White and Mulley (1989) as factors influencing patients' decisions to self-fund foot care. The high proportion of patients who had accessed foot care and their willingness to self-fund add weight to the argument that foot problems were seen by many patients as important health care needs.

By comparing the characteristics of those patients who had and had not accessed foot care services, the strongest determinants of access identified in the multivariate analyses in Study 2 were age, disease duration and gender. However, the effect size for both age and disease duration was small (2% and 4% per year, respectively). The highest predictor of access to foot care was female gender with an odds ratio of 1.74. Female gender as a determinant of access to podiatry and orthopaedics has been reported (Backhouse *et al*, 2011). However, variation in mean age was detected in foot care services accessed between Study 2 (podiatry 68 years, orthopaedics 67 years) and Backhouse *et al* report (podiatry 59 years, orthopaedics 49 years). Discordance of the Study 2 results with data reported by Backhouse *et al* may be accounted for by variation in patient populations. Reporting foot care service access in a restricted patient sample (early arthritis cohort) may not give an indication of access to foot care in the wider patient population. Additionally Backhouse *et al* present retrospective data prior to the introduction of modern treatment paradigms (e.g. biologic therapies) and may not reflect the current population. Nonetheless this earlier work is strengthened by the large sample size and being a multicentre UK based study with a protracted follow up period. Overall, given these results women are more likely to access foot care but gender as a determinant of access to foot care was not as influential as anticipated.

The routes by which patients accessed foot care differed between men and women. For example in relation to access to podiatry, women were more likely to self-refer to NHS podiatry and/or self-fund care. In contrast men more often reported attending podiatry after referral by a clinician. There was a tendency for hospital-based clinicians to refer patients to hospital-based foot care services (e.g. orthotics and orthopaedics) but we have no information about why they did this. It is possible if hospital-based clinicians were more aware of the provision of and access to community-based services for care of foot problems in patients with RA (e.g. podiatry), this may influence referral rates. Additionally informing clinicians of both empirical evidence (e.g. clinical trials and patient reported outcome measures) and anecdotal evidence (e.g. clinician's and patients' perspective) may influence referral rates. Clinicians' knowledge of and access to community foot care services could be explored in future research. Identifying the characteristics of which patients are likely to access care and routes of access to foot care is of interest in general terms, but in contrast to our early assumptions it seems that most patients do (one way or another) gain access to foot care services.

It is widely recognised that social deprivation is associated with poor health and subsequently influences health care needs. Indeed a large body of literature is devoted to the topic. However, the influence of social deprivation as determinants of access to and use of health care varies in different health care systems (Fitzpatrick *et al,* 2004). Access to and use of health care is a complex issue. Field and Briggs (2001) propose a combination of social demographic characteristics (e.g. social class) and geographical factors (e.g. residential location) influence utilisation of health care services. A population survey conducted by Veugelers and Yip (2003) report highly deprived groups to be frequent users of general practitioners and hospital based services, yet accessed fewer specialist services. In contrast, the uptake of screening programmes is higher in less deprived groups (Moser, Patnick and Beral, 2009). Social deprivation is reported to be an important factor associated with negative outcomes in patients with diabetes (Venermo *et al,* 2013). Additionally there is emergent evidence indicating quality of care in diabetes to be variable in relation to social deprivation (Grintsova, Maier and Mielck, 2014). There is a dearth of evidence regarding the association of social deprivation and access to foot care both in general UK populations and patients with RA. Investigation of social deprivation and access to foot care was therefore required. Comparisons of local deprivation were conducted in Study 2. The distributions of frequencies for all categories of social deprivation were similar between the accessed foot care group

(AFC) and the not accessed foot care group (NAFC). In particular the proportions from more deprived areas were similar for the AFC group (36%) and the NAFC group (40%). Given these results social deprivation is not likely to be a determinant of access to foot care for these patients with RA. Individuals with long term conditions often require complex and integrated health care from a range of disciplines (Beatty *et al,* 2003). The medical management of RA usually involves continuing contacts with rheumatology department clinicians over many years and often requires regular interaction with the health care system (e.g. for haematological monitoring). It is possible that these repeated and long term interactions with the clinical care team help to overcome barriers and thus patients with RA are more likely to access additional health services including foot care.

A substantial body of literature is devoted to discussing factors associated with access to and utilisation of health care. Indeed a number of models and theories have been developed to explore and understand health behaviour, access to and use of health care services. The Health Belief Model (Rosenstock, Stretcher and Becker, 1988) proposes an individual's perceived susceptibility, perceived severity, perceived benefits of health behaviour, perceived barriers to performing the health behaviour, cues for action such as symptom severity and confidence in their ability to perform the behaviour. It would therefore seem reasonable to consider an individual's health beliefs may influence health behaviour such as deciding to access and use health care. However, analyses of the qualitative data collected in all three studies does not fully support components of the Health Belief Model as factors associated with deciding to access foot care. Although patients in all three studies described and reported foot problems to be severe and important issues many patients had not accessed foot care. Additionally the susceptibility of developing foot problems as a consequence of RA was only discussed by two patients in Study 1, and both of these patients had older relatives with arthritis. Despite reporting that their foot problems were impacting on their lives neither of these two participants had accessed foot care. Theories and models of health behaviour therefore do not appear to fully explain why patients with RA do or do not access foot care.

7.5.2 Foot care received and current clinical foot care needs

The clinical management of foot problems in RA aims to reduce pain and maintain function (Jaakkola and Mann, 2004). Of the patients in Study 2 who had accessed foot care (AFC) a range of categories of care were reported. The most frequently reported category of care received was devices (e.g. insoles and prescribed footwear (76%)). Of the accessed foot care group (AFC) two thirds reported to have been issued with insoles and a quarter had received prescribed foot wear. These results indicate that foot care clinicians appear to consider the benefits of devices in the management of foot problems in RA.

A third of the AFC group (Study 2) reported to have received treatment for cutaneous lesions. Of these, over half reported to have received treatment for callosities (corns and calluses). Sharp (scalpel) callus debridement is a standard clinical treatment performed by podiatrists in the UK. The clinical effectiveness of sharp callus debridement in patients with RA has received attention. A blinded randomised controlled trial (RCT) of sharp debridement of forefoot calluses versus sham debridement (reduction not performed) found no clinical benefits in pain, plantar pressure reduction or improvement in walking function (Davys *et al,* 2005). A more recent RCT investigated the clinical benefits of sharp callus debridement in patients with RA over an 18 month period (Siddle *et al,* 2013). The study recruited patients with self-reported painful forefoot callosities. Participants in both arms of the trial received combination individualised therapeutic care as required (footwear advice, prescribed footwear, and/or bespoke orthoses, and advice on self-care and self-management of calluses). Participants in the control arm did not receive any sharp callus debridement. At study exit no major differences were noted in the outcome measures between the groups (e.g. foot function, foot pain, impact or gait parameters). The authors therefore question the clinical value and effectiveness of sharp callus debridement. These studies are of interest. Firstly they provide for the literature evidence from well constructed RCTs. Secondly, Siddle *et al* report data from a trial with a protracted follow up period. However, evidence from two RCTs recruiting relatively small numbers of patients (38 and 65, respectively) is unlikely to provide significant evidence to influence alteration in established podiatric practice nationally. Additionally the influence of self-care and self-management of callosities (filing and applying emollients) cannot be ignored. It is possible the regular filing and applying emollients to calluses alone may contribute to improvement in symptoms patients' experience from painful callosities. Data from all three studies in this thesis indicate the conduct of callus debridement appears to be common in clinical practice. Furthermore this thesis demonstrates that patients with RA face challenges sourcing suitable footwear which will accommodate deformities and/or orthoses (Study 1 and Study 3). However, footwear as a constraint to a combined therapeutic approach to the management of calluses in clinical practice cannot be extrapolated from these data. Patients may prefer possible short term clinical benefits of callus reduction (that would not show up in the trials reported so far) rather than being required to change their footwear and/or use foot orthoses. The patients' perception of the benefits of callus debridement could be the focus of future research.

Data collected in the clinical assessment (Study 3) provides a detailed exploration of foot care received. The categories of foot care patients reported to have received were similar to the self-report in Study 2. Overall a wide range of foot care interventions received was reported in both Study 2 and Study 3. However, only a quarter of patients reported they had received advice from foot care clinicians regarding their foot problems. Providing advice in relation to adverse events (e.g. new pain on commencing using devices) and self-care and self-management (e.g. use of emollients and filling calluses) are fundamental principles of clinical care. The majority of the AFC group (Study 2) did not report having received any foot health or foot care education. Similar conclusions are reported by Graham and Williams (2015). It is possible that foot care clinicians did provide verbal and/or written foot health education but this has been forgotten. These data indicate that patients' perception and/or recall of the provision of foot health education may be variable in clinical consultations. On the whole the findings of all three studies provide the most comprehensive description to date regarding the self-report of foot care received by patients with RA.

7.5.3 Experience of foot care

Despite accessing foot care many patients reported and were observed to have current foot problems (see 7.3.3). These results raise potential issues regarding the quality and effectiveness of care received. Indeed, of the Study 3 patients nearly half were considered by the independent podiatrist to have immediate foot care needs. Of these patients, two thirds had accessed foot care at some time since being diagnosed with RA. However, the trajectory of RA follows a variable and unpredictable clinical course with fluctuations of the inflammatory process and periods of remission. As data by self-report and/or clinical examination at the time foot care was accessed was not available (and nor were data in relation to the clinical significance of foot problems at the time foot care was accessed, or clinical records of care provided), firm conclusions regarding the quality of care received cannot be drawn directly.

A further issue regarding the quality and effectiveness of foot care received relates to the issue of devices (insoles / foot orthoses and prescribed footwear). Many patients in Study 2 reported to have been issued with these but in the subset later seen in Study 3, the majority reported they had stopped using the foot orthoses and/or wearing the prescribed footwear. Evidence indicating the clinical benefits of foot orthoses and insoles is available (Hennessy, Woodburn and Steultjens, 2012). However, the application of the results from clinical trials with stringent inclusion criteria and controlled conditions may not carry through to general patient populations (Rothwell, 2005). Foot care clinicians need to consider the accommodative features of patients’ footwear prior to issuing devices. Dissatisfaction and low usage of prescribed footwear has received attention (e.g. Williams and Meacher, 2001). Data from Study 1 and Study 3 provide supplementary evidence to the existing literature in relation to low satisfaction and usage of prescribed footwear. Prescribing and issuing foot orthoses and prescribed footwear incur financial costs to service providers. In order to reduce wastage of public funds, patients need to be issued with devices that they can accommodate in their footwear and/or be prescribed footwear which are both acceptable and effective. Collaboration with patients in relation to treatment planning may enhance quality outcomes of care provided. If clinicians are considering referring patients for foot orthoses and/or prescribed footwear it may be valuable initially to explore the patients expectations and if they would like to receive these devices, prior to generating a referral.

The findings of Study 1 suggest that patient satisfaction with foot care received influenced further interaction and use of foot care services. Patients who had a positive experience of care received appear to continue to use foot care. In contrast patients with a negative experience did not continue to utilise services. Customer (patient) satisfaction of health care received has been proposed as an important determinant of continued usage of health care by patients (Andersen, 1995). The importance of patient satisfaction is acknowledged as an important outcome measure to monitor access and quality of care (Williams, 1994). In relation to orthopaedics, the majority of patients who had undergone foot surgery reported they were satisfied with the outcome, with proportions similar across Study 2 and Study 3. Data were not specifically collected in relation to satisfaction with orthotic interventions in Study 2. However, it is likely that satisfaction with orthotics was low due to the number of patients who reported they had ceased using the devices issued in Study 3. The majority of patients in both Study 1 and Study 3 reported that they found podiatry care beneficial. It is possible that disclosure of the independent observers' clinical background may have influenced patients' response (Richards and Emslie, 2000). However, the researcher did not disclose her clinical background to participants in Study 1 until after data collection was completed. The findings of Study 1 support the data in Study 3 in relation to overall positive experiences of care received when podiatry was accessed. Therefore disclosure of professional background did not appear to influence patients' responses. Of note a small number of patients in both studies reported concerns regarding clinicians' levels of expertise, the lack of continuity of care (receiving treatment from different clinicians each time) and being unable to access care when needed.

Issues related to foot care being provided by non-specialist clinicians have been discussed in earlier reports (Rome *et al,* 2009; Hendry *et al,* 2013). Additionally non-specialists' knowledge of national guidelines for the management of foot problems in rheumatic diseases shows wide variation (Williams *et al,* 2013). This thesis has demonstrated that many patients with RA do access foot care. However, within the geographical area of the studies there is currently a dearth of podiatrists and orthotists specialising in inflammatory arthritis. Whilst it could be argued that some of the categories of foot problems reported and observed in all three studies are not specific to RA, questioning the need for specialist foot care services. Current foot problems were very common in Study 3 patients. Two thirds were assessed to have one or more tender and swollen joints in their feet, over half were MTP squeeze test positive and a fifth had reduced protective sensation. The presence of joint swelling and involvement of the MTPs are well recognised clinical features of RA (Emery *et al,* 2002). Additionally early review with rheumatology specialist services has demonstrated improvement in clinical outcomes for patients (Nell *et al,* 2004). However, for this to be achieved there is a need for collaboration between primary care based and secondary care based clinicians. In order for patients to be reviewed by rheumatology specialists there is a requirement for non-specialist clinicians to have the clinical skills to assess and identify patients who require specialist review. This can be achieved through education and training of non-specialist clinicians by specialist clinicians (Scott *et al,* 1998), specifically those with knowledge and expertise in rheumatology. This issue warrants further enquiry. Developing the clinical assessment skills of non-specialist foot clinicians to a level which recognises the need for specialist referral could probably be achieved through relatively brief training and education provided by clinical specialists, as advocated by Scott *et al.* Indeed the independent observer in Study 3 had limited previous clinical experience of assessing patients with inflammatory arthritis. Nevertheless after concise training she was competent and confident in assessing patients' feet for clinical indications of inflammation.

Variation in provision of specialist foot care services for patients with rheumatic diseases has been reported (Redmond, Waxman and Helliwell, 2006). In contrast, the role of the diabetes specialist podiatrist is widely implemented in the UK, and specialist podiatrists are widely viewed as an essential member of the multidisciplinary team in managing "diabetic foot disease" (e.g. Singh, Armstrong and Lipsky, 2005). Many of these specialist podiatrists are based in secondary care (hospital based) as recommended in national guidelines (NICE NG19). Hospital based specialist podiatry provides opportunities for close collaboration with all members of the multidisciplinary team (MDT). Additionally, Integrated Care Pathways (ICPs) are advocated for many health conditions to facilitate translation of national guidelines into clinical practice to improve both patient outcomes and patient "flow" through the health care system (Campbell *et al,* 1998). Local ICPs have been developed and implemented for the management of diabetic foot disease. The provision of foot care services for patients with RA could be organised to reflect the diabetes model. The implementation of specialist foot care clinicians (podiatrists and orthotists) in RA would provide the opportunity to support non-specialist foot care clinicians through education and training as described above. Additionally specialist clinicians based within rheumatology departments would enable close collaboration with the MDT, facilitating opportunities for a multidisciplinary approach to the care of foot problems in patients with RA. Indeed close collaboration between clinicians for the assessment and management of foot problems in patients with arthritis has long been advocated (Helliwell*,* 2003) and national guidelines are available for the management of foot problems in RA (NICE CG 79). Examples of rheumatology ICPs are available (e.g. Williams *et al,* 2011). However, for local ICPs to be implemented there needs to be support and "buy in" from all stakeholders (clinicians, commissioners and service providers, as well as patients). If specialist foot care services are not available locally the benefits to improving patient care and outcomes through the introduction of a local ICP will not be possible or achievable.

7.5.4 Self-care and self-management strategies adopted by patients

The self-care and self-management strategies adopted by patients to manage foot problems have not been previously reported. This thesis therefore presents novel contributions to knowledge regarding self-care and self-management strategies patients with RA adopt to manage foot problems. A wide range of strategies were reported by patients in Study 2. Self-management programmes are effective in improving health behaviours and health outcomes, and reducing health care costs in patients with RA (Lorig, Mazonson and Holman*,* 1993). Self-management is advantageous in other long term conditions, for example in improving glycaemic control and health outcomes for patients with diabetes (McMurray *et al,* 2002). Self-management programmes have not, however, been shown to be effective at reducing foot problems in diabetes (Apelqvist and Larsson, 2000). Semple *et al* (2009) conducted a small study (n=30) to evaluate the benefits of a self-management foot care programmes for patients with RA and found half of the participants were unable to perform basic self-care and self-management of their feet (e.g. cut toe nails and/or inspect their feet) due to physical disability. Although the study sample was small it raises an important clinical issue regarding patients with RA having the ability to self-care their basic foot health care needs. It is not possible to conclude whether the self-management and self-care strategies reported in Study 2 were self-initiated or recommendation by clinicians. Nonetheless some strategies reported could be detrimental to patients' foot health, particularly in feet with poor tissue viability (e.g. commercially sourced topical keratolytics). Patients with RA have to live and manage their condition and Bodenheimer *et al* (2002 b) suggest patients with long term conditions make decisions on a daily basis on how to do this. There is a body of literature describing and discussing personal, social and environmental factors associated with participation and non-participation in self-management of long term conditions. The factors influencing patients' decisions to self-care and self-manage their foot problems is beyond the scope of this thesis.

7.5.5 Overview of foot care received and self-care and self-management strategies adopted by patients

This thesis raises important issues regarding foot care received. Firstly, although data are not available regarding the classification, severity and/or clinical significance of foot problems at the time when care was accessed, a number of patients who had accessed foot care were deemed on examination to have foot health care needs requiring immediate attention (Study 3). Secondly, the most frequent category of foot care reported was the issue of devices (insoles / foot orthoses and prescribed footwear) but, many patients were no longer using the devices issued. Thirdly, the role of patient satisfaction in relation to care already received is an important determinant of future action, as those who had positive experiences and high satisfaction of care received were more likely to continue to access foot care.

To condense the findings of this thesis into the briefest of statements: overall access to foot care for patients with RA is (for a variety of reasons) less of a concern than first thought, but the provision of effective, timely and targeted care appears to be the more pressing issue for both research and clinical care.

7.6 Limitations

The strengths and limitations of each study have been addressed in detail in the chapters for the individual studies. Potential limitations (some touched on briefly above) inherent in the studies which might relate to the overall collective findings on the impact, prevalence and care of foot problems in RA is discussed below in relation to: data when foot care was accessed; sample bias; and clinicians' perspective.

Of the patients in Study 2 and study 3 who had accessed foot care, many reported one or more current foot problems; potentially raising issues regarding the quality and effectiveness of care received. However, data were not collected at the time when foot care was accessed, which is a limitation of the study. Further a description of the nature and clinical severity of those foot problems prior to and after care was not available. Cross checking with medical records could have provided the opportunity to extrapolate historical clinical data in relation to the presence, clinical importance and care of foot problems at the time of the original foot care episode. This was considered to be unachievable. Firstly, because many patients had accessed independent sector foot care and access to private practitioners' clinical records was not possible. Secondly, the method of recording clinical features may vary between health professions and health professionals, as it has done in previously published research. Thirdly, during the current study's data collection the community podiatry service implemented use of electronic patient records, meaning that the earlier paper records were no longer readily available. It is also possible that a small number of patients may have received foot care from outside the geographical boundary, further limiting access to foot care clinical records.

As discussed in 7.3 it is possible that participation in both Study 2 and Study 3 was subject to some bias because patients with foot problems and/or foot related disability might be more likely to participate as these patients were experiencing the very topic that was described in each study's invitation letter and patient information sheets. Almost all patients reported (Study 2) or were observed (Study 3) to have one or more current foot problems. It is therefore possible to conclude that data in both studies can only be directly attributable to the participants in each study. Nevertheless Study 2 was a population based sample of patients with a large sample size. Additionally the general characteristics (gender, social deprivation and hospital site) were similar for Study 2 non-responders, Study 2 responders, Study 3 non-participants, and Study 3 participants. Furthermore the clinical characteristics (age, disease duration, disability; arthritis medications and additional morbidity) were comparable for both Study 2 responders and Study 3 participants. Also the categories of foot problems reported in both Study 2 and observed in Study 3 were similar. Finally the self-report of most foot problems is reliable. Therefore the self-report of foot problems in Study 2 can be utilised with a high degree of confidence. Even if not all patients within the target population had current foot problems this thesis has demonstrated that they are widely prevalent in a sample of the population.

Failure to capture the clinicians' perspective regarding the prevalence, impact and care of foot problems may be considered a further limitation of this thesis. As discussed above, the time at which foot care was accessed was unknown. Additionally, identifying which clinicians assessed patients, provided care and their clinical evaluation of the effectiveness and benefits of treatment provided was not possible. Clinicians and patients may have differing priorities in the outcome of clinical care (Sandersen *et al,* 2010). However, clinician input into the study design was obtained from members of the clinical rheumatology teams at both hospital sites and a representative of the community based podiatry service. Collaborations with clinicians were conducted at the initial research advisory group (RAG). The level of clinical research experience differed between the clinicians. However, the clinical members of the RAG provided valuable comments and insight to the overall approach and the conduct of each of the studies. Capturing the clinicians' perspective was not identified as a topic to be investigated. However, this could be addressed in future research.

7.7 Implications for clinical practice

Rheumatology clinicians need to be aware that foot problems in patients with RA are common, can be variable and complex in clinical presentation, and follow a fluctuating clinical presentation. Additionally, foot problems impact on many aspects of patients' lives including work related disability. Foot problems are important issues for patients and should not be trivialised.

Non-specialist foot clinicians need to be conscious of the wide range of the clinical presentation of RA foot problems, and have the clinical skills to differentiate between these features in order to provide timely and appropriate care. Clinicians also need to consider if a foot problem is mechanical or inflammatory in nature. For example prescribing foot orthoses for a patient with inflammatory foot pain may be beneficial as a method for joint protection. Study 3 demonstrated that the self-report of most foot problems was reliable. However, rheumatology clinicians and non-specialist foot care clinicians need to consider a direct examination of patients' feet is required to identify reduced sensation, pes planus and most importantly joint swelling. Furthermore non-rheumatology specialist foot care clinicians need to identify and recognise the presence of joint swelling. If joint swelling is detected, a review with rheumatology clinicians could then be initiated. Non-specialist clinicians need to consider the importance of the pharmacological management of disease in conjunction with non-pharmacological management.

Assessment of the disease features are fundamental components of the remit of rheumatology clinicians. However, patients in all three studies perceived that the feet can be ignored in rheumatology clinical practice. This may be an unintended consequence of the omission of the feet in validated measures of disease status (van der Heijde *et al,* 1993). Additionally, asking patients to remove footwear and hosiery can incur extra time during clinical consultations. Nevertheless, clinicians need to consider conducting direct examination of patients' feet for more complex foot problems and disease features as discussed previously. Foot examination can be performed relatively quickly and does not require expensive assessment tools (Boulton *et al,* 2008). The clinicians' perspective of the clinical value in the conduct of foot examinations, the timing of when they should be performed and/or the value of clinicians asking patients if they have any foot problems during clinical consultations is not known. These issues warrant further inquiry.

Clinical experience indicates PROMs utilised in clinical practice do not capture foot problems in RA. Rheumatology specialist clinics are often supported by health care assistants who provide valuable contributions to both clinicians and patients (e.g. collecting PROMs data). However, community NHS podiatry clinics and hospital based orthotic services locally are not supported by healthcare assistants. The collection of PROMs data may therefore be a challenge in routine clinical foot care practice. The use of validated outcome measures (e.g. FIS) in clinical practice by both rheumatology clinicians and non-specialist rheumatology clinicians and their further development could be the focus of future study.

7.8 Implications for health policy and commissioners of health care

Clinical research provides evidence to improve care and clinical outcomes. These aims can be achieved through development of diagnostic tools, screening programmes, novel therapies, effective interventions and estimates of cost (Clancy, Glied and Lurie, 2012). Clinical research can then be used by policy makers and commissioners of health care services to help inform decisions regarding the funding, organisation and delivery of health care for the population. However, the budget for the NHS is under immense strain due to increasing demands coupled with variation in levels of public funding in recent years (Lafond, Charlesworth and Roberts, 2015). An aging population and the proportion of the population living with one or more long term conditions are likely to have future economic consequences for the funding and provision of health care (Wiener and Tilly, 2002). In this regard that the majority of patients in Study 2 reported to have at least one or more co-morbidity is therefore relevant. The care of patients with long term health conditions is complex and often involves care being provided by multiple clinicians at more than one site (e.g. community based clinicians and hospital based clinicians). Schoen *et al* (2009) suggest co-ordination of care across the primary care and secondary care providers can be challenging and potentially sub-optimal. These challenges may result in consequences which are detrimental to patients. Ensuring coordinated care across different health disciplines, the community and hospitals could form part of the role of a specialist foot clinician.

Diabetes is an example of a long term condition with many clinical features (e.g. cardiovascular disease, renal disease, retinal disease and foot disease) requiring complex and co-ordinated health care. Diabetes has been reported to account for approximately 10% of the entire NHS budget, with foot ulceration and lower limb amputations estimated to account for 0.7% of the total NHS budget (Hex *et al*, 2012). This substantially increases when indirect costs (e.g. work related disability) are considered (McInnes, 2012). Diabetic foot disease is therefore receiving interest at a national policy level and with local commissioning groups of health care in the UK. The negative consequences of diabetic foot disease tend to be reported in terms of hospital episode statistics (e.g. amputation rates and hospital days of inpatient stay). In contrast musculoskeletal problems are reported to have the 4th largest budget spend by the NHS. Of this budget, an estimated £3.8 million - £4.75 million is spent on RA in terms of both direct and indirect costs (NICE CG79). An estimation of the economic cost of foot problems in RA and other long term conditions in relation to the NHS budget is not available. The proportion of patients in Study 2 reporting an episode of foot ulceration since being diagnosis with RA was 9%. The prevalence of foot ulceration in RA has elsewhere been estimated to be approximately 10% (Firth *et al,* 2008). However, an association between foot ulceration and lower limb amputation in patients with RA has not been established. Nonetheless this thesis has demonstrated that foot problems are both common in RA and important issues for patients. Additionally many patients reported that their foot problems were important, severe and they were not coping well with them. Furthermore foot problems impact on many aspects of patients' lives including their ability to work. Policy makers and commissioners of foot care services need to consider that diabetes is not the only condition in which significant and important foot problems are common clinical features. Recognition of the value of the patient perspective and patient reported data rather than reliance on administrative data (e.g. hospital inpatient days) would enable more equitable care provision. Finally, providers of foot care for patients with RA need to consider the effectiveness and quality of care provided. If policy makers, commissioners and clinicians considered severity, patient priorities and impact of foot problems across all long term conditions then services could be commissioned and organised to address a wider patient population, not just patients with diabetes.

Access to foot care in this study was higher than anticipated. However, despite accessing foot care many patients reported high levels of current foot problems, variable perceived benefits of foot care received and high levels of stopping using foot orthoses and wearing prescribed footwear. The development of the role specialist foot care clinicians in rheumatology warrants consideration. Specialist foot care clinicians (e.g. specialist podiatrists) would have clinical expertise in the assessment, clinical management and co-coordination of care which would be tailored to the individual patient’s needs. As the demands on health service budgets are likely to increase, the economic costs of developing specialists roles requires justification. However, these costs are likely to be considerably less then redesigning current foot care services through employing additional non-specialist clinicians and training them sufficiently well to deal with rheumatological problems. The monetary implications could be offset against improvements in the organisation and delivery of care coupled with education and training of non-specialist foot care clinicians to better manage the more straightforward, less specialised problems. Evaluation of foot care services provided by specialist clinicians in relation to improving clinical outcomes for patients, including economic evaluation and the effectiveness of care received from the patient perspective would then be required.

A further consideration for health policy and commissioners of health care relates to the training aspect of specialist foot health care clinicians. Modernisation of health services including promoting inter-professional practice has received attention from health policy makers in the UK. This has seen the emergence of extended scope non-medical practitioners. Indeed extending the role of non-medical clinicians is viewed as being essential for developing a flexible health work force (McPherson *et al,* 2006). In relation to podiatry in the UK there have been developments in extended scope practice in relation to post graduate training and qualifications in podiatric surgery, non–medical prescribing, requesting and interpretation of imaging and intra-articular injections. Although these extended roles are welcomed and may support a more flexible work force, other issues need to be considered. For example in the UK the post graduate training of orthopaedic surgeons follows a formal and structured programme with successful completion of which being the award of a Certificate of Completion in Training (Frostick *et al,* 2013). Formal training is not only a prerequisite registration with the General Medical Council but fully funded and supported by the NHS. In contrast post graduate training of non-surgical foot care specialists does not receive the same formal recognition as the training of surgical colleagues. The maintenance and further development of specialist foot care roles therefore requires not only recognition from policy makers and funding by commissioners of health care but the wider health care community. Such recognition and support is vital to improve clinical outcomes for patients with foot problems as consequence of RA.

7.9 Future research

There are many issues of the impact, prevalence and care of foot problems in RA that warrant further investigation. The specific areas for further research will be considered in relation to each of those in turn.

7.9.1 Prevalence of foot problems

The data in this thesis were collected from a random sample an RA patient population but they were within a fixed geographical area. As the organisation, delivery and funding of health care in general, varies nationally and internationally so too might the provision of and access to foot care for patients with RA. In order to expand on the generalisability of the data from the studies reported here it would be appropriate for further research be conducted in other locations. This could be investigated through multi-centre based studies in other areas of the UK. Any geographical variation in patient populations and access to foot care or not could then be investigated. Population based surveys conducted on other patient populations in fixed geographical areas reflecting primary and secondary care foot care provision are therefore warranted.

7.9.2 Impact of foot problems in RA

The Foot Impact Scale (FIS, Helliwell *et al,* 2005) provides the opportunity to capture the impact of foot problems in patients with RA. However, the findings of Study 1 indicated that the FIS did not capture all important issues regarding impact (e.g. severity and ability to work). Additionally analyses of those extra measures of impact that were incorporated into Study 2 indicated that they provided additional information not included in the FIS. However the length of the FIS may limit its usage in clinical practice (although there is currently no information regarding the use of PROMs capturing impact of foot problems in general clinical practice). Development of a shorter validated questionnaire using current methodological techniques and capturing important issues of foot problems from both the patient's and the clinician's perspective warrants further investigation.

7.9.3 Care of foot problems in RA

The most important area to be considered for further research relates to care of foot problems in RA. The findings of Study 1 indicated patients perceived that foot problems can be overlooked in clinical practice as they are not included in measures of disease activity. Annual assessment of patients' feet is recommended in national guidelines (Luqmani *et al,* 2006; NICE CG79). However, the conduct of foot examinations appears to vary in clinical practice (Study 1 and Study 2). Data were not collected from the clinicians' perspective regarding the frequency and rationale for conducting foot examinations. Nonetheless, Study 3 demonstrated that the self-report of most foot problems is reliable. The value of a simple screening question enquiring about the presence of foot problems such as; "Do you have any problems with your feet?" could be the focus of further study.

Additionally there is increasing evidence supporting the clinical benefits of foot orthoses for patients with RA. The results of Study 2 indicated foot orthoses / insoles were the most common foot care intervention received by patients but during the clinical interviews conducted in Study 3 many patients reported to have ceased using the devices issued. Reasons for cessation of use included: difficulty accommodating the devices in footwear, devices increased pain levels and/or were not effective. For the clinical benefits of foot orthoses to be fully established, patients need to firstly be issued with devices which can be accommodated in footwear. Secondly, foot orthoses need to be effective in reducing symptoms. Research programmes are required to develop devices to address these issues which include the patent perspective and avoid subsequent wastage of health care resources.

7.9.4 Clinicians' and patients' perspectives

To date the focus of the literature regarding best practice for the management of foot problems in patients with RA has been on empirical evidence and expert clinical opinion. Rheumatology clinicians and non-specialist foot care clinicians' perspective of the provision and effectiveness of dedicated foot care services for patients with RA has not been fully investigated. Additionally non-specialist clinicians' opinions regarding the need for training and education on the assessment and management of foot problems as a consequence of RA are not known. The clinical benefits of non-pharmacological interventions improving outcomes for patients with RA have been demonstrated (e.g. orthopaedic surgery). However, there is a paucity of evidence demonstrating the perceived benefits of foot care from the patient perspective. This could be the focus of future research.

7.9.5 Future research summary

To summarise, fruitful areas of future research include firstly confirmation of the prevalence and categories of foot pathology and patients' access to foot care services in other geographical regions. Secondly, build on the FIS to develop a more comprehensive PROM to measure the effects of RA foot problems. Thirdly, integrate the perspective and intentions of clinicians with those of patients in relation to foot problems. Fourthly, find simple ways to bring foot problems and resources for dealing with them to the attention of clinicians. Finally, explore the likely benefits of supporting community based podiatrists with the provision of a specialist rheumatology podiatry service for education and referral of more complex problems.

7.10 Personal reflections

Undertaking this work has been an immensely challenging but rewarding journey. The academic training and supervision I have received have been vital to enhance my knowledge of the research process and overcome challenges encountered. As a podiatrist with a clinical interest in long term conditions, I was concerned that my professional background would bias my approach to the research process. That is, my own personal clinical experiences and knowledge of foot involvement in long term conditions might be at the forefront driving the process, rather than the patients' experience. I was therefore particularly aware that my own personal experiences and clinical background had to be acknowledged. I was also concerned how I would feel and cope if participants disclosed negative experiences of foot care received.

My interactions with patients prior to conducting this work had primarily occurred during clinical consultations. I have conducted previous research activities involving patients with RA. However, these earlier works involved clinical examinations and I had no prior experience of conducting qualitative research. My relationship and discussions with patient research partners were of great value to facilitate my transition from a podiatrist to a clinical researcher. Throughout the Study 1 interviews, data collection and analyses I endeavoured to maintain a neutral position. I have no way of knowing the effect of my influence on the research process, particularly in this qualitative phase. However, this is an issue for all researchers utilising qualitative research methods. I therefore recognised the need for reflection and reflectivity in my overall approach to the work. Further, acknowledging I was an integral part of the research process at an early stage was essential. This was achieved by accepting I am who I am.

Despite having limited qualitative research experience, Study 1 had the greatest impact on me both personally and professionally. In spite of my clinical work over many years, the full extent of the impact of foot problems and how they affect so many aspects of patients' lives were issues that I had not fully appreciated. In particular, the impact of foot problems on activity levels, participation in valued activities, relationships with others and ability to work. Furthermore, patients' choice of clothes being dictated by what shoes they could wear was an unexpected insight. Exploring the patient experience of foot involvement as a consequence of RA has led to alterations in my clinical practice. During clinical consultations I have always strived to discuss all treatment options with patients, in order for them to be able to make informed decisions about their care. As a clinician I appreciate the clinical benefits of prescribed footwear and orthotics can have in relation to improving foot symptoms. However, in order for patients to accommodate foot orthoses in their shoes this can often require changes in current footwear selection or require prescribed footwear. I now have a greater understanding of the challenges patients encounter in relation to obtaining footwear that is comfortable and aesthetically acceptable, and how this has consequences for a patient's identity and choice of clothing.

The greatest intellectual challenge of this research was conducting the quantitative analyses. I had no previous experience of working with and analysing large data sets. Becoming familiar with the functions of SPSS was a lengthy process. I now appreciate both the strengths and weakness of the package. I also was required to learn and be familiar with a variety of statistical techniques, as well as being able to interpret results. I am incredibly grateful to both Professor John Kirwan and Dr Jon Pollock for their guidance and patience with a quantitative novice.

My academic training has altered how I process ideas and make decisions, and ultimately encourages me to think more laterally. The knowledge and skills I have developed during this piece of work will strengthen my future academic work and clinical practice.

7.11 Thesis summary

This thesis builds on the literature that foot problems are common in patients with RA and impact on many aspects of patients' lives. The findings presented here provide a more accurate estimation of the prevalence and nature of foot problems in RA than previous publications. This can be demonstrated firstly by the representativeness of responders to the main study (Study 2) to the target population. The classifications and categories of foot problems (reported and observed by direct clinical examination in Study 3) provide the most comprehensive description of current clinical foot features in RA to date. Additionally foot problems are important issues for patients. However, many patients perceive that foot problems can be ignored in clinical practice.

Access to foot care services was greater than anticipated, but despite accessing foot care many patients reported current foot problems, raising issues regarding the quality of care received. Additionally, satisfaction of care received was variable particularly in relation to many patients ceasing to use devices issued (e.g. foot orthoses and prescribed footwear), further raising issues of the quality and effectiveness of foot care received.

This thesis has demonstrated that the self-report of most common foot problems is reliable. However, a direct examination is required for more complex foot problems such as pes planus) and most importantly for joint swelling. Nonetheless the self-report of foot problems can be used in clinical practice with a high degree of confidence. In conclusion foot problems are common in patients with RA taken from a random sample of the population.

To improve outcomes for patients, future work is required not only to develop further interventions which are both effective and acceptable to patients but to support the provision specialist foot care services for patients to receive timely, appropriate, clinically effective and cost-effective care.

> *“It's actually my feet is what's preventing me from getting around.” (BR09M)*

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Appendices

Appendix A1: Study 1 patient information sheet

University of the West of England
BRISTOL

Department of Nursing and Midwifery

University of BRISTOL
School of Clinical Sciences

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

A Research Study to Explore the Experience and Impact of Foot Problems in people with Rheumatoid Arthritis.

Patient information sheet

Introduction

You are being invited to take part in a research study to explore the experience and impact of foot problems in rheumatoid arthritis (RA) and accessing foot care (podiatry, chiropody, insoles and hospital issued footwear).

Rheumatoid arthritis is a disease which causes pain, swelling and deformity in the joints. The feet are often involved. This can lead to difficulty obtaining comfortable shoes and developing skin problems such as corns and callus (hard skin), which can make walking very painful.

There are many ways to improve symptoms in the feet of people with RA, such as the use of insoles, special shoes and regular foot care. However, we do not know how many patients need professional foot care and if they actually receive it.

Before you decide to take part in our research, it is important to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or you would like more information.

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Rheumatology Unit Fax Number +44 (0)117 342 3841

Who is asking me to take part? .

I am Oonagh Wilson, a PhD student at the University of the West of England. This research study is the first of three research studies which will form part of my PhD.

What is the purpose of the study?

We want to find out how foot problems affect people with RA and how people with RA feel about their foot problems and foot care services.

What will happen during the study?

You will be asked to attend for a one to one interview with the researcher at the Bristol Royal Infirmary or North Bristol NHS Trust Rheumatology Departments. Before the interview, the researcher will ask you to read and sign the consent form and ask you some questions about your medical history.

In the interview, she will invite you to discuss the problems you have with your feet, what it feels like to have problems with your feet, whether you have received any treatment for these problems and if you did, what was your experience. You can say as much or as little as you like, there are no right or wrong answers - we are looking for your own individual experience. The discussions will last for about an hour. We will offer you refreshments and are happy to pay your travel costs.

The interviews will be audio recorded, transcribed (typed) and then analysed. This means we will examine the typed transcripts for different themes about foot problems and accessing foot care. All the information in the transcripts will be anonymous so the only person who will know who the transcript belongs to is the researcher.

Why have I been chosen?

You have been chosen because you have a diagnosis of RA and have problems with your feet.

We will be inviting a maximum of 20 patients to take part within the Bristol area from both Bristol Royal Infirmary and North Bristol NHS Trust Rheumatology Departments.

Do I have to take part in the study?

No, you do not have to take part. If you do decide to take part you will be given a copy of the information sheet and a signed consent form to keep and a copy will be kept in your hospital records.

If you decide to take part, you are still free to withdraw from the study at any time and do not need to give a reason for doing so. If you decide to withdraw or not take part, this will not affect the standard of care you receive from any hospital or your GP.

What are the risks or benefits of the study?

We do not believe there are any risks in being involved in this study. We appreciate that there may be some inconvenience to you by having to come into the hospital for the interview. However we will try and minimize this by arranging a suitable date and time for you to come which is convenient.

The benefits of taking part in this study are that you will be helping us to have a clearer understanding of the impact of foot problems in patients with RA and accessing treatment for foot care, and this will help us to improve treatment.

Will my taking part in the study be kept confidential?

Yes. When the audio recording of the interview is written up, your name will be replaced by a code. No one will be able to identify you from the typed transcript. The study reports will include quotations from the interviews but no names will be used. The recordings will be kept securely for 6 years and then destroyed, in accordance with best practice in research guidelines. The analysis of the transcripts will be done by the research team.

What will happen to the results of this research study?

Results will be presented at conferences and in professional journals. The results should be ready for publication about 12 months after the completion of the study. No identification of any of the study participants will be possible from any publications of the research. The findings of the study will help with the design of the next stages of research studies in this area. We will also offer participants the opportunity to hear the results at the end of the study.

Who is funding the research and who has reviewed the research?

The research has been funded by the National Institute for Health Research (NIHR). The study has been peer reviewed by the NIHR and the University of the West of England Research Degree Committee and has been approved by the South West 4 Research Ethics Committee. A research ethics committee is a group of people who look at trial plans to see whether they have been properly thought out and prepared. The committee usually includes doctors, nurses, lawyers and members of the public. They are responsible for checking that the best interests of patients have been considered. The Research and Development Department at the University Hospitals Foundation Trust have also reviewed and approved this study.

What do I do now?

Thank you for considering taking part in this research. Please complete the slip if you are interested in taking part and either hand it in to the clinic nurse, or return it in the pre-paid reply envelope. A researcher will then contact you with further information.

If you have any concerns about participating in this study and would like to receive free independent advice please contact PALS (Patient Advice and Liaison Service) NHS Bristol on 0117 900 3433, email pals@bristolpct.nhs.uk or by post:
PALS, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX.

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Professor Sarah Hewlett, Professor of Rheumatology Nursing, UWE Bristol
Dr Jon Pollock, Reader in Epidemiology, UWE Bristol
Professor Jim Woodburn, Professor of Rehabilitation GCAL Glasgow
Dr Emma Dures, Research Fellow, UWE Bristol
Mrs Enid Quest, Patient Research Partner

Appendix A2: Study 1 reply slip

University of the West of England
BRISTOL

Department of Nursing and Midwifery

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

University of BRISTOL
School of Clinical Sciences

YES. I am interested in helping with the experience and impact of foot problems in RA
study and may be contacted by Oonagh Wilson.

Name:

Address:

Phone number:

Email address:

Thank you for your interest.

Oonagh Wilson
Researcher
Academic Rheumatology Unit
Bristol Royal Infirmary
0117 342 4972

Appendix B: Study 1 participant consent form

University of the West of England
BRISTOL
Department of Nursing and Midwifery

University of Bristol
School of Clinical Sciences

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

A Research Study to Explore the Experience and Impact of Foot Problems in people with Rheumatoid Arthritis.

Consent form for research study

Please initial each box

1 I confirm that I have read and understand the information sheet version 2 dated 29th June 2010 for the above study. ☐

2 I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐

3 I am willing for the interview to be audio-recorded. ☐

4 I understand that quotes from the interview will be anonymised and may be used in publications and conference presentations. ☐

5 I understand that relevant sections of my medical notes and study data may be accessed (in confidence) by the study research team, regulatory authorities or relevant members of the NHS Trust. I give permission for these individuals to have access to my records. ☐

6 I agree to take part in the above study. ☐

____________________	__________	____________________
Name of patient	Date	Signature
____________________	__________	____________________
Name of researcher	Date	Signature

Appendix C: Topic guide for Study 1 one-to-one interviews

I am interested in people’s thoughts and experiences about foot problems in rheumatoid arthritis (RA).

- Before we go on to talk about your feet can you tell me a couple of sentences about you and your arthritis, so I can understand a bit more.

- Tell me the story about your feet?
    - How important are your foot problems to you?
    - Were you surprised when you developed foot problems?
    - Have you discussed your foot problems with anyone?
    - If you were having foot problems who would you talk to?
    - What would prompt you to talk to someone about your feet?

- What are your foot problems?
    - Have your feet changed?
    - Are you feet painful?
    - Can you describe the pain?
    - Can you tell me what part of your feet, cause you problems?
    - Has anyone examined your feet?

- Are you able to manage your foot problems?
    - Can you give an example?
    - Have you tried any other treatments e.g. hot, cold, massage?
    - How much do you think you have spent on your feet?

- Have you had any experience of foot care services?
    - If so, how did you access care?
    - Was it easy / difficult?
    - How long did you have to wait to get an appointment?

- How much do your foot problems affect your activity?
    - Are you able to drive, work, and take part in leisure activities?
    - How do you feel about your foot problems affecting your activity levels?
    - Do your foot problems affect the way you feel about things?

  - Do your foot problems impact on your choice of shoes and clothes?
  - Have you feet problems made you feel less feminine / masculine?
  - Do you think foot problems have the same impact on men / women?
  - How do you feel about your feet?

- Have you been given prescribed shoes?
  - How much did you feel included about your opinions of them?
  - Did you wear them? If not why not?
  - Do you have any concerns / worries about not wearing them?
  - Would men be more likely to wear hospital shoes?

- What advice would you give someone about their feet if they have just been diagnosed with RA?

- If we could make things better, do you have a wish list for foot care services?

Appendix D1: Demographic and clinical data Study 1 (one-to-one interviews)

Pre-interview case record form

Study ID: ....
Date: ....
Date of birth (dd/mm/yyyy): ..../.........../............
Gender (please circle): male / female
Disease duration (Years) ……..
Current arthritis medication:
....
....
....

Scores:
Q1……..
Q2……..
HAQ……..
Interview start time …………
Interview end time…………..

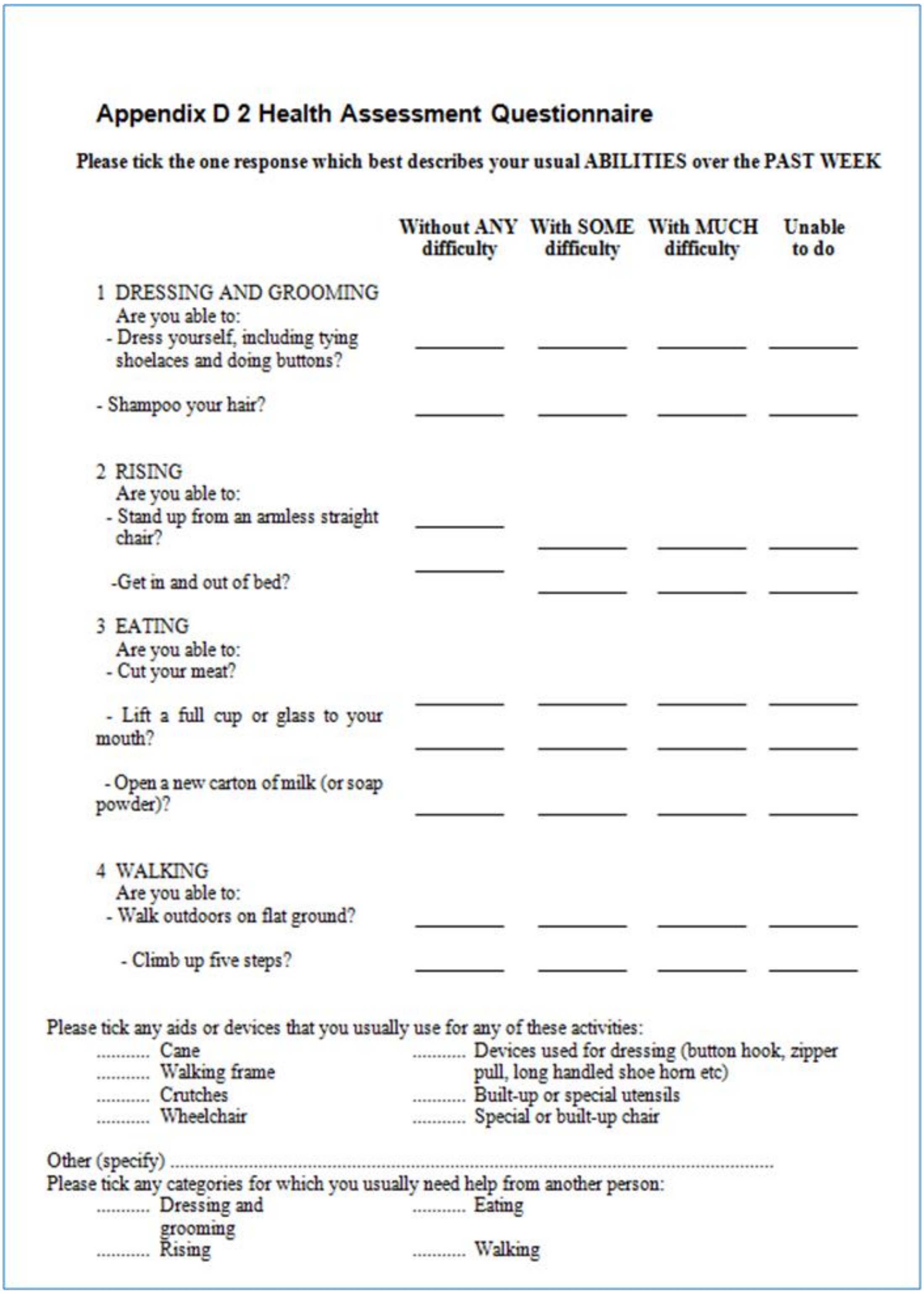
Q1 Please circle the number which shows how much of a problem (on average) your feet have been in the last week.

No problem 0 1 2 3 4 5 6 7 8 9 10 Severe problem

Q2 Considering all the ways your arthritis affects you, please circle the number which shows how well you are doing:

Very well 0 1 2 3 4 5 6 7 8 9 10 Very badly

Appendix D2 Health Assessment Questionnaire



Appendix D 2 Health Assessment Questionnaire

Please tick the one response which best describes your usual ABILITIES over the PAST WEEK

	Without ANY difficulty	**With SOME difficulty**	**With MUCH difficulty**	**Unable to do**
1 DRESSING AND GROOMING Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	______	______	______	______
- Shampoo your hair?	______	______	______	______
2 RISING Are you able to:				
- Stand up from an armless straight chair?	______	______	______	______
-Get in and out of bed?	______	______	______	______
3 EATING Are you able to:				
- Cut your meat?	______	______	______	______
- Lift a full cup or glass to your mouth?	______	______	______	______
- Open a new carton of milk (or soap powder)?	______	______	______	______
4 WALKING Are you able to:				
- Walk outdoors on flat ground?	______	______	______	______
- Climb up five steps?	______	______	______	______

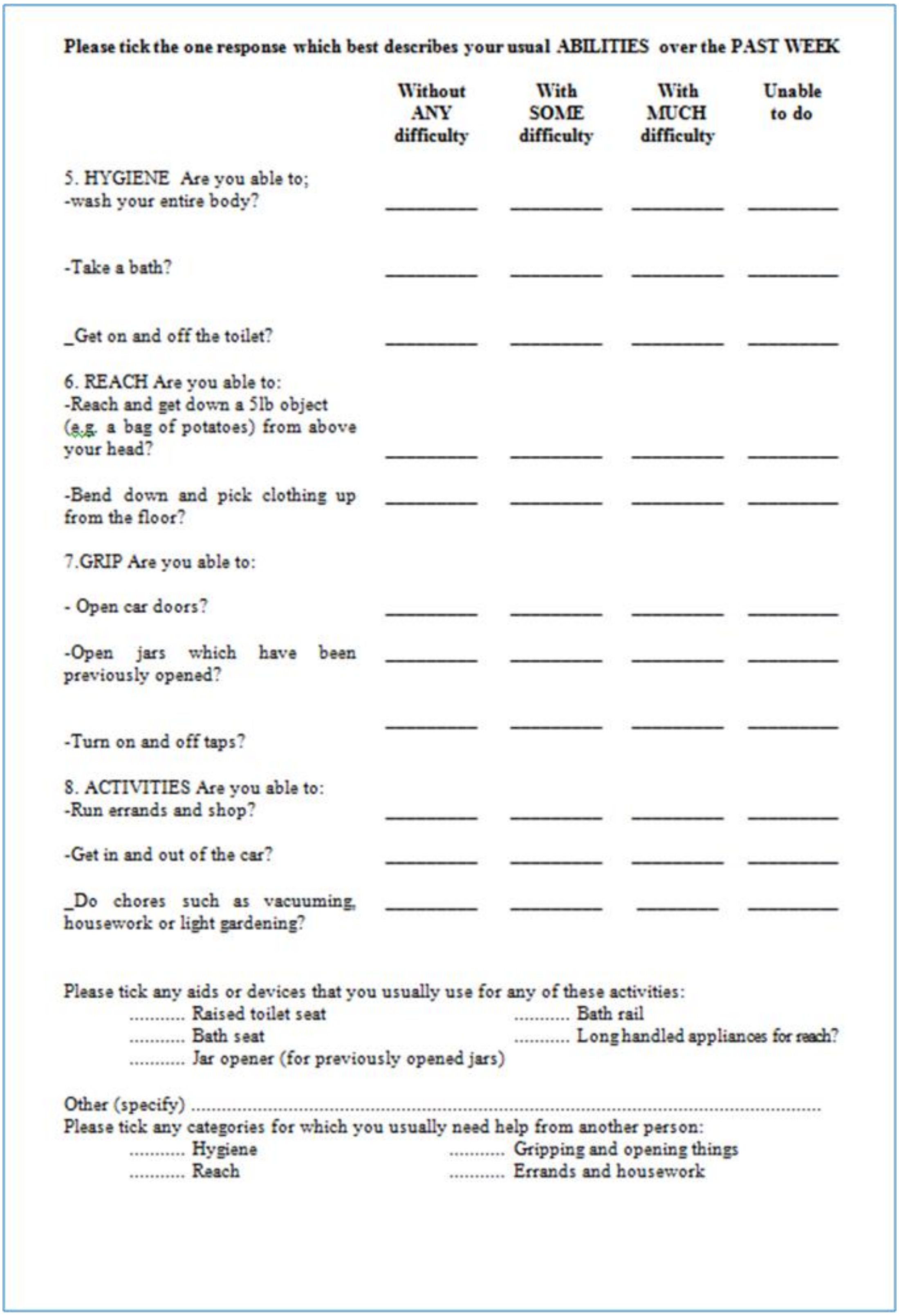
Please tick any aids or devices that you usually use for any of these activities:

.... Cane	.... Devices used for dressing (button hook, zipper pull, long handled shoe horn etc)
.... Walking frame	
.... Crutches	.... Built-up or special utensils
.... Wheelchair	.... Special or built-up chair

Other (specify) ....

Please tick any categories for which you usually need help from another person:

.... Dressing and grooming	.... Eating
.... Rising	.... Walking



Please tick the one response which best describes your usual ABILITIES over the PAST WEEK

	Without ANY difficulty	**With SOME difficulty**	**With MUCH difficulty**	**Unable to do**
5. HYGIENE Are you able to;				
-wash your entire body?	________	________	________	________
-Take a bath?	________	________	________	________
_Get on and off the toilet?	________	________	________	________
6. REACH Are you able to:				
-Reach and get down a 5lb object (e.g. a bag of potatoes) from above your head?	________	________	________	________
-Bend down and pick clothing up from the floor?	________	________	________	________
7.GRIP Are you able to:				
- Open car doors?	________	________	________	________
-Open jars which have been previously opened?	________	________	________	________
-Turn on and off taps?	________	________	________	________
8. ACTIVITIES Are you able to:				
-Run errands and shop?	________	________	________	________
-Get in and out of the car?	________	________	________	________
_Do chores such as vacuuming, housework or light gardening?	________	________	________	________

Please tick any aids or devices that you usually use for any of these activities:

.... Raised toilet seat
.... Bath seat
.... Jar opener (for previously opened jars)
.... Bath rail
.... Long handled appliances for reach?

Other (specify) ....

Please tick any categories for which you usually need help from another person:

.... Hygiene
.... Reach
.... Gripping and opening things
.... Errands and housework

Appendix D3: Full coding tree overview impact and foot problems in RA

Codes	**Subthemes**	**Organising themes**	**Under pinning theme**	**Global theme**
1^{st} foot symptoms	Feet first	Foot symptoms	Impact	Decision to access foot care of not
Balls of feet painful				
Couldn't walk				
Feet and toes stiff				
Feet changed shape				
Feet painful at rest				
Feet sensitive				
Feet were bad				
Feet were really uncomfortable				
Foot problems came later				
Foot problems didn't go away				
Pain started in feet				
Started (RA) in feet				
Surprised by foot involvement				
Swelling in feet				
Ankle problems	Articular involvement			
Bunions				
Current foot problems				
Fallen arches				
Feet ache				
Feet always hurting				
Feet painful at rest				

Feet painful in the morning				
Feet throb				
Feet uncomfortable				
Foot deformity				
Foot pain				
Foot pain crippling				
Consequences of foot pain				
Misshapen toes				
No foot deformity				
Pain like a broken bone				
Secondary OA				
Burase	Extra articular			
Feet burn				
Nodules				
Numbness in feet				
Swelling in feet				
Advise for patients newly diagnosed with RA	Other features RA			
Concerns about the future				
Fatigue				
Feet part of whole RA				
General RA symptoms				
Hand problems				
Morning stiffness				
Other joints				
Pain				
RA and activities of daily living				
RA and pregnancy				
RA and relationships with others				
Blisters	Cutaneous lesion			

Calluses / hard skin				
Corns / stone bruises				
Ingrown toe nails				
Nails changed				
Skin infections				
Skin problems				
Driving	Activities	Consequences		
Can’t brake suddenly				
Can’t depress clutch				
Can’t stand for long				
Reliance on others				
Social life				
Couldn’t stand for long	Work			
Couldn’t wear safety boots				
Falls at work				
Feet and work				
Had to stop work				
Receiving financial assistance				
Retired				
Work adaptations				
Work not an issue				
Can’t walk around the shops	Walking			
Can’t walk as far as I used to				
Can’t walk far				
Can’t walk up hills				
Feet stopping me getting around				
Feet stopping me walking				
Have to plan ahead				
Have to walk more slowly				
Painful to walk				

Steps difficult				
Walking on bag of bones				
Walking on glass				
Walking on pebbles				
Walking on uneven surfaces				
Benefits of exercise	Exercise			
Can't exercise because of feet				
Cycling and feet				
Exercise and feet				
Exercise and mood				
Feel depressed when can't exercise				
Had to look for other types of activity				
Choice of clothes	Footwear			
Comfortable footwear				
Difficult to get shoes				
Difficult to get shoes to fit				
Femininity and masculinity				
Fluctuating comfort of shoes				
Foot deformity and footwear				
Footwear and body image				
Footwear and gender				
Footwear and identity				
Footwear and walking				
Footwear and work				
Footwear soles				
Given shoes away				
Had to stop wearing certain shoes				
Footwear fastenings				
Importance of shoes fitting				
Improvements to footwear				
Looking for shoes disheartening				

Need different types of shoes				
Not ready to get rid of shoes				
Visual appearance of footwear				
Can't dance anymore	Participation			
Can't do what my friends do				
Can't participate in team sports				
Don't go out any more				
Don't the things I used to				
Everyone else having a conversation				
Isolation				
Missing out				
Can't be a good parent	Social and emotional well being	Cost		
Don't like situation				
Embarrassed about appearance of feet				
Embarrassed to show feet				
Feet frustrating				
Feet make me look old				
Foot problems annoying				
Holding everyone back				
Makes me snappy				
Reliance on others				
Cost of insoles	Financial detriment			
Cost of shoes				
Had to change type of car				
Had to give up work				
Money spent on feet				
Comes and goes	Fluctuations and combinations			
Evolving foot symptoms				
Feet and arthritis medications				
Feet and flare				

Fluctuating foot symptoms				
Foot problems unpredictable				
It varies (foot symptoms)				
Today is a good day				
Concern about foot problems developing	Personal importance			
Current foot symptoms big problems				
Feel trapped				
Feet biggest problem of RA				
Feet effect everything				
Feet not a problem				
Feet ok at the moment				
Have to get on with it				
Importance of foot problems				
Importance of looking after feet				
Individual symptoms and need				
Something I have to put up with				
Worst bit of me				

Appendix D4: Full coding tree decision to access foot care

Codes	Subthemes	Organising themes	Global theme
Acceptance	Another complication of RA	Access hindered by patient's perception	Decision to access foot care or not
Been lucky			
Feet minor part of RA			
Fluctuating symptoms			
Foot problems due to RA			
Foot problems unpredictable			
Least of my worries			
Loss			
More appointments			
Other priorities			
Other RA symptoms a priority			
Terrible disease			
Bombarded with information	MDT will refer if needed		
Changed my life			
Clinicians very helpful			
Doctor knows best			
Doctor organised education sessions			
Doctor organises what I need			
Doctor very good			
Doctor very thorough			
Doctor will refer if I need it			
Don't want RA care anywhere else			
Focus on development and research			
Grateful for treatment			
Lots of support			
Miracle cure			
Physiotherapy helped			

RA well managed			
Referred to OT			
Very grateful for care			
Can't arrange an appointment myself	Lack of knowledge how to access foot care		
Didn't know could get help			
Doctor has to organised it			
Doctor hasn't arranged it			
Don't know how to get an appointment			
Don't know how to get to see a podiatrist			
Don't know what an orthotics is			
Lack of knowledge of service location			
Nobody has suggested			
Thought they were all private			
Another nail in the coffin	Feet ignored		
Been recommended but resisting			
Clinicians focus on hands			
Clinicians focus on large joints			
Didn't associate foot problems with RA			
Don't want prescribed shoes			
Don't want surgery			
Feet not examined			
Feet not examined regularly			
Feet not obvious			
Feet not on any questionnaires			
Feet not on assessments			
Frankenstein boots			
Limited clinical experience of assessing feet			
Limited clinical experience of foot problems			
No advise about foot problems			
Not asked about feet			
Not ready for prescribed shoes			

Not ready for surgery			
Not talked about feet			
RA only affects joints			
Don’t know what they do	Limited awareness of treatment options		
Don’t know what will help			
Everyone’s different			
It’s an operation or nothing			
Just cut toe nails			
Just plodded on			
Need a magic wand			
No advise about treatment options			
Nothing can be done			
Podiatrist only cut corns			
Comes and goes	Fluctuating symptoms	Access perceived unnecessary by patient	
Enough pain for one day			
Feet came later			
Feet more painful in the morning			
Feet bad today			
Pain usually somewhere			
Pain not everyday			
Some days I can’t walk			
Some days ok			
Sometimes can’t get shoes			
Sometimes need crutches			
Swelling (feet) varies			
Today is a good day			
Varying degrees of pain			
Worried will end up in wheelchair			
Worse (feet) in the morning			
Feet just uncomfortable	Feet not a problem		
Feet not a big problem			

Feet not changed shape			
Feet ok today			
Foot problems calmed down			
Foot problems improved when RA controlled			
Injections helped			
Never had calluses			
Not much of an issue (feet)			
Bought my own insoles	Can self-manage		
Cream my feet			
Cycling helps foot pain			
Experiment with shoes			
Family help me (with feet)			
Good shoes important			
Know how to look after my feet			
Know which shoes I need			
Massage my feet			
Old lady shoes			
Take a second pair of shoes			
Use a foot file			
Use cold			
Use heat			
Wear comfortable shoes			
Could be worse	Positive coping		
I’m lucky			
Meet them half way			
Not as bad as others			
Not on my own			
You’ve got to try			
Can’t manage feet because of hands	Can’t self-manage	Access supported by patient and clinician	
Can’t reach feet			
Can’t tie shoe laces because of hands			

Don’t know which insole to try			
Foot care helped others			
Have to rely on others			
Husband told me to go and see someone			
Other joint problems			
Wife won’t cut toe nails			
Always tell the doctor feet bad	Talked about feet in clinic		
Clinician asked about feet			
Foot pain severe			
Others told me insoles helped			
The bunion was hurting			
Told foot problems due to RA			
Told nurse about feet			
Wife told me to tell them about ankles			
Bare foot examinations	Feet examined		
Feet examined at diagnosis			
Had scan of feet			
Had x-rays of feet			
Regular foot examination			
Calluses painful	Foot problems a priority		
Can’t cut toe nails			
Can’t do what I want to do			
Can’t get shoes to fit			
Can’t stand for long			
Can’t walk			
Can’t walk round the shops			
Don’t want them (feet) to get bad			
Feet so painful			
Feet stopping me being a parent			
Feet stopping me doing things			
Feet stopping me getting about			

Feet stopping me working			
Foot problems getting worse			
Need to do something about feet			
Suffer if I walk to far			
Took shoes off and showed the nurse			
Trapped in the house			
Walk more slowly			
Feet worst part of me			
Can wear nice shoes again	Positive experience	Continue to access foot care	
Due for new insoles			
Feet better after surgery			
Foot problems improved			
It helps			
Lucky to have insoles made			
Podiatrist gives advice			
Podiatrist keeps an eye on feet			
Podiatrist treats problems as they occur			
Worth the money			
Insoles didn’t help	Negative experience		
Couldn’t afford to keep paying for podiatry			
Couldn’t be bothered to argue about shoes			
Couldn’t get an appointment when needed			
Couldn’t get insoles in shoes			
Difficult to get appointments			
Disappointed with podiatry			
Didn’t cut toe nails			
Hated the shoes			
Long time to recover after surgery			
Nice (podiatrist) but inexperienced			
No advice given			
No follow up care			

Not much benefit from podiatry Only shaved hard skin off Operation didn’t help Poor follow up care Post surgery complications Shoes didn’t fit Shoes looked awful Shoes too heavy Waited a long time to be seen			

Appendix E: Foot survey patient information sheet

University of the West of England
UWE BRISTOL

Department of Nursing and
Midwifery

University of BRISTOL
School of Clinical Sciences

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Learning about feet in rheumatoid arthritis

Foot survey - Patient information sheet

Introduction:

You are being invited to take part in a research study to explore how many people with rheumatoid arthritis (RA) have problems with their feet. We would like both people who do and people who do not have foot problems to take part in the study. We also want to find out the impact of their foot problems and if they have received any foot care such as seeing a podiatrist, chiropodist or being given insoles or hospital issued footwear.

Rheumatoid arthritis is a disease which causes pain and in the joints. The feet are often involved and in some people this can be very troublesome. This can lead to difficulty obtaining comfortable shoes and the development of skin problems such as corns and callus (hard skin), which can make walking very painful.

There are many ways to improve symptoms in the feet of people with RA, such as the use of insoles, special shoes and regular foot care. However, we do not know how many people need professional foot care, nor if they actually receive it.

Before you decide to whether or not take part in our research, it is important to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or you would like more information.

Who is asking me to take part?

I am Oonagh Wilson, a PhD student at the University of the West of England. This research study is the second of two research studies which will form part of my PhD.

What is the purpose of the study?

We want to find out about the type of foot problems which can affect people with RA and if people with RA have received any treatment for their foot problems.

What will happen during the study?

The study involves completing a questionnaire about your feet. We would like both people who do and people who do not have foot problems to fill out a questionnaire. The questionnaire will also ask about your arthritis in general, and whether you have had any care to help with any foot problems.

Later on we will be inviting some people who complete the questionnaire to attend their rheumatology department for a research appointment. This will involve a one-off clinical interview and foot examination. If you are invited later on to come for a research appointment, you will be able to decide then whether or not you wish to take part in the second part of the research.

Why have I been chosen?

You have been chosen because you have a diagnosis of RA.

We are inviting approximately 500 people to take part within the Bristol area from both Bristol Royal Infirmary and North Bristol NHS Trust Rheumatology Departments, selected at random (by chance). We want everyone to answer our questionnaire, whether or not they have foot problems, otherwise we will not be able to calculate how widespread the problem is.

Do I have to take part in the study?

No, you do not have to take part. If you do decide to take part please complete the enclosed questionnaire and return it to us in the prepaid stamped address envelope.

If you decide to take part, you are still free to withdraw from the study at any time and do not need to give a reason for doing so. The only personal information that will be kept will be your age, post code and whether you are male or female. If you decide to withdraw or not take part, this will not affect the standard of care you receive from any hospital or your GP.

What are the risks or benefits of the study?

We do not believe there are any risks in being involved in this study.

There are no personal benefits to you in taking part. However, you will be helping us to get a clearer understanding of how many people with RA have foot problems. It will help us understand the type of problems people have and whether they have been able to access foot care. This will help us plan future services and understand how to improve access to foot care services, and to provide people with RA better help in the future.

Will my taking part in the study be kept confidential?

Yes. Names on the questionnaires will be replaced by a code by the principal investigator (Oonagh Wilson). No one will be able to identify you from the questionnaires apart from the principal investigator. Your name will not be used in the study reports. The study records will be kept securely for 6 years and then destroyed, in accordance with best practice in research guidelines.

What will happen to the results of this research study?

Results will be presented at conferences and in professional journals. The results should be ready for publication about a year after the completion of the study. You will not be identified from any publications of the research. The findings of the study will help with recommendations for the care of foot problems in people with RA. We will also offer participants the opportunity to hear the results at the end of the study.

Who is funding the research and who has reviewed the research?

The research has been funded by the National Institute for Health Research (NIHR), the research arm of the NHS. The study has been peer reviewed by the NIHR and the University of the West of England Research Degree Committee and has been approved by a NHS Research Ethics Committee (South West 4). A research ethics committee is a group of people who look at research study plans to see whether they have been properly thought out and prepared. The committee usually includes doctors, nurses, lawyers and members of the public. They are responsible for checking that the best interests of people taking part in research have been considered. The Research and Development Department at two local hospital trusts have also reviewed and approved this study.

What do I do now?

Thank you for considering taking part in this research. Please complete the questionnaire if you are interested in taking part and return it in the pre-paid addressed envelope.

If you have any concerns about participating in this study and would like to receive free independent advice please contact PALS (Patient Advice and Liaison Service) NHS Bristol on 0117 900 3433, email pals@bristolpct.nhs.uk or by post:
PALS, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX.

Researcher details:

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Oonagh Wilson, NIHR Clinical Doctoral Research Fellow, UWE Bristol
Professor John Kirwan, Professor of Rheumatic Diseases, UoB Bristol

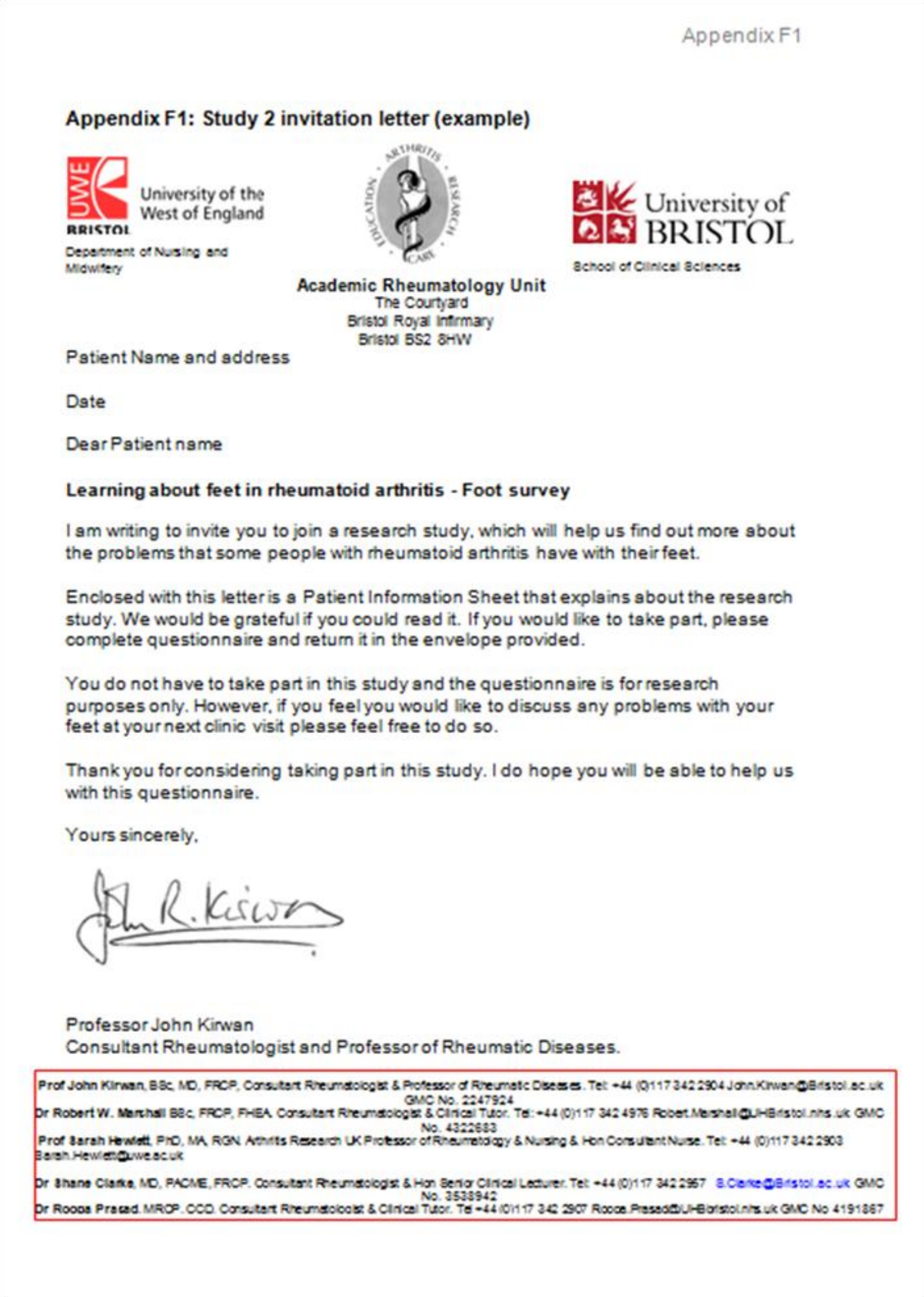
Professor Sarah Hewlett, Professor of Rheumatology Nursing, UWE Bristol

Dr Jon Pollock, Reader in Epidemiology, UWE Bristol

Professor Jim Woodburn, Professor of Rehabilitation GCAL Glasgow

Mrs Enid Quest, Patient Research Partner

Appendix F1: Study 2 invitation letter (example)



Appendix F1

Appendix F1: Study 2 invitation letter (example)

University of the West of England
BRISTOL
Department of Nursing and Midwifery

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

University of BRISTOL
School of Clinical Sciences

Patient Name and address

Date

Dear Patient name

Learning about feet in rheumatoid arthritis - Foot survey

I am writing to invite you to join a research study, which will help us find out more about the problems that some people with rheumatoid arthritis have with their feet.

Enclosed with this letter is a Patient Information Sheet that explains about the research study. We would be grateful if you could read it. If you would like to take part, please complete questionnaire and return it in the envelope provided.

You do not have to take part in this study and the questionnaire is for research purposes only. However, if you feel you would like to discuss any problems with your feet at your next clinic visit please feel free to do so.

Thank you for considering taking part in this study. I do hope you will be able to help us with this questionnaire.

Yours sincerely,

John R. Kirwan

Professor John Kirwan
Consultant Rheumatologist and Professor of Rheumatic Diseases.

Prof John Kirwan, BSc, MD, FRCP, Consultant Rheumatologist & Professor of Rheumatic Diseases. Tel: +44 (0)117 342 2904 John.Kirwan@Bristol.ac.uk GMC No. 2247924
Dr Robert W. Marshall BSc, FRCP, FHEA. Consultant Rheumatologist & Clinical Tutor. Tel: +44 (0)117 342 4976 Robert.Marshall@UHBristol.nhs.uk GMC No. 4322683
Prof Sarah Hewlett, PhD, MA, RGN. Arthritis Research UK Professor of Rheumatology & Nursing & Hon Consultant Nurse. Tel: +44 (0)117 342 2903 Sarah.Hewlett@uwe.ac.uk

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Dr Rooaa Prasad. MRCP. CCD. Consultant Rheumatologist & Clinical Tutor. Tel +44 (0)117 342 2907 Rooaa.Prasad@UHBristol.nhs.uk GMC No 4191867

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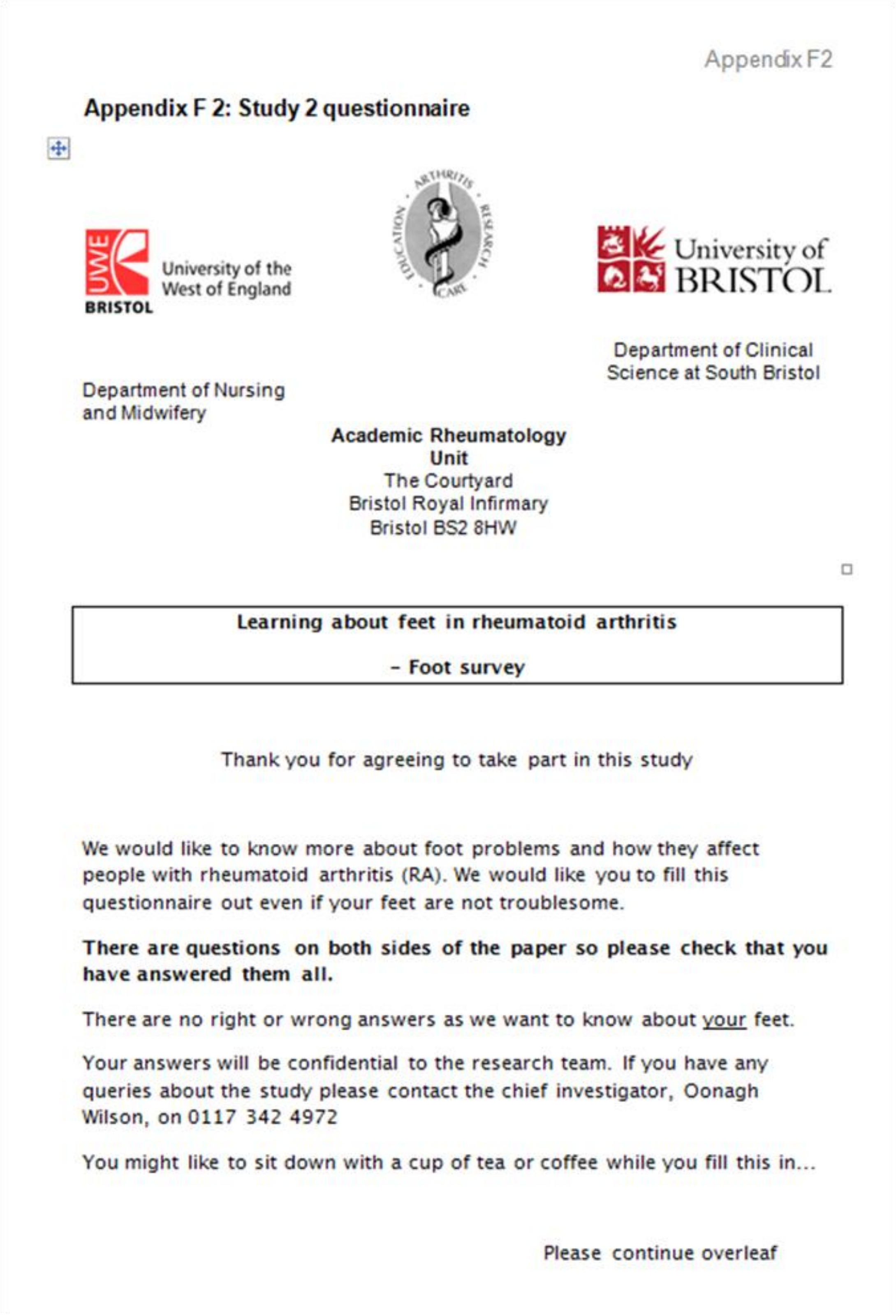
Appendix F2: Study 2 questionnaire



Appendix F2

Appendix F 2: Study 2 questionnaire

UWE University of the West of England
BRISTOL

Department of Nursing
and Midwifery

University of BRISTOL

Department of Clinical
Science at South Bristol

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Learning about feet in rheumatoid arthritis

– Foot survey

Thank you for agreeing to take part in this study

We would like to know more about foot problems and how they affect people with rheumatoid arthritis (RA). We would like you to fill this questionnaire out even if your feet are not troublesome.

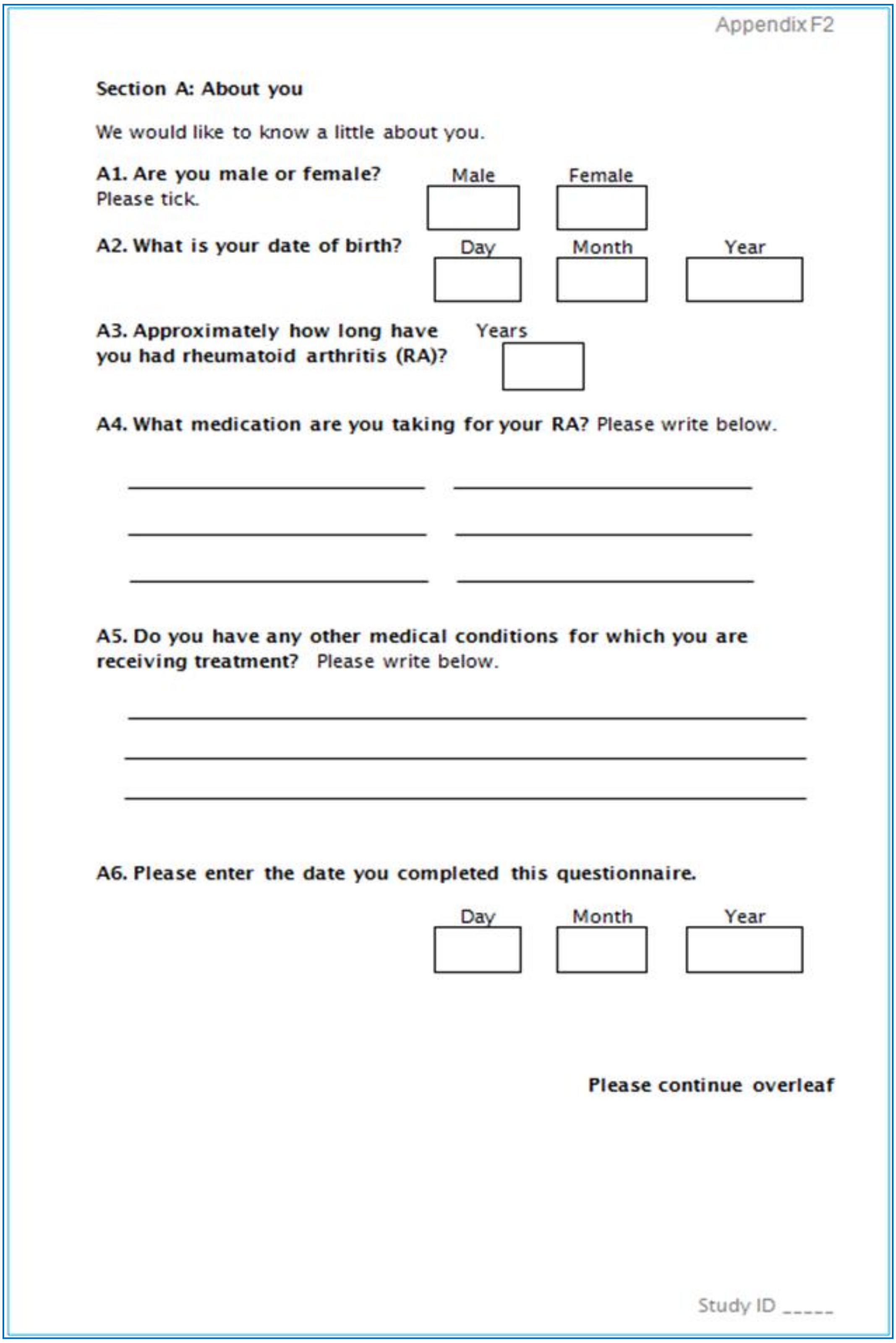
There are questions on both sides of the paper so please check that you have answered them all.

There are no right or wrong answers as we want to know about <u>your</u> feet.

Your answers will be confidential to the research team. If you have any queries about the study please contact the chief investigator, Oonagh Wilson, on 0117 342 4972

You might like to sit down with a cup of tea or coffee while you fill this in…

Please continue overleaf



Appendix F2

Section A: About you

We would like to know a little about you.

A1. Are you male or female? Please tick.

Male ☐ Female ☐

A2. What is your date of birth?

Day ☐ Month ☐ Year ☐

A3. Approximately how long have you had rheumatoid arthritis (RA)?

Years ☐

A4. What medication are you taking for your RA? Please write below.

________________ ________________

________________ ________________

________________ ________________

A5. Do you have any other medical conditions for which you are receiving treatment? Please write below.

____

____

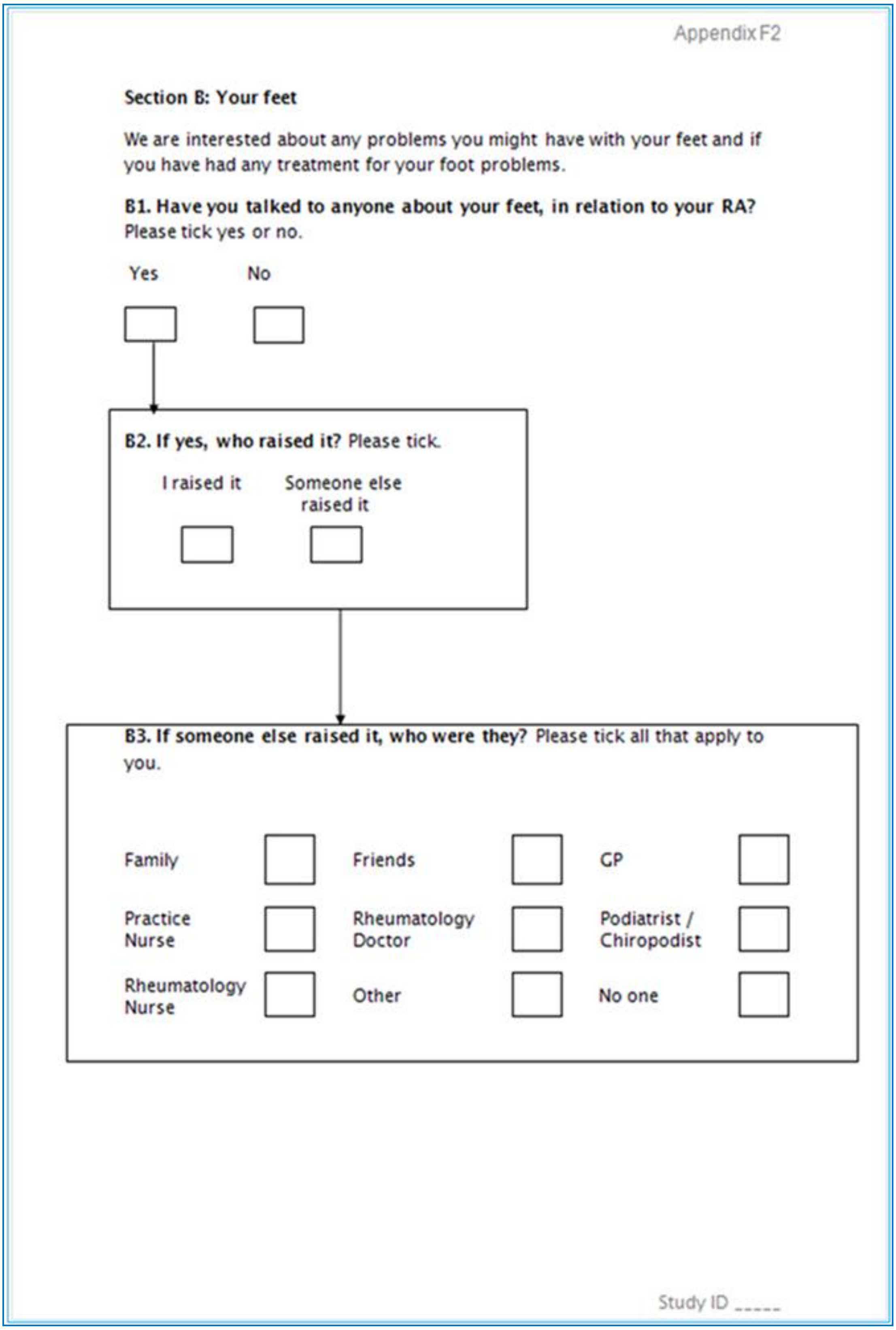
____

A6. Please enter the date you completed this questionnaire.

Day ☐ Month ☐ Year ☐

Please continue overleaf

Study ID _____



Section B: Your feet

We are interested about any problems you might have with your feet and if you have had any treatment for your foot problems.

B1. Have you talked to anyone about your feet, in relation to your RA? Please tick yes or no.

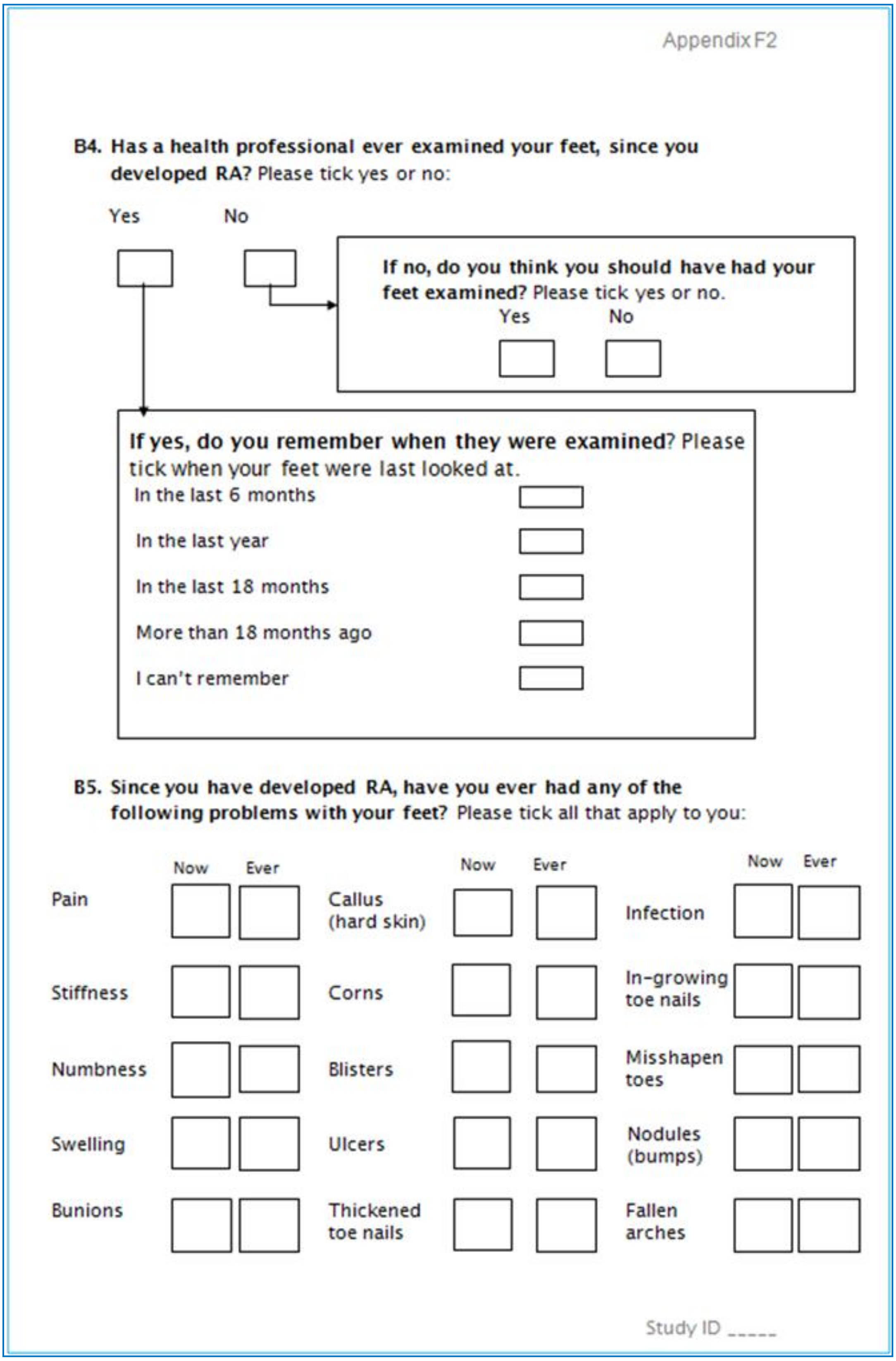
Yes ☐ No ☐

B2. If yes, who raised it? Please tick.

I raised it ☐ Someone else raised it ☐

B3. If someone else raised it, who were they? Please tick all that apply to you.

Family	☐	Friends	☐	GP	☐
Practice Nurse	☐	Rheumatology Doctor	☐	Podiatrist / Chiropodist	☐
Rheumatology Nurse	☐	Other	☐	No one	☐



B4. Has a health professional ever examined your feet, since you developed RA? Please tick yes or no:

Yes ☐ No ☐

If no, do you think you should have had your feet examined? Please tick yes or no.

Yes ☐ No ☐

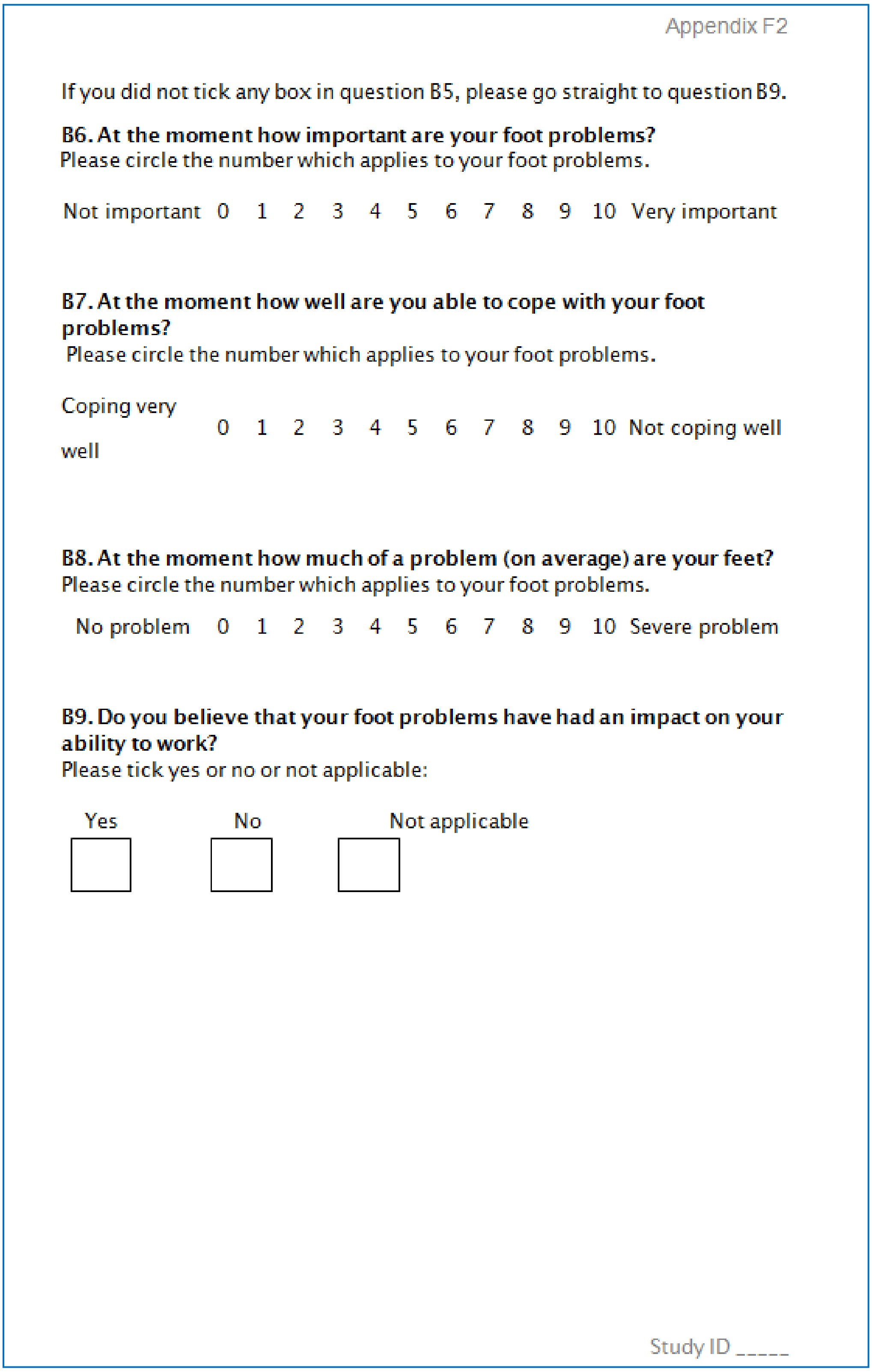
If yes, do you remember when they were examined? Please tick when your feet were last looked at.

In the last 6 months ☐
In the last year ☐
In the last 18 months ☐
More than 18 months ago ☐
I can't remember ☐

B5. Since you have developed RA, have you ever had any of the following problems with your feet? Please tick all that apply to you:

	Now	Ever		Now	Ever		Now	Ever
Pain	☐	☐	Callus (hard skin)	☐	☐	Infection	☐	☐
Stiffness	☐	☐	Corns	☐	☐	In-growing toe nails	☐	☐
Numbness	☐	☐	Blisters	☐	☐	Misshapen toes	☐	☐
Swelling	☐	☐	Ulcers	☐	☐	Nodules (bumps)	☐	☐
Bunions	☐	☐	Thickened toe nails	☐	☐	Fallen arches	☐	☐

Study ID _____



If you did not tick any box in question B5, please go straight to question B9.

B6. At the moment how important are your foot problems?
Please circle the number which applies to your foot problems.

Not important 0 1 2 3 4 5 6 7 8 9 10 Very important

B7. At the moment how well are you able to cope with your foot problems?
Please circle the number which applies to your foot problems.

Coping very well 0 1 2 3 4 5 6 7 8 9 10 Not coping well

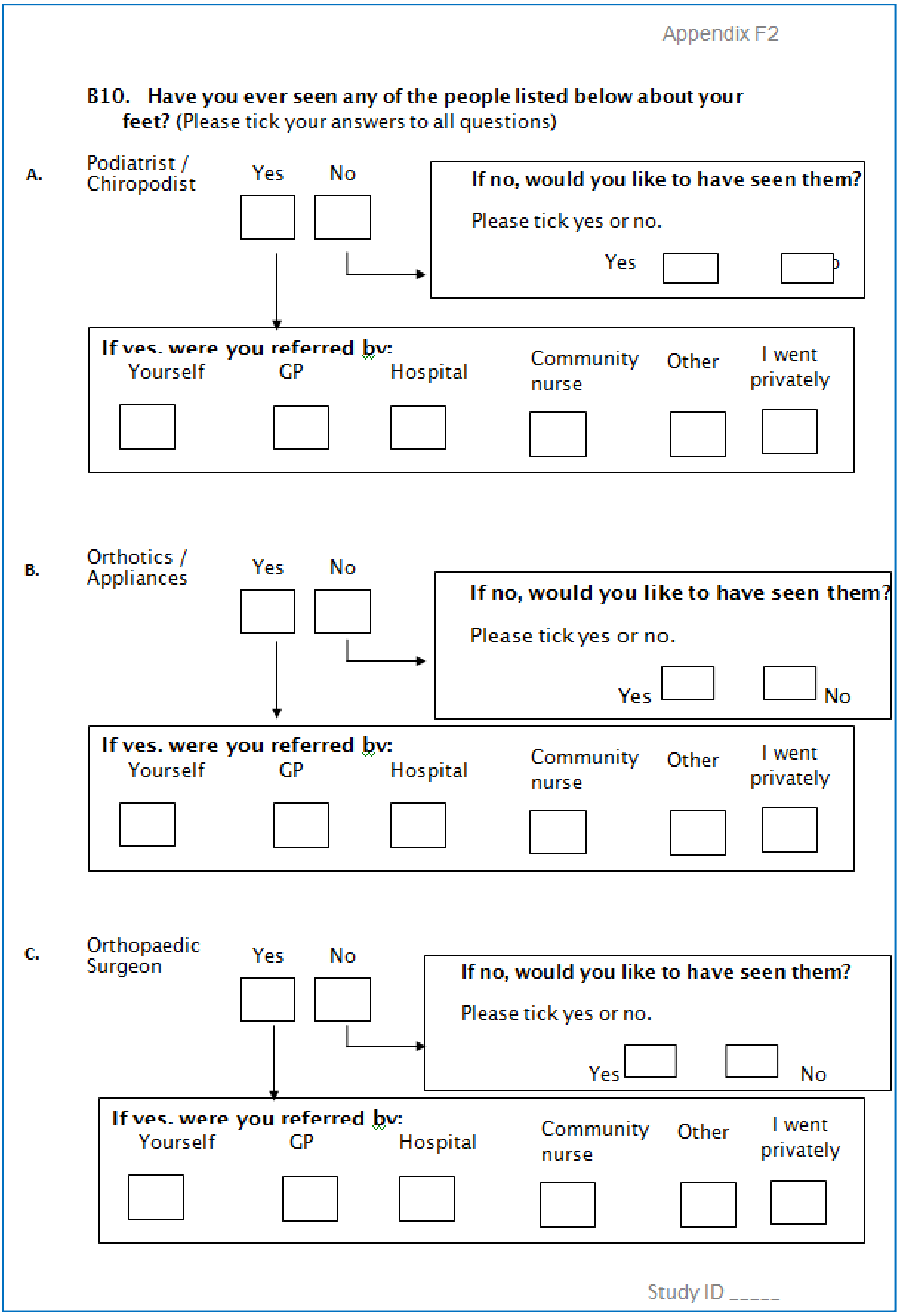
B8. At the moment how much of a problem (on average) are your feet?
Please circle the number which applies to your foot problems.

No problem 0 1 2 3 4 5 6 7 8 9 10 Severe problem

B9. Do you believe that your foot problems have had an impact on your ability to work?
Please tick yes or no or not applicable:

Yes ☐ No ☐ Not applicable ☐

Study ID _____



B10. Have you ever seen any of the people listed below about your feet? (Please tick your answers to all questions)

A. Podiatrist / Chiropodist

Yes ☐ No ☐

If no, would you like to have seen them?

Please tick yes or no.

Yes ☐ ☐

If yes, were you referred by:

Yourself	GP	Hospital	Community nurse	Other	I went privately
☐	☐	☐	☐	☐	☐

B. Orthotics / Appliances

Yes ☐ No ☐

If no, would you like to have seen them?

Please tick yes or no.

Yes ☐ ☐ No

If yes, were you referred by:

Yourself	GP	Hospital	Community nurse	Other	I went privately
☐	☐	☐	☐	☐	☐

C. Orthopaedic Surgeon

Yes ☐ No ☐

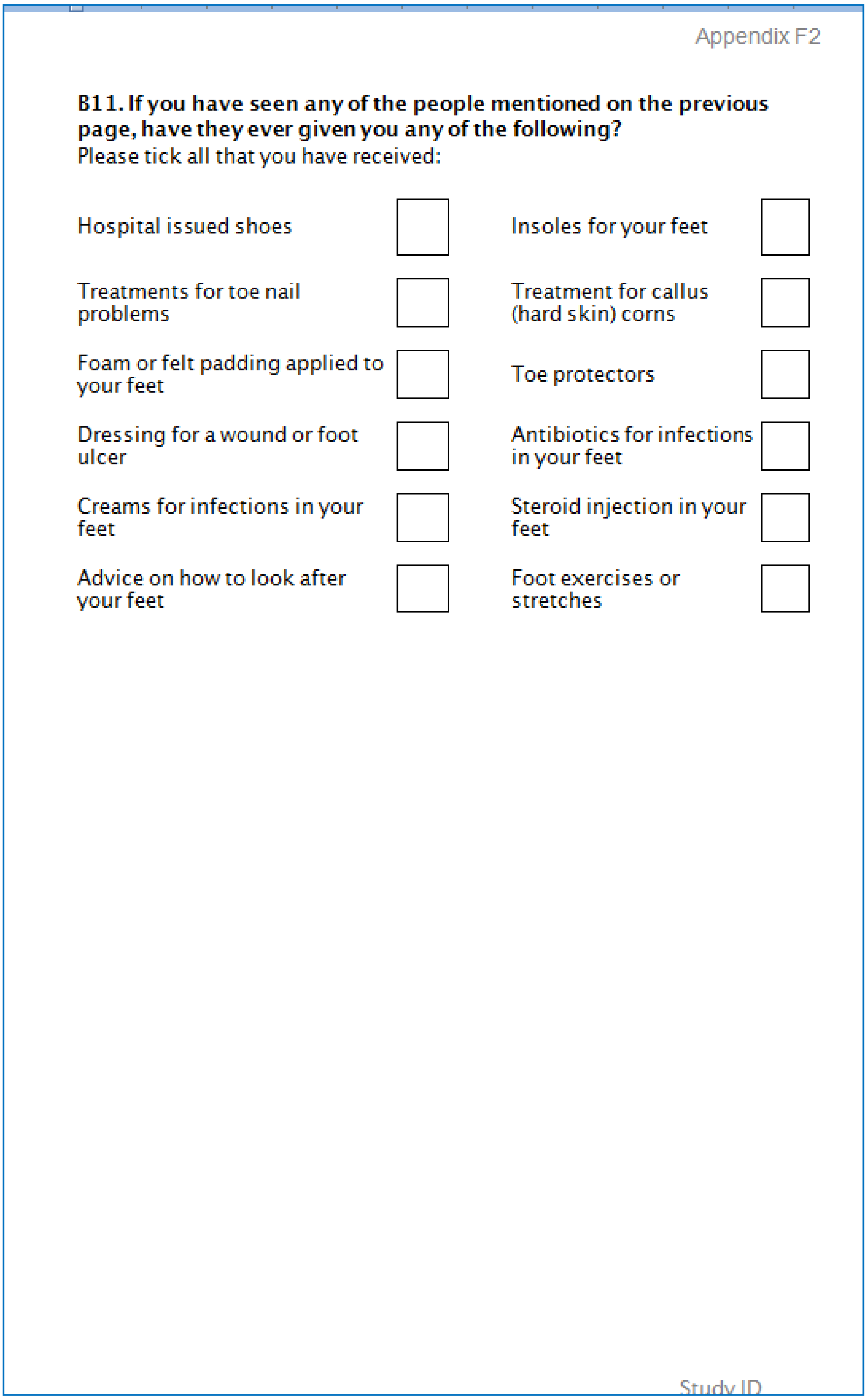
If no, would you like to have seen them?

Please tick yes or no.

Yes ☐ ☐ No

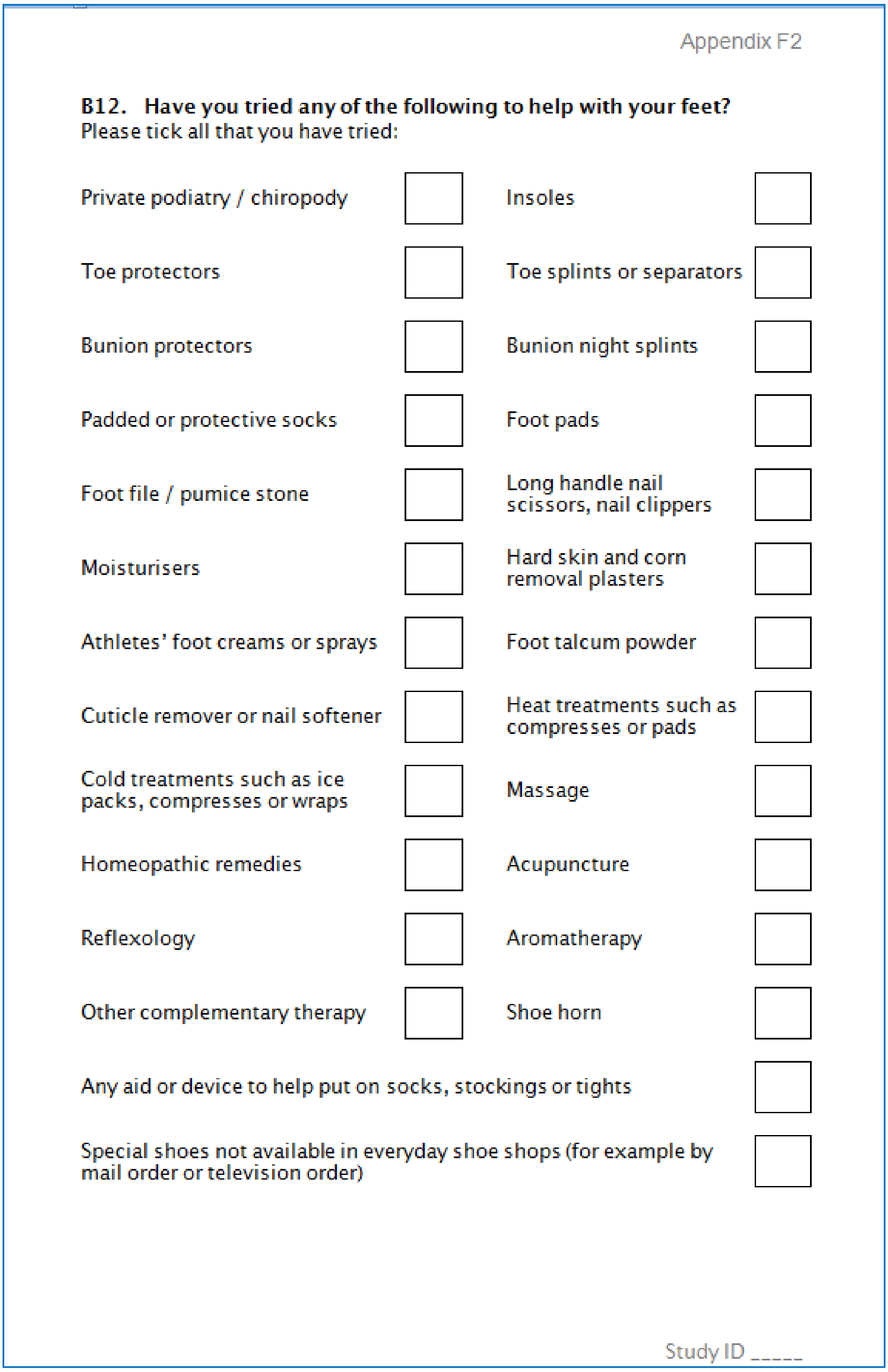
If yes, were you referred by:

Yourself	GP	Hospital	Community nurse	Other	I went privately
☐	☐	☐	☐	☐	☐



B11. If you have seen any of the people mentioned on the previous page, have they ever given you any of the following?
Please tick all that you have received:

- Hospital issued shoes ☐
- Treatments for toe nail problems ☐
- Foam or felt padding applied to your feet ☐
- Dressing for a wound or foot ulcer ☐
- Creams for infections in your feet ☐
- Advice on how to look after your feet ☐
- Insoles for your feet ☐
- Treatment for callus (hard skin) corns ☐
- Toe protectors ☐
- Antibiotics for infections in your feet ☐
- Steroid injection in your feet ☐
- Foot exercises or stretches ☐

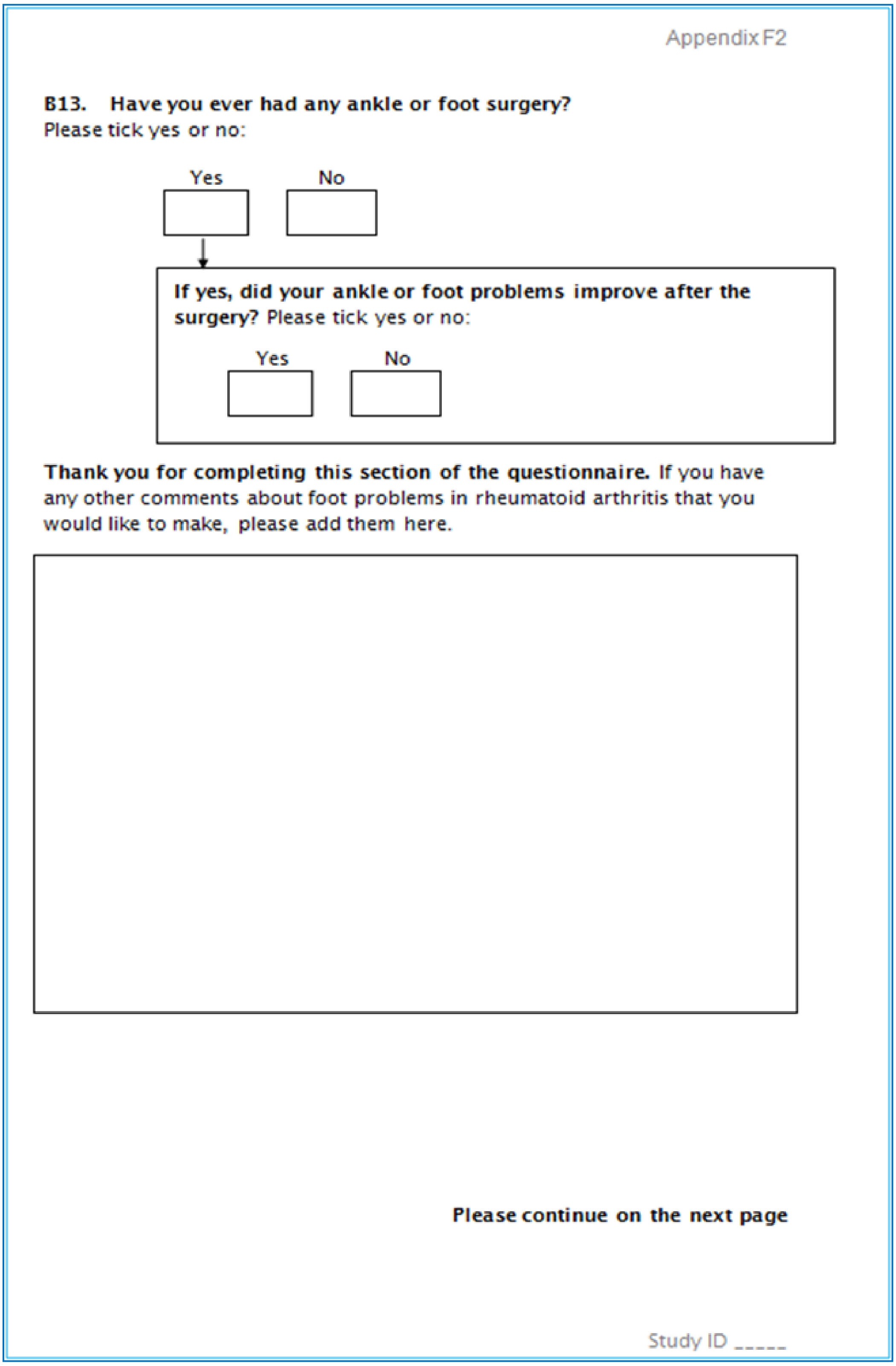


Appendix F2

B12. Have you tried any of the following to help with your feet?
Please tick all that you have tried:

- Private podiatry / chiropody ☐
- Toe protectors ☐
- Bunion protectors ☐
- Padded or protective socks ☐
- Foot file / pumice stone ☐
- Moisturisers ☐
- Athletes' foot creams or sprays ☐
- Cuticle remover or nail softener ☐
- Cold treatments such as ice packs, compresses or wraps ☐
- Homeopathic remedies ☐
- Reflexology ☐
- Other complementary therapy ☐
- Insoles ☐
- Toe splints or separators ☐
- Bunion night splints ☐
- Foot pads ☐
- Long handle nail scissors, nail clippers ☐
- Hard skin and corn removal plasters ☐
- Foot talcum powder ☐
- Heat treatments such as compresses or pads ☐
- Massage ☐
- Acupuncture ☐
- Aromatherapy ☐
- Shoe horn ☐
- Any aid or device to help put on socks, stockings or tights ☐
- Special shoes not available in everyday shoe shops (for example by mail order or television order) ☐

Study ID _____



Appendix F2

B13. Have you ever had any ankle or foot surgery?
Please tick yes or no:

Yes ☐ No ☐

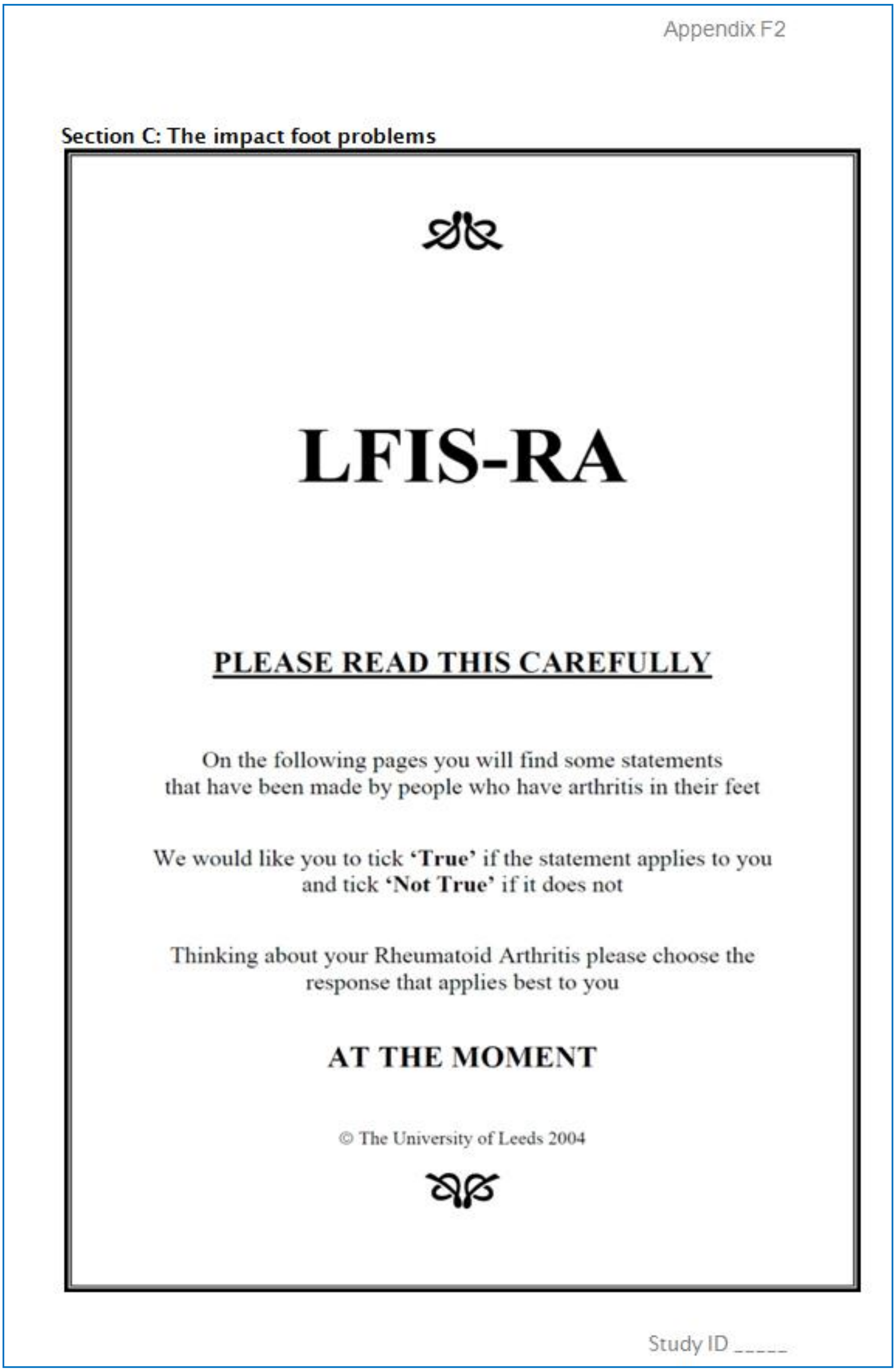
If yes, did your ankle or foot problems improve after the surgery? Please tick yes or no:

Yes ☐ No ☐

Thank you for completing this section of the questionnaire. If you have any other comments about foot problems in rheumatoid arthritis that you would like to make, please add them here.

Please continue on the next page

Study ID _____



Section C: The impact foot problems

LFIS-RA

PLEASE READ THIS CAREFULLY

On the following pages you will find some statements
that have been made by people who have arthritis in their feet

We would like you to tick **'True'** if the statement applies to you
and tick **'Not True'** if it does not

Thinking about your Rheumatoid Arthritis please choose the
response that applies best to you

AT THE MOMENT

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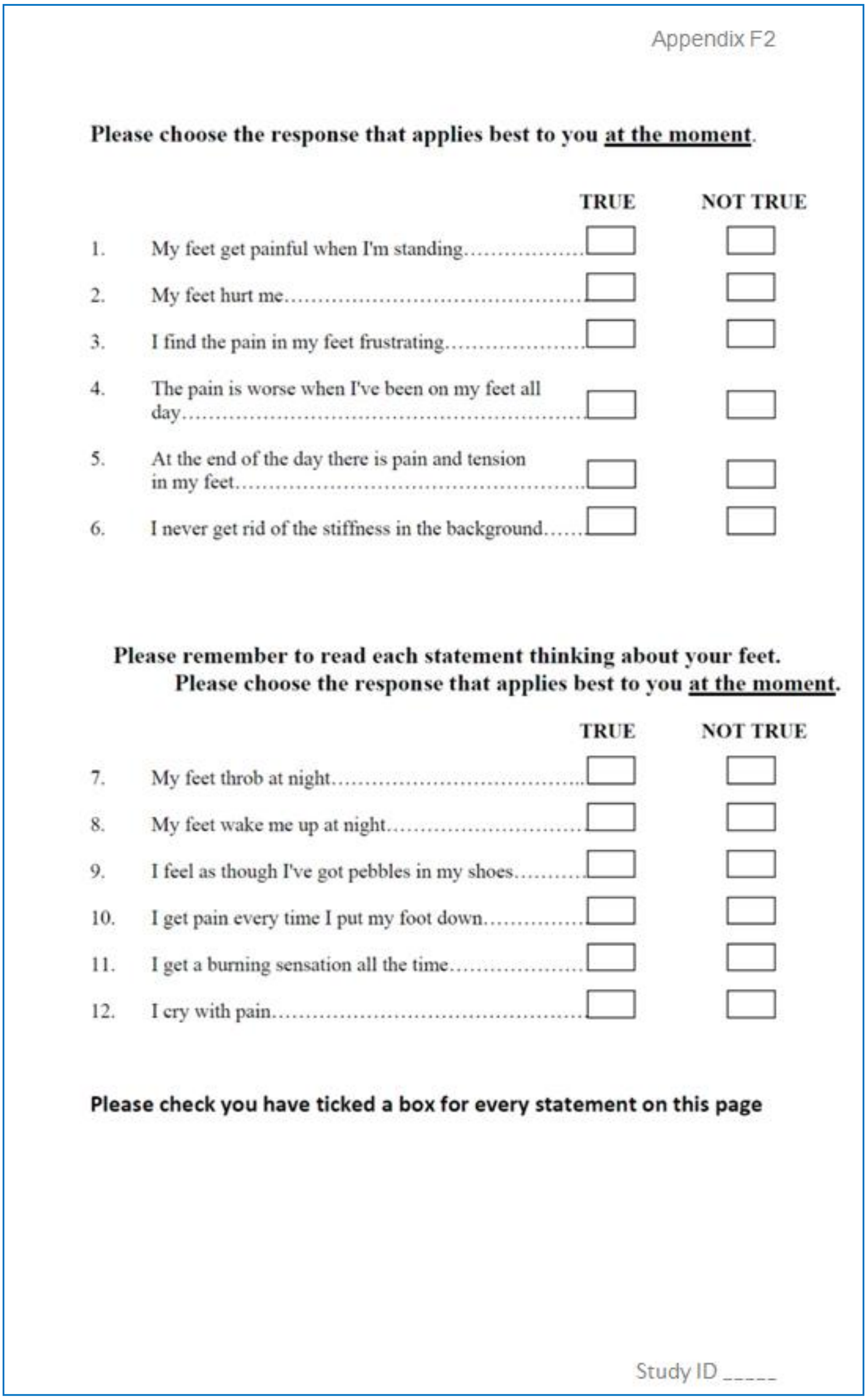
Study ID _____



Please choose the response that applies best to you at the moment.

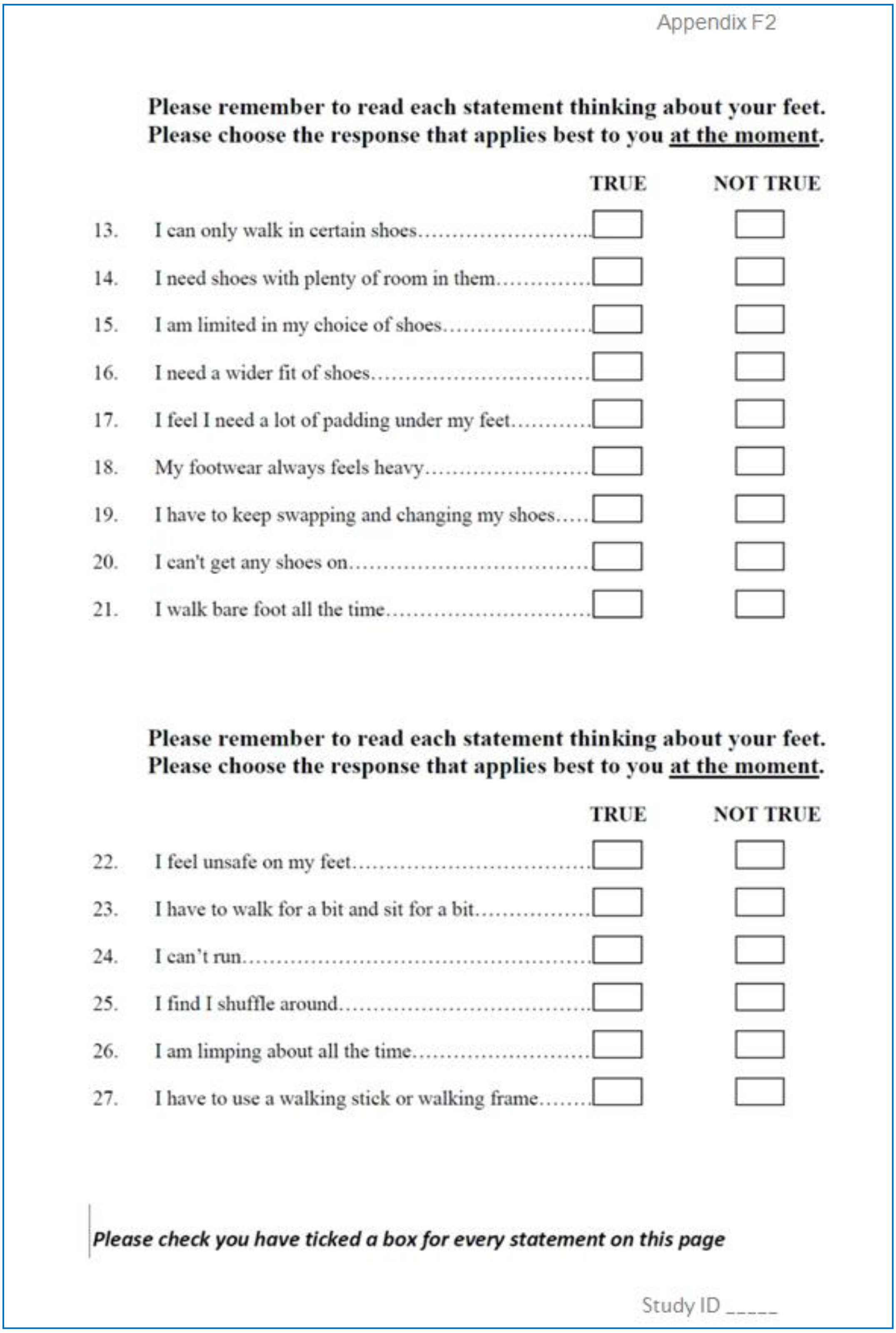
		TRUE	NOT TRUE
1.	My feet get painful when I'm standing………………	☐	☐
2.	My feet hurt me……………………………………	☐	☐
3.	I find the pain in my feet frustrating…………………	☐	☐
4.	The pain is worse when I've been on my feet all day………………………………………………	☐	☐
5.	At the end of the day there is pain and tension in my feet………………………………………	☐	☐
6.	I never get rid of the stiffness in the background……	☐	☐

Please remember to read each statement thinking about your feet.
Please choose the response that applies best to you at the moment.

		TRUE	NOT TRUE
7.	My feet throb at night……………………………….	☐	☐
8.	My feet wake me up at night…………………………	☐	☐
9.	I feel as though I've got pebbles in my shoes……….	☐	☐
10.	I get pain every time I put my foot down……………	☐	☐
11.	I get a burning sensation all the time…………………	☐	☐
12.	I cry with pain………………………………………	☐	☐

Please check you have ticked a box for every statement on this page

Study ID _____



Please remember to read each statement thinking about your feet.
Please choose the response that applies best to you <u>at the moment</u>.

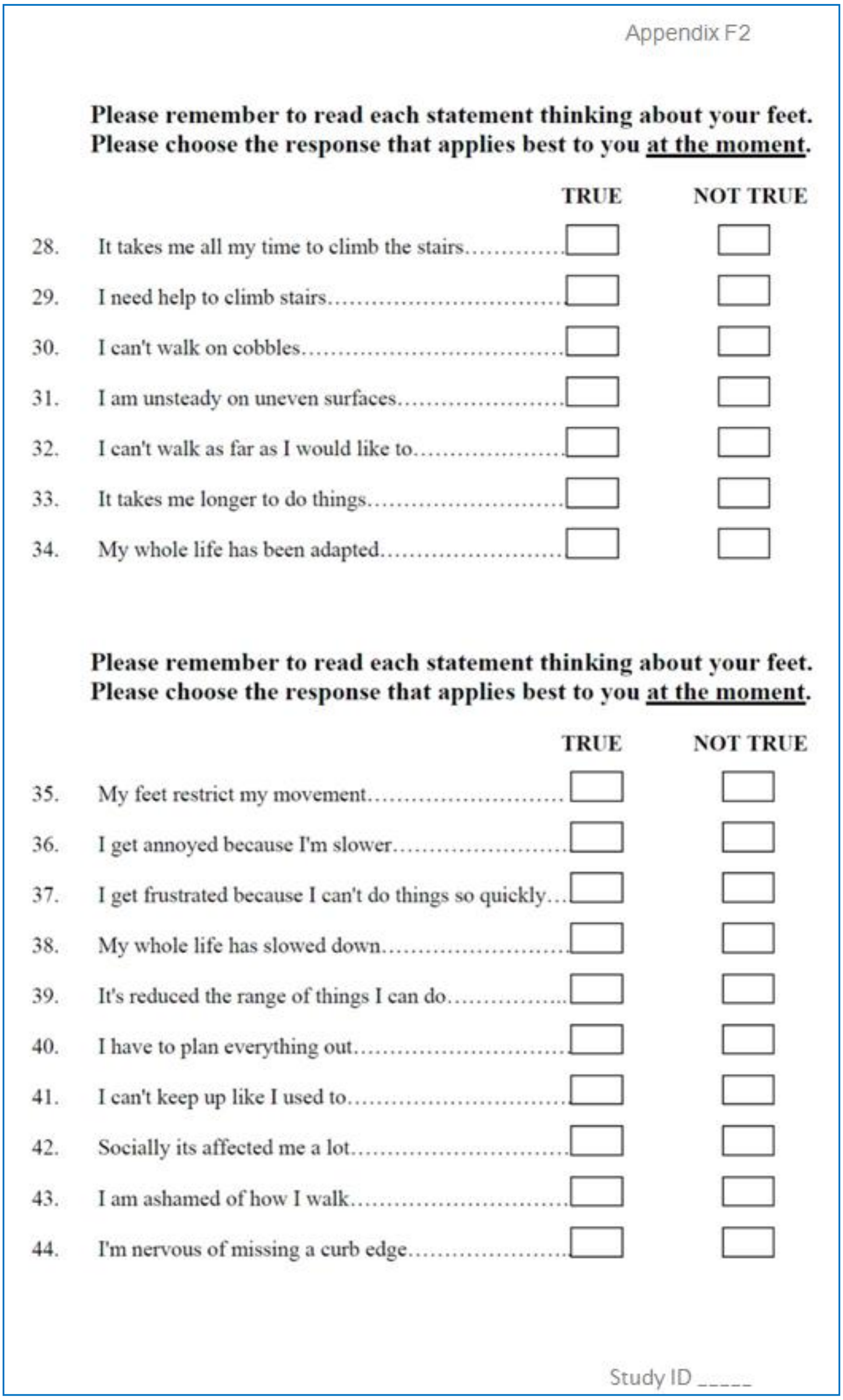
		TRUE	NOT TRUE
13.	I can only walk in certain shoes........................	☐	☐
14.	I need shoes with plenty of room in them.............	☐	☐
15.	I am limited in my choice of shoes.....................	☐	☐
16.	I need a wider fit of shoes...............................	☐	☐
17.	I feel I need a lot of padding under my feet...........	☐	☐
18.	My footwear always feels heavy........................	☐	☐
19.	I have to keep swapping and changing my shoes.....	☐	☐
20.	I can't get any shoes on..................................	☐	☐
21.	I walk bare foot all the time.............................	☐	☐

Please remember to read each statement thinking about your feet.
Please choose the response that applies best to you <u>at the moment</u>.

		TRUE	NOT TRUE
22.	I feel unsafe on my feet..................................	☐	☐
23.	I have to walk for a bit and sit for a bit................	☐	☐
24.	I can't run..	☐	☐
25.	I find I shuffle around.....................................	☐	☐
26.	I am limping about all the time..........................	☐	☐
27.	I have to use a walking stick or walking frame........	☐	☐

Please check you have ticked a box for every statement on this page

Study ID _____



Appendix F2

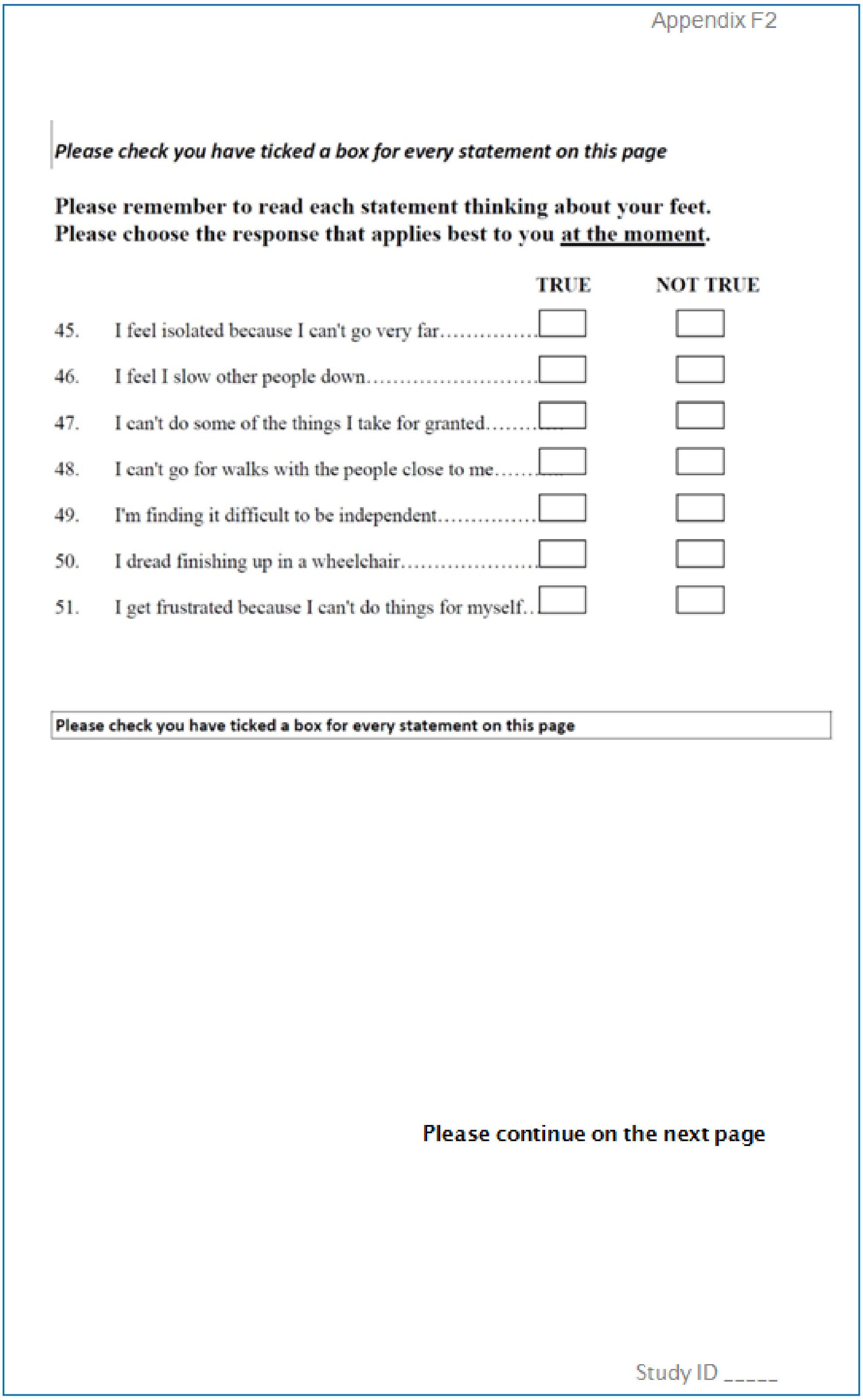
Please remember to read each statement thinking about your feet. Please choose the response that applies best to you <u>at the moment</u>.

		TRUE	**NOT TRUE**
28.	It takes me all my time to climb the stairs	☐	☐
29.	I need help to climb stairs	☐	☐
30.	I can't walk on cobbles	☐	☐
31.	I am unsteady on uneven surfaces	☐	☐
32.	I can't walk as far as I would like to	☐	☐
33.	It takes me longer to do things	☐	☐
34.	My whole life has been adapted	☐	☐

Please remember to read each statement thinking about your feet. Please choose the response that applies best to you <u>at the moment</u>.

		TRUE	**NOT TRUE**
35.	My feet restrict my movement	☐	☐
36.	I get annoyed because I'm slower	☐	☐
37.	I get frustrated because I can't do things so quickly	☐	☐
38.	My whole life has slowed down	☐	☐
39.	It's reduced the range of things I can do	☐	☐
40.	I have to plan everything out	☐	☐
41.	I can't keep up like I used to	☐	☐
42.	Socially its affected me a lot	☐	☐
43.	I am ashamed of how I walk	☐	☐
44.	I'm nervous of missing a curb edge	☐	☐

Study ID _____



Please check you have ticked a box for every statement on this page

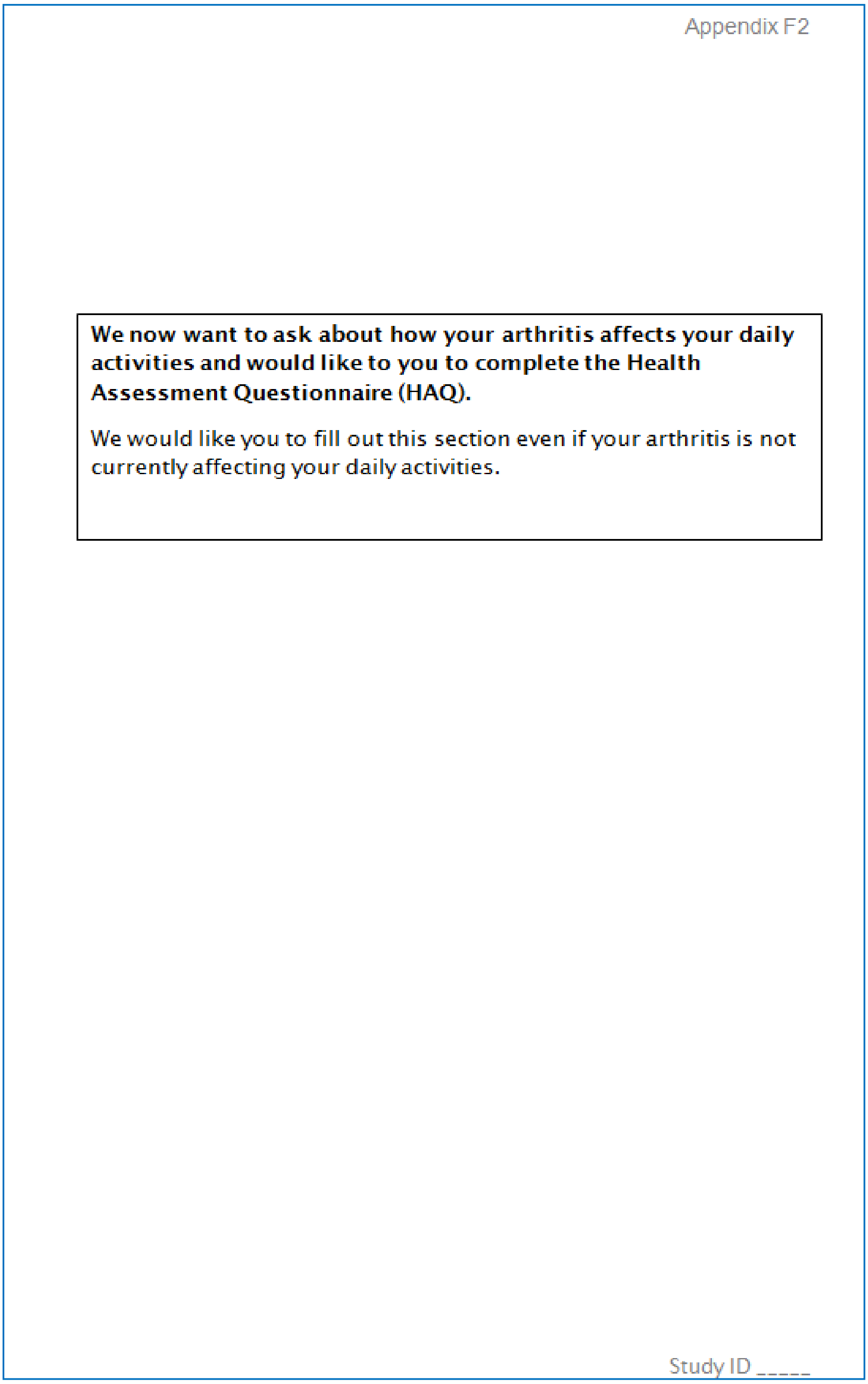
Please remember to read each statement thinking about your feet.
Please choose the response that applies best to you __at the moment__.

		TRUE	NOT TRUE
45.	I feel isolated because I can't go very far..............	☐	☐
46.	I feel I slow other people down..........................	☐	☐
47.	I can't do some of the things I take for granted........	☐	☐
48.	I can't go for walks with the people close to me......	☐	☐
49.	I'm finding it difficult to be independent..............	☐	☐
50.	I dread finishing up in a wheelchair....................	☐	☐
51.	I get frustrated because I can't do things for myself..	☐	☐

Please check you have ticked a box for every statement on this page

Please continue on the next page

Study ID _____

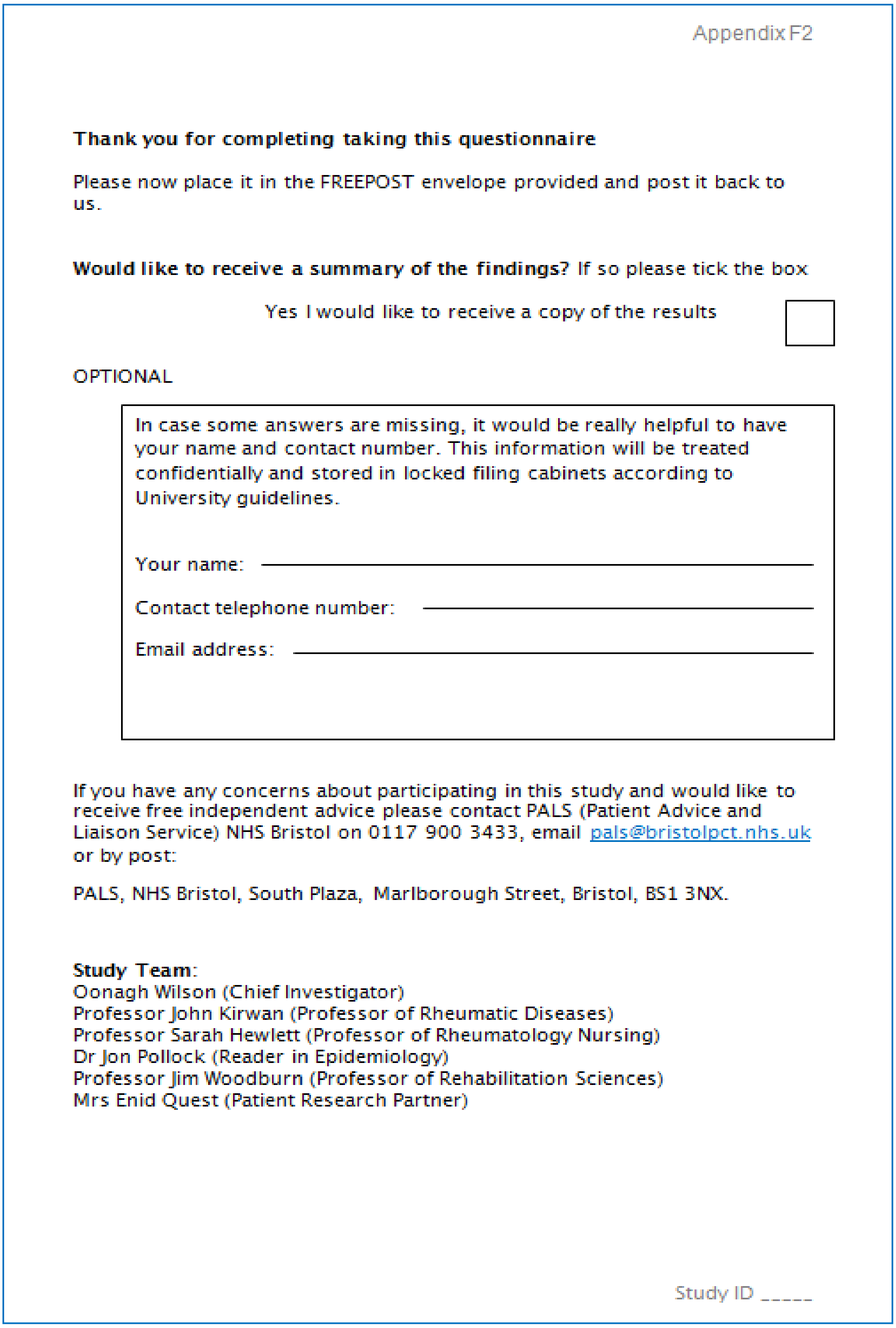


We now want to ask about how your arthritis affects your daily activities and would like to you to complete the Health Assessment Questionnaire (HAQ).

We would like you to fill out this section even if your arthritis is not currently affecting your daily activities.

Study ID _____

Followed by HAQ (as in Appendix D2).



Appendix F2

Thank you for completing taking this questionnaire

Please now place it in the FREEPOST envelope provided and post it back to us.

Would like to receive a summary of the findings? If so please tick the box

Yes I would like to receive a copy of the results ☐

OPTIONAL

In case some answers are missing, it would be really helpful to have your name and contact number. This information will be treated confidentially and stored in locked filing cabinets according to University guidelines.

Your name: ____________________

Contact telephone number: ____________________

Email address: ____________________

If you have any concerns about participating in this study and would like to receive free independent advice please contact PALS (Patient Advice and Liaison Service) NHS Bristol on 0117 900 3433, email pals@bristolpct.nhs.uk or by post:

PALS, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX.

Study Team:
Oonagh Wilson (Chief Investigator)
Professor John Kirwan (Professor of Rheumatic Diseases)
Professor Sarah Hewlett (Professor of Rheumatology Nursing)
Dr Jon Pollock (Reader in Epidemiology)
Professor Jim Woodburn (Professor of Rehabilitation Sciences)
Mrs Enid Quest (Patient Research Partner)

Study ID _____

Appendix G1: Study 3 Patient information Sheet

UWE BRISTOL University of the West of England
Department of Nursing and Midwifery

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

University of BRISTOL
School of Clinical Sciences

Learning about feet in rheumatoid arthritis

Clinical assessment - Patient information sheet

Introduction:
You recently took part in a survey to find out how many people with rheumatoid arthritis (RA) have problems with their feet. We are now inviting some of the people who took part in the survey to help us once more, by coming in to have their feet examined.

Before you decide to take part in our research, it is important to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or you would like more information.

Who is asking me to take part?
I am Oonagh Wilson, a PhD student at the University of the West of England. This research study is the second of two research studies which will form part of my PhD.

What is the purpose of the study?
We have conducted a questionnaire survey to find out about the type of foot problems which can affect people with RA. Thank you for your help with that survey. We now want to check the feet of some of the people who told us they had foot problems, and some who felt they had not. This will help us understand the type of foot problems people have and whether they have been able to access foot care. This will help us plan future services.

What will happen during the study?
You will be asked to attend your rheumatology department for a research appointment. This will involve a clinical interview when you will be asked about your arthritis in general and your feet examined. The research appointment will be with a podiatrist (a health professional who manages problems with the feet and ankle). Before the research appointment, the podiatrist will ask you to read and sign the consent form and ask you some questions about your medical history.

You will be asked about your arthritis and your feet, whether you have received any treatment for these problems and if you did, what was your experience. You will also have your feet examined (no treatment will be given). The research appointment will last for about an hour. We will offer you refreshments and are happy to pay your travel costs.

The podiatrist will make a record of your foot problems and if you have received any treatment for your feet. All the information from the research appointment will be confidential. The only people who will know which research appointment record belongs to each patient will be the podiatrist and the principal investigator (Oonagh Wilson).

Why have I been chosen?
You have been chosen because you have a diagnosis of RA and because you kindly replied to our earlier survey.

We will be inviting approximately 120 people to take part within the Bristol area from both Bristol Royal Infirmary and North Bristol NHS Trust Rheumatology Departments.

Do I have to take part in the study?
No, you do not have to take part. If you do decide to take part you will be given a copy of the information sheet and a signed consent form to keep and a copy will be kept in your hospital records.

If you decide to take part, you are still free to withdraw from the study at any time and do not need to give a reason for doing so. If you decide to withdraw or not take part, this will not affect the standard of care you receive from any hospital or your GP.

What are the risks or benefits of the study?
We do not believe there are any risks in being involved in this study. We appreciate that there may be some inconvenience to you by having to come into the hospital for a research appointment. However we will try and minimize this by arranging a suitable date and time for you to come which is convenient.

If the podiatrist who examines you feels you have a foot problem that requires treatment, you will be advised to contact your GP or rheumatology department via your specialist nurse telephone helpline.

There are no personal benefits to you in taking part in this study. However, you will be helping us to have a clearer understanding of how many people with RA have foot problems, the type of problems they have and whether they have been able to access foot care services. This will help us plan future services and understand how to improve access to care, and to provide people with RA better help in the future.

Will my taking part in the study be kept confidential?
Yes. When the record of the research appointment is given to the principal researcher (Oonagh Wilson), your name will be replaced by a code. No one will be able to identify you from the research appointment record. The study reports will include a summary of foot problems and how many people are receiving foot care and if not why not. Your name will not be used in the reports. The study records will be kept securely for 6 years and then destroyed, in accordance with best practice in research guidelines.

What will happen to the results of this research study?

Results will be presented at conferences and in professional journals. The results should be ready for publication about a year after the completion of the study. No identification of any of the study participants will be possible from any publications of the research. The findings of the study will help with recommendations for the care of foot problems in people with RA. We will also offer participants the opportunity to hear the results at the end of the study.

Who is funding the research and who has reviewed the research?
The research has been funded by the National Institute for Health Research (NIHR), the research arm of the NHS. The study has been peer reviewed by the NIHR and the University of the West of England Research Degree Committee and has been approved by a NHS Research Ethics Committee (South West 4). A research ethics committee is a group of people who look at research study plans to see whether they have been properly thought out and prepared. The committee usually includes doctors, nurses, lawyers and members of the public. They are responsible for checking that the best interests of people taking part in research have been considered. The Research and Development Department at two local hospital trusts have also reviewed and approved this study.

What do I do now?
Thank you for considering taking part in this research. Please complete the slip and return it in the pre-paid reply envelope. The principal researcher (Oonagh Wilson) will contact you with further information.

If you have any concerns about participating in this study and would like to receive free independent advice please contact PALS (Patient Advice and Liaison Service) NHS Bristol on 0117 900 3433, email pals@bristolpct.nhs.uk or by post:
PALS, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX.

Researcher details:

Oonagh Wilson
Academic Rheumatology Unit,
Bristol Royal Infirmary
Bristol
BS2 8HW
0117 342 4972
Oonagh2.Wilson@uwe.ac.uk

Professor John Kirwan
Academic Rheumatology Department
Bristol Royal Infirmary
Bristol
BS2 8HW
0117 342 2901
John.Kirwan@bristol.ac.uk

Research team:

Oonagh Wilson, NIHR Clinical Doctoral Research Fellow, UWE Bristol
Professor John Kirwan, Professor of Rheumatic Diseases, UoB Bristol
Professor Sarah Hewlett, Professor of Rheumatology Nursing, UWE Bristol
Dr Jon Pollock, Reader in Epidemiology, UWE Bristol
Professor Jim Woodburn, Professor of Rehabilitation GCAL Glasgow
Mrs Enid Quest, Patient Research Partner
Mrs Wendy Briggs HPC Registered Podiatrist

Appendix G2: Study 3 invitation letter

University of the West of England
BRISTOL
Department of Nursing and Midwifery

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

University of BRISTOL
School of Clinical Sciences

Date

Dear

Learning about feet in rheumatoid arthritis – Clinical assessment

You recently took part in a survey to help us find out how many people with rheumatoid arthritis (RA) have problems with their feet. Thank you very much for helping us with the survey.

We are now inviting some of the people who took part in the survey to help us once more, by having their feet examined.

Enclosed with this letter is a patient information sheet that explains about the research study. If you would like to take part, please complete the reply slip and return it in the stamped addressed envelope provided.

Thank you for your interest and I hope you will be able to help us again by taking part in this last phase of the study.

Yours sincerely

Oonagh Wilson
NIHR Clinical Doctoral Research Fellow
University of the West of England, Bristol
Academic Rheumatology Unit, The Court Yard
Bristol Royal Infirmary, BS2 8HW
Tel: 0117 342 4972

Appendix G3: Study 3 reply slip

UWE
BRISTOL
University of the
West of England
Department of Nursing and
Midwifery

ARTHRITIS · RESEARCH · CARE · EDUCATION

University of
BRISTOL
School of Clinical Sciences

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Learning about feet in rheumatoid arthritis

Clinical assessment study – reply slip

YES ☐ I am interested in helping with the study and may be contacted by Oonagh Wilson

NO ☐ I am not interested in helping with the study

Name:

Thank you for your interest

Oonagh Wilson
Researcher
Academic Rheumatology Unit
Bristol Royal Infirmary
0117 342 4972

Study ID _ _ _ _ _ _

Prof John Kirwan, BSc, MD, FRCP, Consultant Rheumatologist & Professor of Rheumatic Diseases, Tel: +44 (0)117 342 2904 John.Kirwan@Bristol.ac.uk GMC No. 2247924
Dr Robert W. Marshall, BSc, MRCP, Consultant Rheumatologist & Clinical Tutor, Tel: +44 (0)117 342 4976 Robert.Marshall@UHBristol.nhs.uk GMC No. 4322683
Prof Sarah Hewlett, PhD, MA, RGN, ARC Professor of Rheumatology & Nursing & Hon, Consultant Nurse. Tel: +44 (0)117 342 2903 Sarah.Hewlett@uwe.ac.uk
Dr Shane Clarke, MD, PACME, FRCP, Consultant Rheumatologist & Hon. Senior Clinical Lecturer, Tel: +44 (0)117 342 2957 S.Clarke@Bristol.ac.uk GMC No. 3538942
Dr Shea Palmer, PhD, MCSP FHEA, Principal Lecturer in Physiotherapy & Hon, Senior Clinical Lecturer Tel: +44 (0)117 3288919 Shea.Palmer@uwe.ac.uk
Rheumatology Unit Fax Number +44 (0)117 342 3841

Appendix G4: Study 3 appointment letter

UWE BRISTOL
University of the
West of England
Department of Nursing and
Midwifery

ARTHRITIS • RESEARCH • CARE • EDUCATION •

University of
BRISTOL
School of Clinical Sciences

**Academic Rheumatology
Unit**
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

Date

Dear

Learning about feet in rheumatoid arthritis – Clinical assessment study

You recently took part in a survey to help us find out how many people with rheumatoid arthritis (RA) have problems with their feet. Thank you very much for helping us with the survey.

We are now inviting some of the people who took part in the survey to help us once more, by having their feet examined. An appointment has been arranged for you to attend the Rheumatology Department at the BRI for a foot examination on:

Thank you for your interest and for helping us again by taking part in this last phase of the study.

Yours sincerely

Oonagh Wilson
NIHR Clinical Doctoral Research Fellow
University of the West of England, Bristol
Academic Rheumatology Unit, The Court Yard
Bristol Royal Infirmary, BS2 8HW
Tel: 0117 342 4972
Email: Oonagh2.Wilson@uwe.ac.uk

Prof John Kirwan, BSc, MD, FRCP, Consultant Rheumatologist & Professor of Rheumatic Diseases. Tel: +44 (0)117 342 2904 John.Kirwan@Bristol.ac.uk GMC No. 2247924
Dr Robert W. Marshall, BSc, MRCP, Consultant Rheumatologist & Clinical Tutor, Tel: +44 (0)117 342 4976 Robert.Marshall@UHBristol.nhs.uk GMC No. 4322683
Prof Sarah Hewlett, PhD, MA, RGN, ARC Professor of Rheumatology & Nursing & Hon, Consultant Nurse. Tel: +44 (0)117 342 2903 Sarah.Hewlett@uwe.ac.uk
Dr Shane Clarke, MD, PACME, FRCP, Consultant Rheumatologist & Hon, Senior Clinical Lecturer, Tel: +44 (0)117 342 2957 S.Clarke@Bristol.ac.uk GMC No. 3538942
Dr Shea Palmer, PhD, MCSP FHEA, Principal Lecturer in Physiotherapy & Hon, Senior Clinical Lecturer Tel: +44 (0)117 3288919 Shea.Palmer@uwe.ac.uk
Rheumatology Unit Fax Number +44 (0)117 342 3841

Appendix H1: Study 3 consent form

University of the West of England
BRISTOL
Department of Nursing and Midwifery

Academic Rheumatology Unit
The Courtyard
Bristol Royal Infirmary
Bristol BS2 8HW

University of BRISTOL
School of Clinical Sciences

Learning about feet in rheumatoid arthritis – clinical assessment study.

Consent form for research study

Please initial each box

1 I confirm that I have read and understand the information sheet version 1 dated 13th September 2011 for the above study. ☐

2 I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐

3 I am willing to have my feet examined and be asked questions about my medical history. ☐

4 I understand information from the interview will be anonymised and may be used in publications and conference presentations. ☐

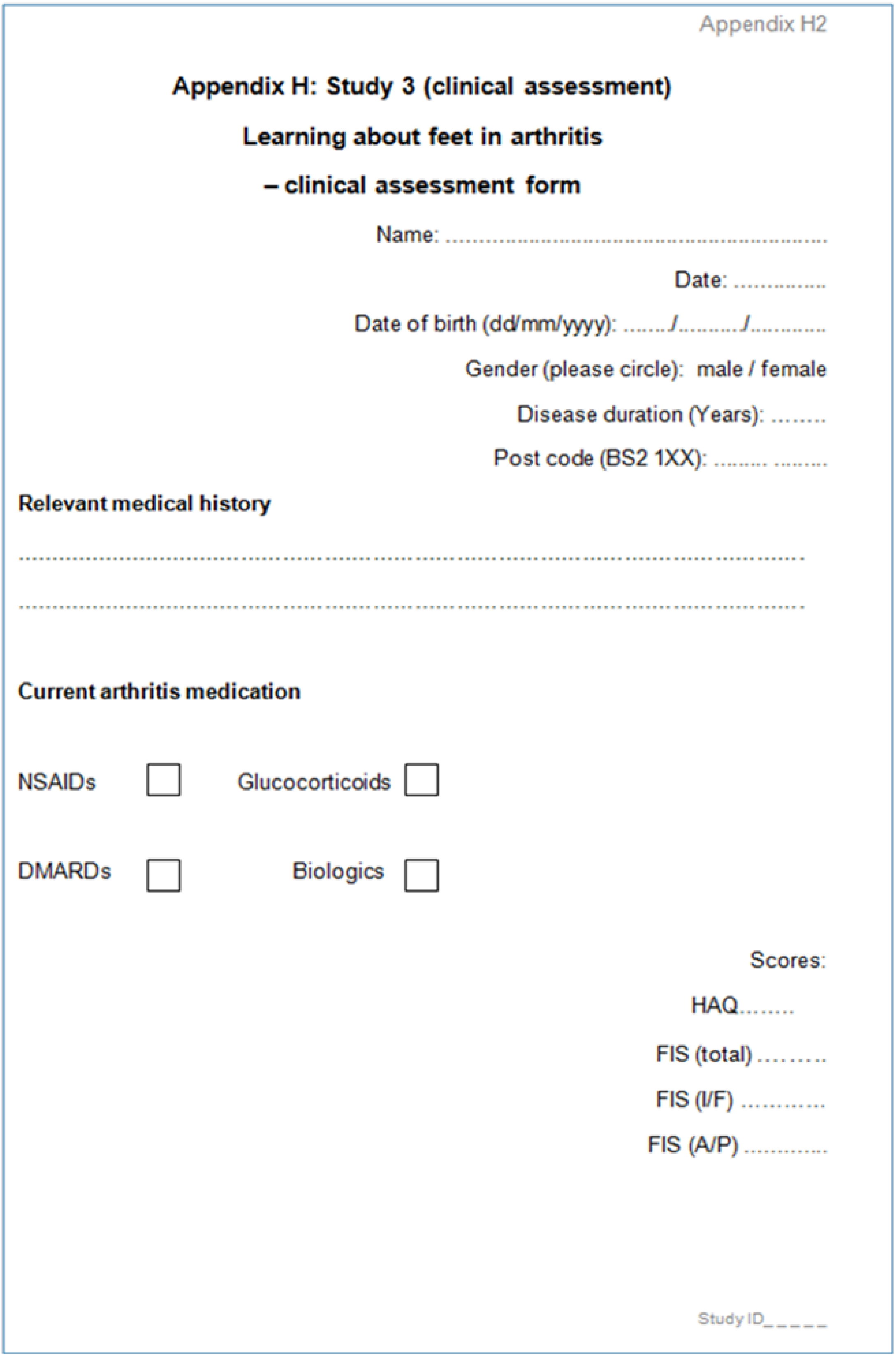
5 I understand that relevant sections of my medical notes and study data may be accessed (in confidence) by the study research team, regulatory authorities or relevant members of the NHS Trust. I give permission for these individuals to have access to my records. ☐

6 I agree to take part in the above study. ☐

Name of patient	Date	Signature
Name of researcher	Date	Signature

Prof John Kirwan, BSc, MD, FRCP, Consultant Rheumatologist & Professor of Rheumatic Diseases. Tel: +44 (0)117 342 2904 John.Kirwan@Bristol.ac.uk GMC No. 2247924
Dr Robert W. Marshall, BSc, MRCP, Consultant Rheumatologist & Clinical Tutor, Tel: +44 (0)117 342 4976 Robert.Marshall@UHBristol.nhs.uk GMC No. 4322683
Prof Sarah Hewlett, PhD, MA, RGN, ARC Professor of Rheumatology & Nursing & Hon, Consultant Nurse. Tel: +44 (0)117 342 2903 Sarah.Hewlett@uwe.ac.uk
Dr Shane Clarke, MD, PACME, FRCP, Consultant Rheumatologist & Hon, Senior Clinical Lecturer, Tel: +44 (0)117 342 2957 S.Clarke@Bristol.ac.uk GMC No. 3538942
Dr Shea Palmer, PhD, MCSP FHEA, Principal Lecturer in Physiotherapy & Hon, Senior Clinical Lecturer Tel: +44 (0)117 3288919 Shea.Palmer@uwe.ac.uk
Rheumatology Unit Fax Number +44 (0)117 342 3841

Appendix H2: Study 3 case record form



Appendix H2

Appendix H: Study 3 (clinical assessment)

Learning about feet in arthritis

– clinical assessment form

Name: ....

Date: ....

Date of birth (dd/mm/yyyy): ..../........../............

Gender (please circle): male / female

Disease duration (Years): ....

Post code (BS2 1XX): ....

Relevant medical history

....

....

Current arthritis medication

NSAIDs ☐ Glucocorticoids ☐

DMARDs ☐ Biologics ☐

Scores:

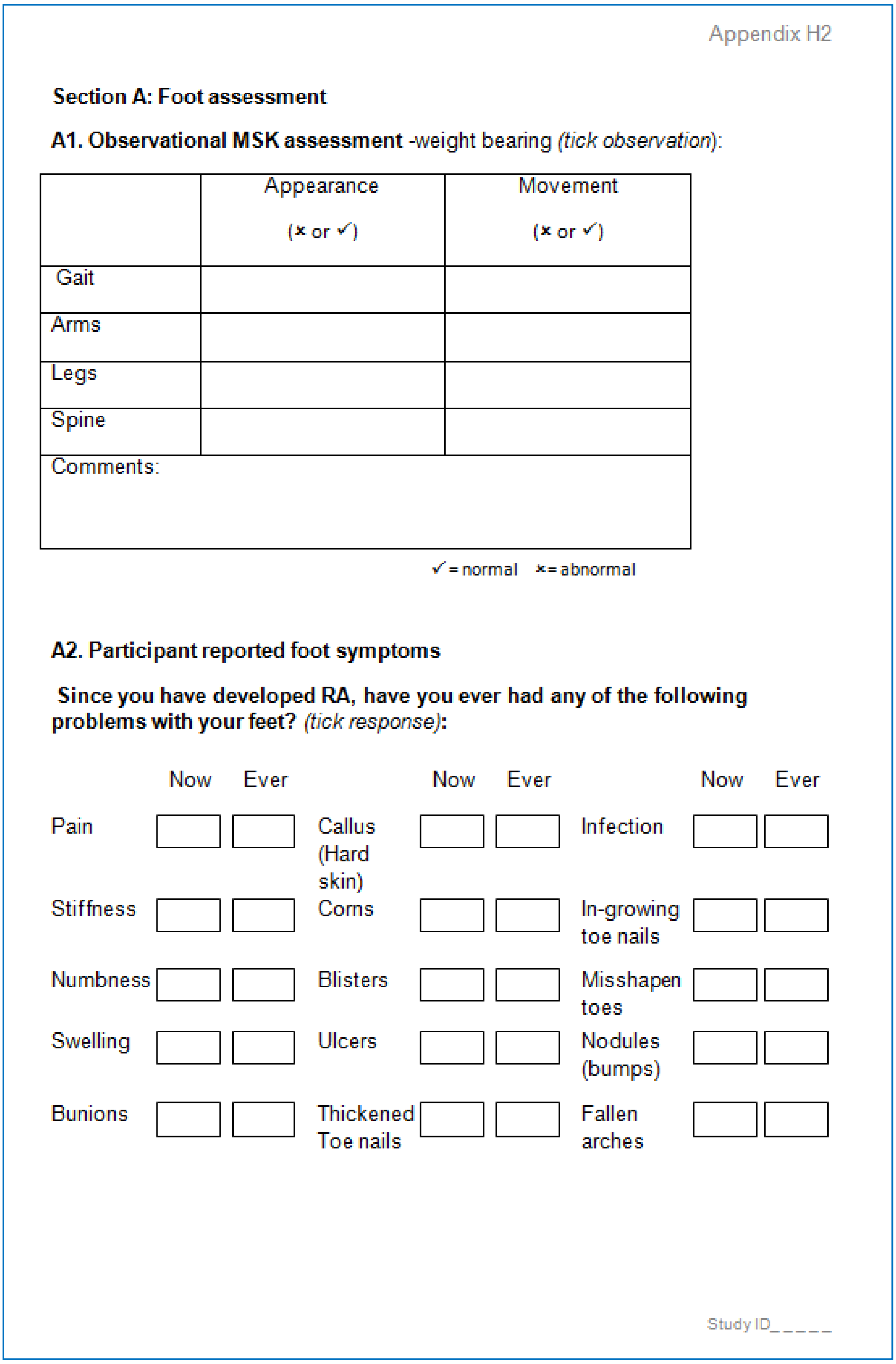
HAQ........

FIS (total) ....

FIS (I/F) ....

FIS (A/P) ....

Study ID_ _ _ _ _



Section A: Foot assessment

A1. Observational MSK assessment -weight bearing *(tick observation)*:

	Appearance (× or ✓)	Movement (× or ✓)
Gait		
Arms		
Legs		
Spine		
Comments:		

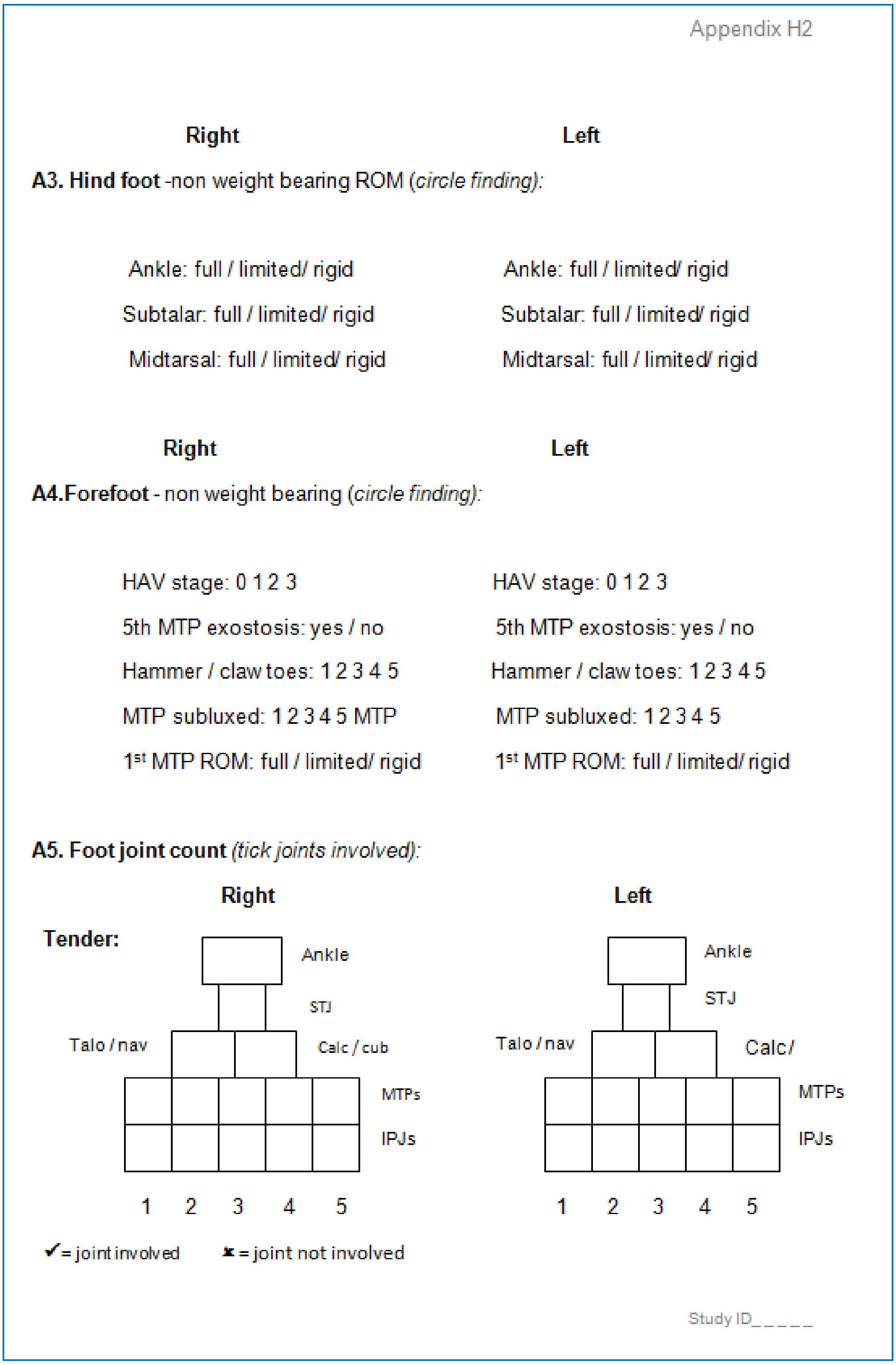
✓ = normal ×= abnormal

A2. Participant reported foot symptoms

Since you have developed RA, have you ever had any of the following problems with your feet? *(tick response)*:

	Now	Ever		Now	Ever		Now	Ever
Pain	☐	☐	Callus (Hard skin)	☐	☐	Infection	☐	☐
Stiffness	☐	☐	Corns	☐	☐	In-growing toe nails	☐	☐
Numbness	☐	☐	Blisters	☐	☐	Misshapen toes	☐	☐
Swelling	☐	☐	Ulcers	☐	☐	Nodules (bumps)	☐	☐
Bunions	☐	☐	Thickened Toe nails	☐	☐	Fallen arches	☐	☐

Study ID_ _ _ _ _



Right **Left**

A3. Hind foot -non weight bearing ROM (*circle finding*):

Right	Left
Ankle: full / limited/ rigid	Ankle: full / limited/ rigid
Subtalar: full / limited/ rigid	Subtalar: full / limited/ rigid
Midtarsal: full / limited/ rigid	Midtarsal: full / limited/ rigid

Right **Left**

A4.Forefoot - non weight bearing (*circle finding*):

Right	Left
HAV stage: 0 1 2 3	HAV stage: 0 1 2 3
5th MTP exostosis: yes / no	5th MTP exostosis: yes / no
Hammer / claw toes: 1 2 3 4 5	Hammer / claw toes: 1 2 3 4 5
MTP subluxed: 1 2 3 4 5 MTP	MTP subluxed: 1 2 3 4 5
1st MTP ROM: full / limited/ rigid	1st MTP ROM: full / limited/ rigid

A5. Foot joint count (*tick joints involved*):

Right **Left**

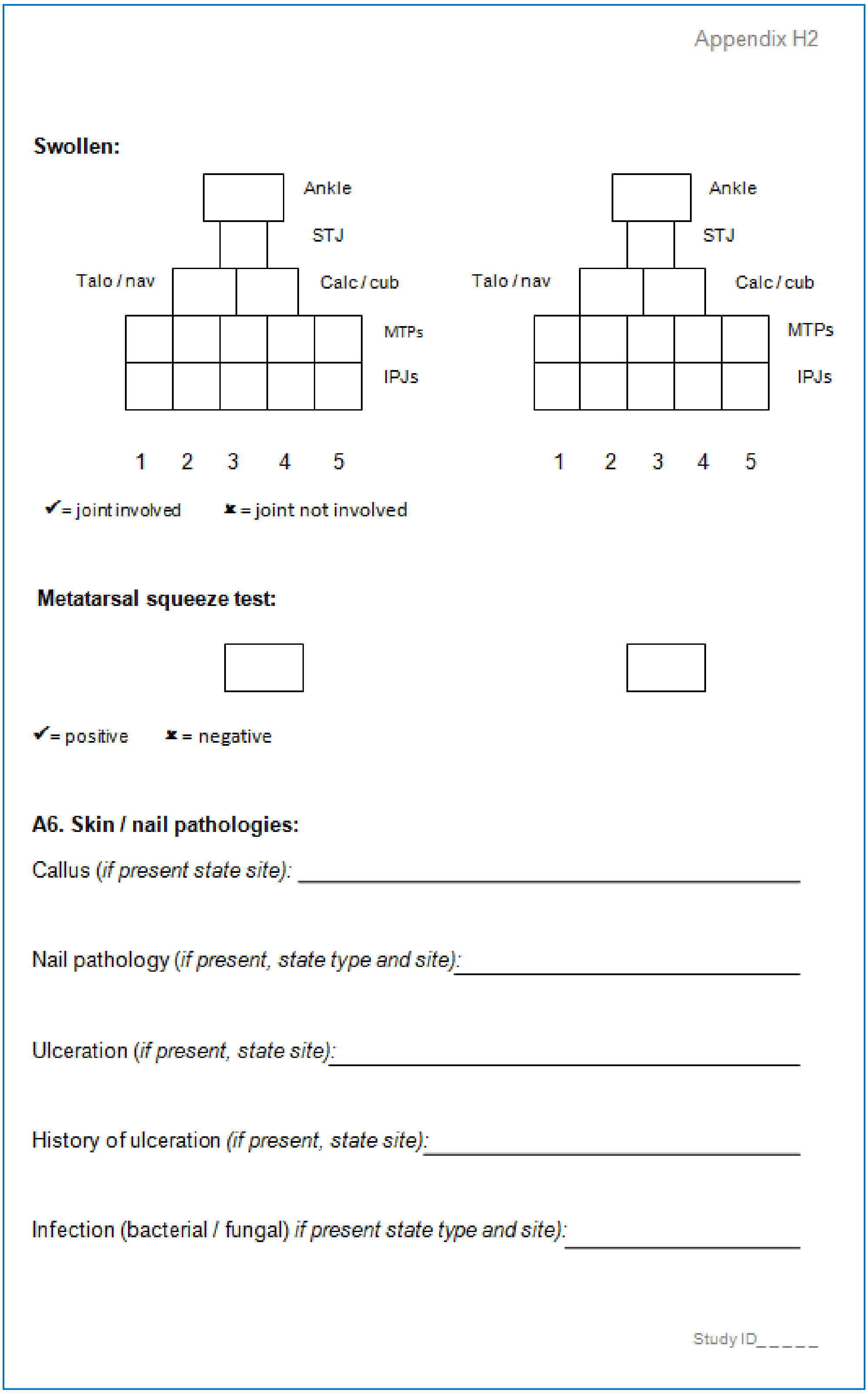
Tender:

Ankle
STJ
Talo / nav
Calc / cub
MTPs
IPJs
1 2 3 4 5

Ankle
STJ
Talo / nav
Calc /
MTPs
IPJs
1 2 3 4 5

✓= joint involved ✗ = joint not involved

Study ID_ _ _ _ _



Swollen:

	Ankle		Ankle
	STJ		STJ
Talo / nav	Calc / cub	Talo / nav	Calc / cub
	MTPs		MTPs
	IPJs		IPJs
1 2 3 4 5		1 2 3 4 5	

✓ = joint involved ✗ = joint not involved

Metatarsal squeeze test:

☐ ☐

✓ = positive ✗ = negative

A6. Skin / nail pathologies:

Callus (*if present state site*): ____________________

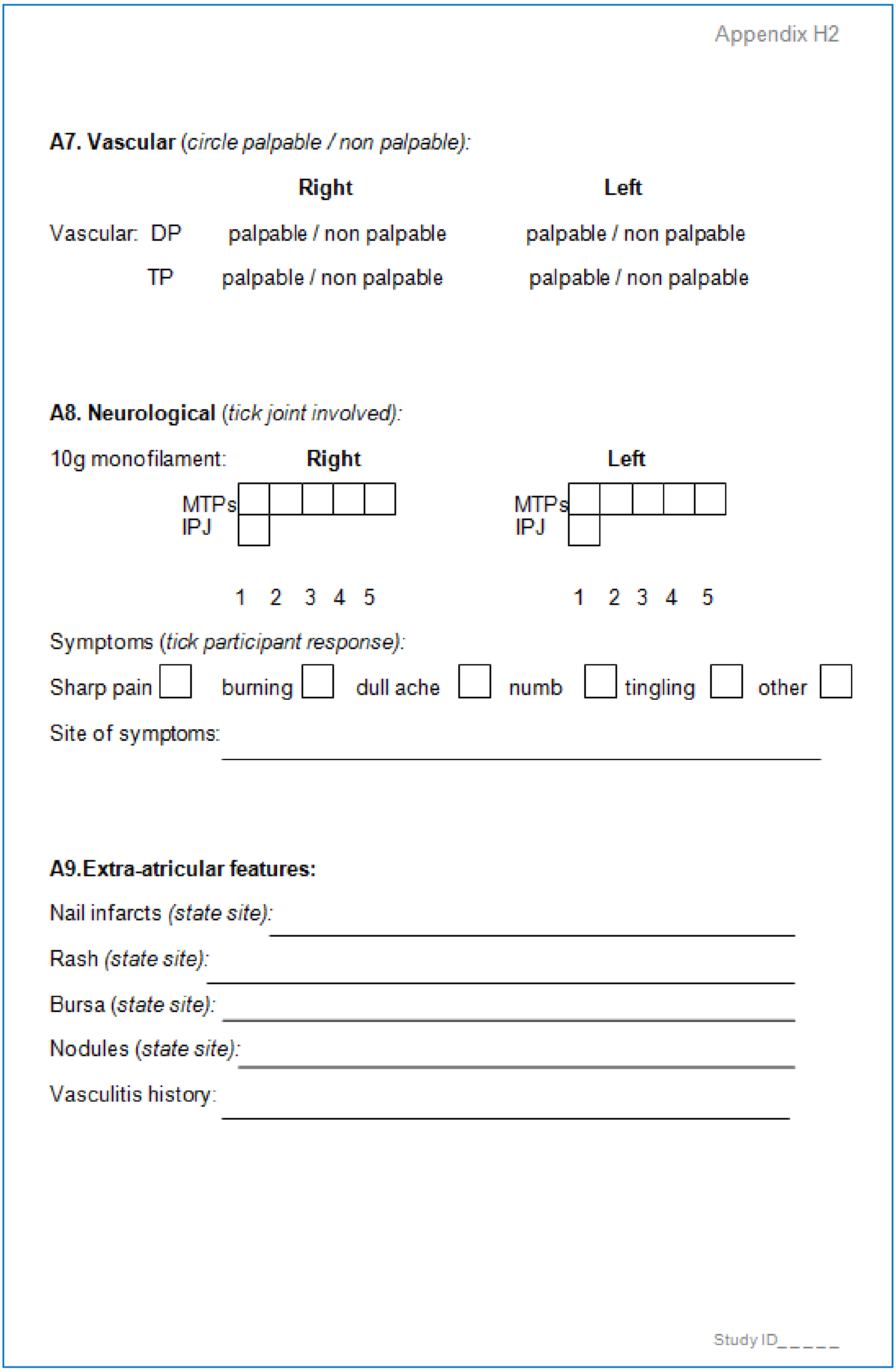
Nail pathology (*if present, state type and site*): ____________________

Ulceration (*if present, state site*): ____________________

History of ulceration (*if present, state site*): ____________________

Infection (bacterial / fungal) *if present state type and site*: ____________________

Study ID_ _ _ _ _



A7. Vascular (*circle palpable / non palpable*):

		Right	Left
Vascular:	DP	palpable / non palpable	palpable / non palpable
	TP	palpable / non palpable	palpable / non palpable

A8. Neurological (*tick joint involved*):

10g monofilament: **Right**

MTPs	☐	☐	☐	☐	☐
IPJ	☐				
	1	2	3	4	5

Left

MTPs	☐	☐	☐	☐	☐
IPJ	☐				
	1	2	3	4	5

Symptoms (*tick participant response*):

Sharp pain ☐ burning ☐ dull ache ☐ numb ☐ tingling ☐ other ☐

Site of symptoms: ______________________________

A9.Extra-atricular features:

Nail infarcts *(state site)*: ______________________________

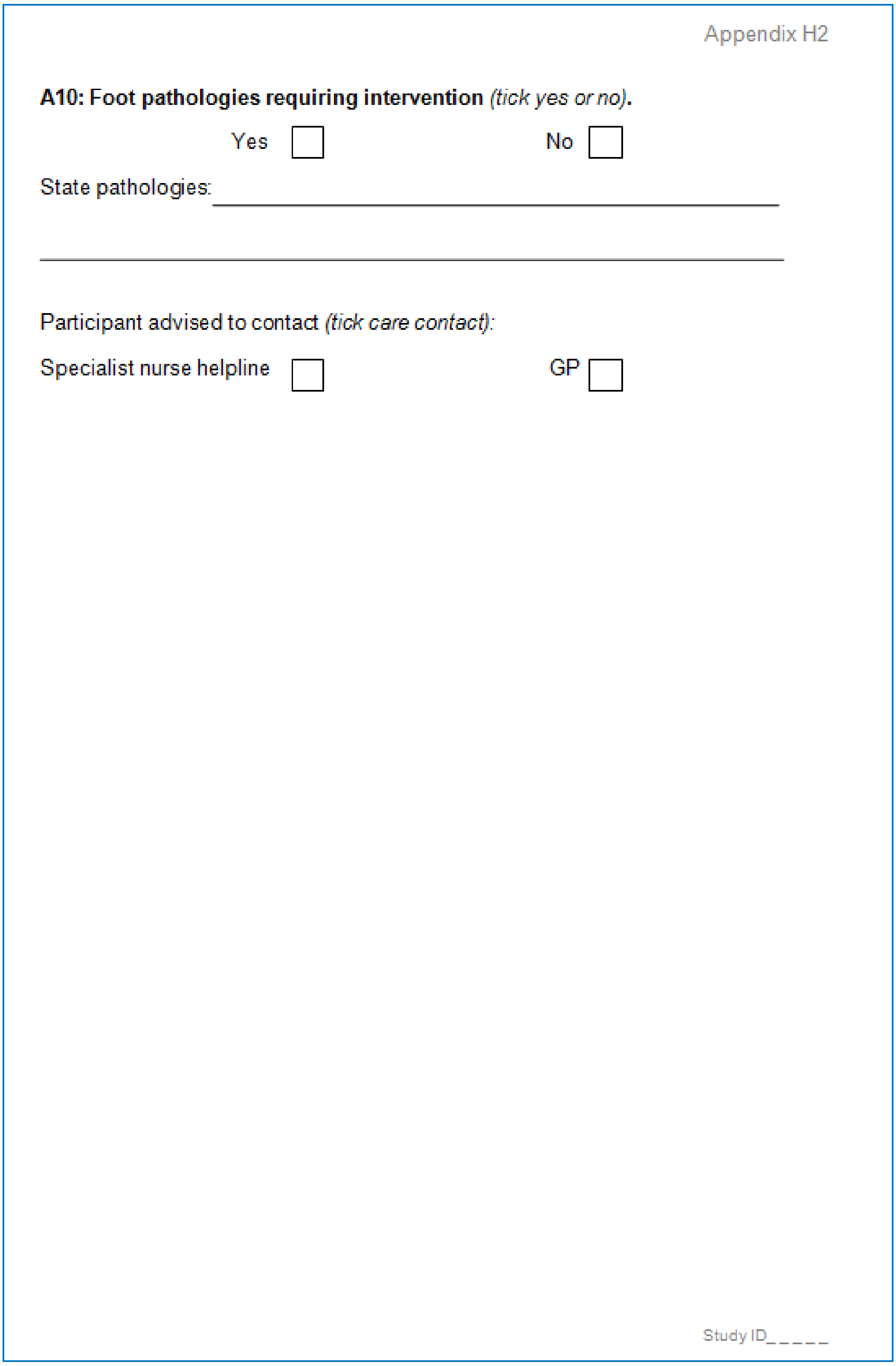
Rash *(state site)*: ______________________________

Bursa (*state site*): ______________________________

Nodules (*state site*): ______________________________

Vasculitis history: ______________________________

Study ID_____



Appendix H2

A10: Foot pathologies requiring intervention *(tick yes or no)*.

Yes ☐ No ☐

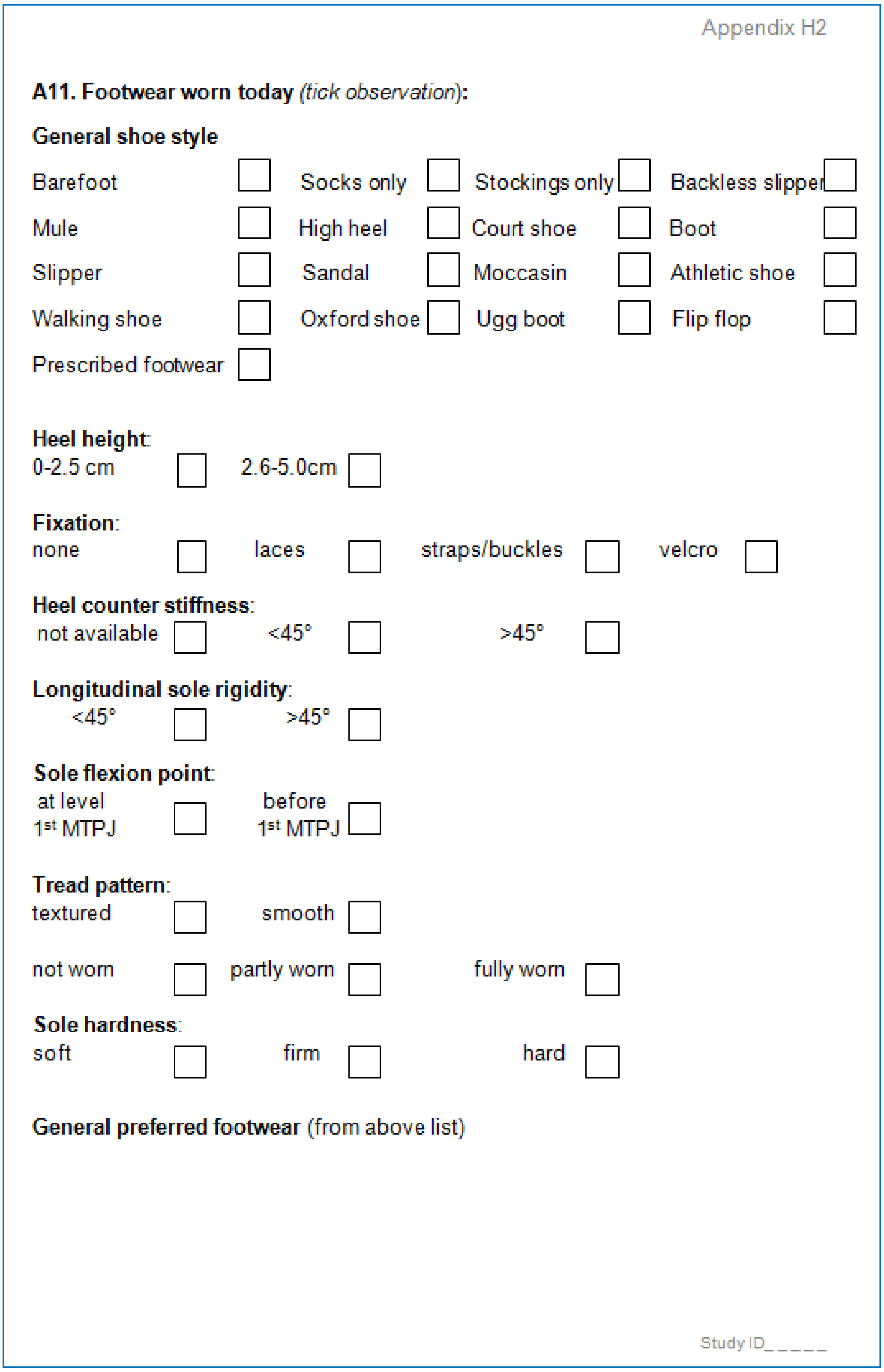
State pathologies: ____

____

Participant advised to contact *(tick care contact)*:

Specialist nurse helpline ☐ GP ☐

Study ID_ _ _ _ _



A11. Footwear worn today *(tick observation)*:

General shoe style

Barefoot	☐	Socks only	☐	Stockings only	☐	Backless slipper	☐
Mule	☐	High heel	☐	Court shoe	☐	Boot	☐
Slipper	☐	Sandal	☐	Moccasin	☐	Athletic shoe	☐
Walking shoe	☐	Oxford shoe	☐	Ugg boot	☐	Flip flop	☐
Prescribed footwear	☐						

Heel height:
0-2.5 cm ☐ 2.6-5.0cm ☐

Fixation:
none ☐ laces ☐ straps/buckles ☐ velcro ☐

Heel counter stiffness:
not available ☐ <45° ☐ >45° ☐

Longitudinal sole rigidity:
<45° ☐ >45° ☐

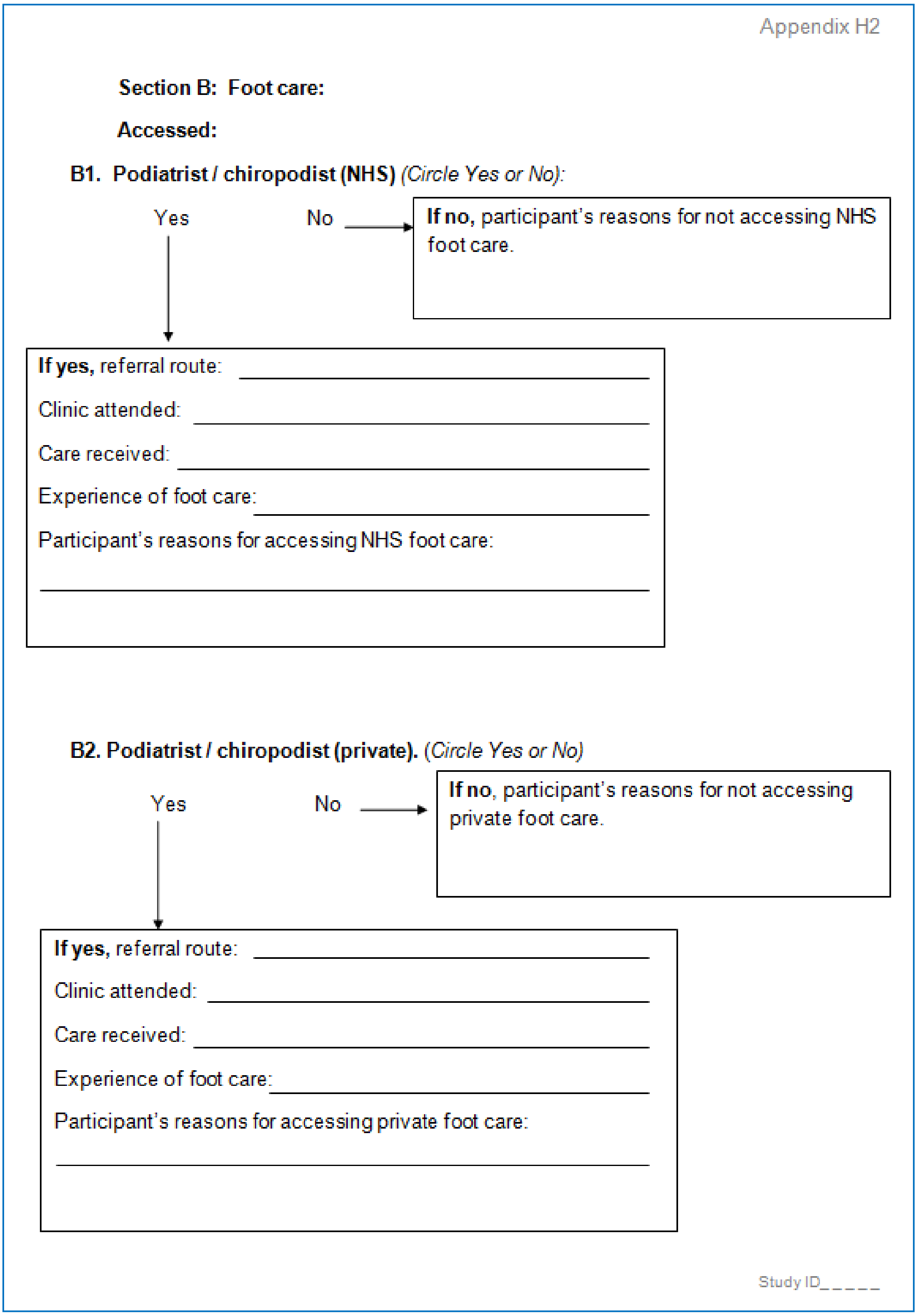
Sole flexion point:
at level 1st MTPJ ☐ before 1st MTPJ ☐

Tread pattern:
textured ☐ smooth ☐

not worn ☐ partly worn ☐ fully worn ☐

Sole hardness:
soft ☐ firm ☐ hard ☐

General preferred footwear (from above list)



Section B: Foot care:

Accessed:

B1. Podiatrist / chiropodist (NHS) *(Circle Yes or No):*

Yes No

If no, participant's reasons for not accessing NHS foot care.

If yes, referral route: ____________________

Clinic attended: ____________________

Care received: ____________________

Experience of foot care: ____________________

Participant's reasons for accessing NHS foot care:

____

B2. Podiatrist / chiropodist (private). *(Circle Yes or No)*

Yes No

If no, participant's reasons for not accessing private foot care.

If yes, referral route: ____________________

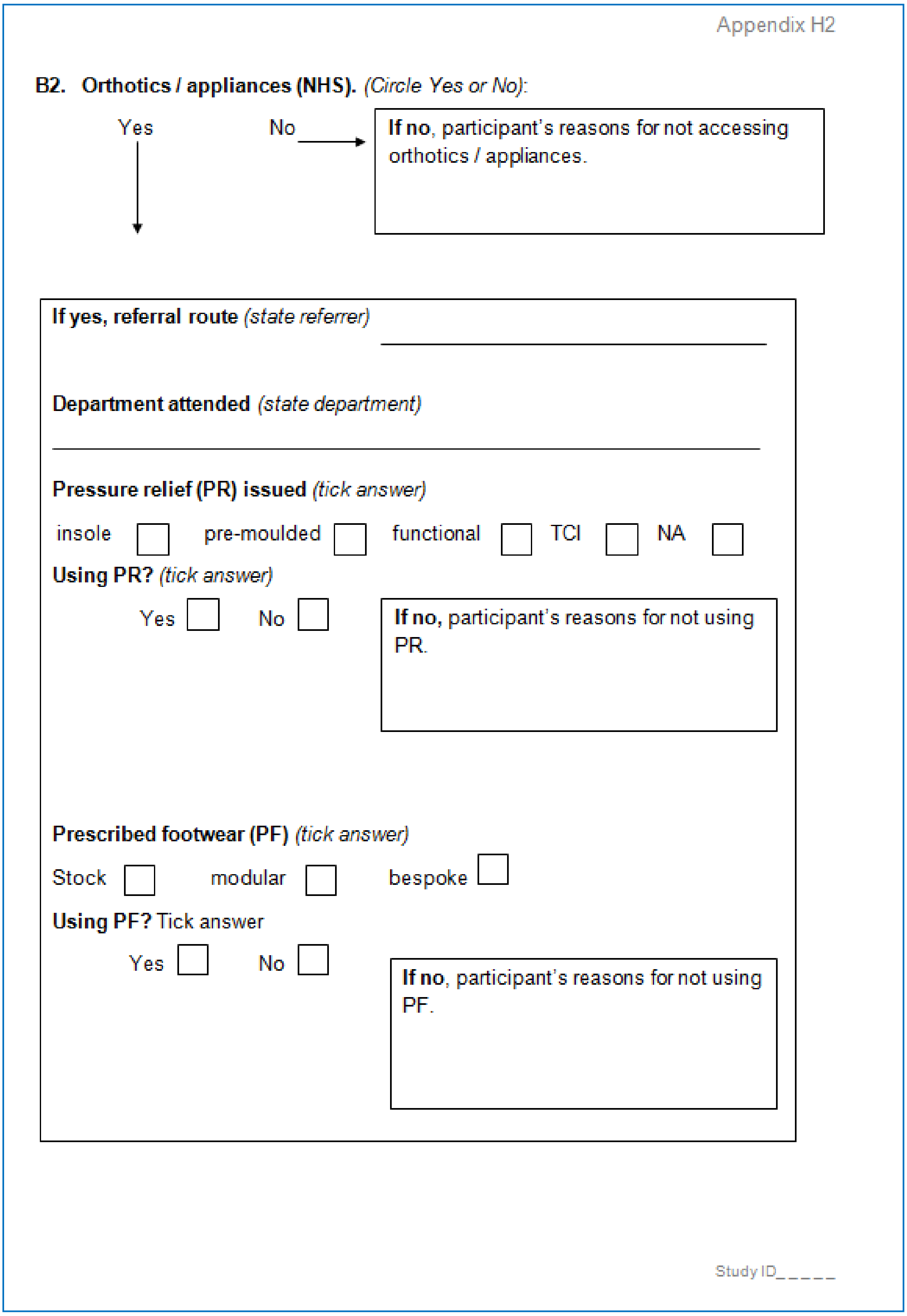
Clinic attended: ____________________

Care received: ____________________

Experience of foot care: ____________________

Participant's reasons for accessing private foot care:

____



B2. Orthotics / appliances (NHS). *(Circle Yes or No):*

Yes No

If no, participant's reasons for not accessing orthotics / appliances.

If yes, referral route *(state referrer)* ______________________

Department attended *(state department)*

____

Pressure relief (PR) issued *(tick answer)*

insole ☐ pre-moulded ☐ functional ☐ TCI ☐ NA ☐

Using PR? *(tick answer)*

Yes ☐ No ☐

If no, participant's reasons for not using PR.

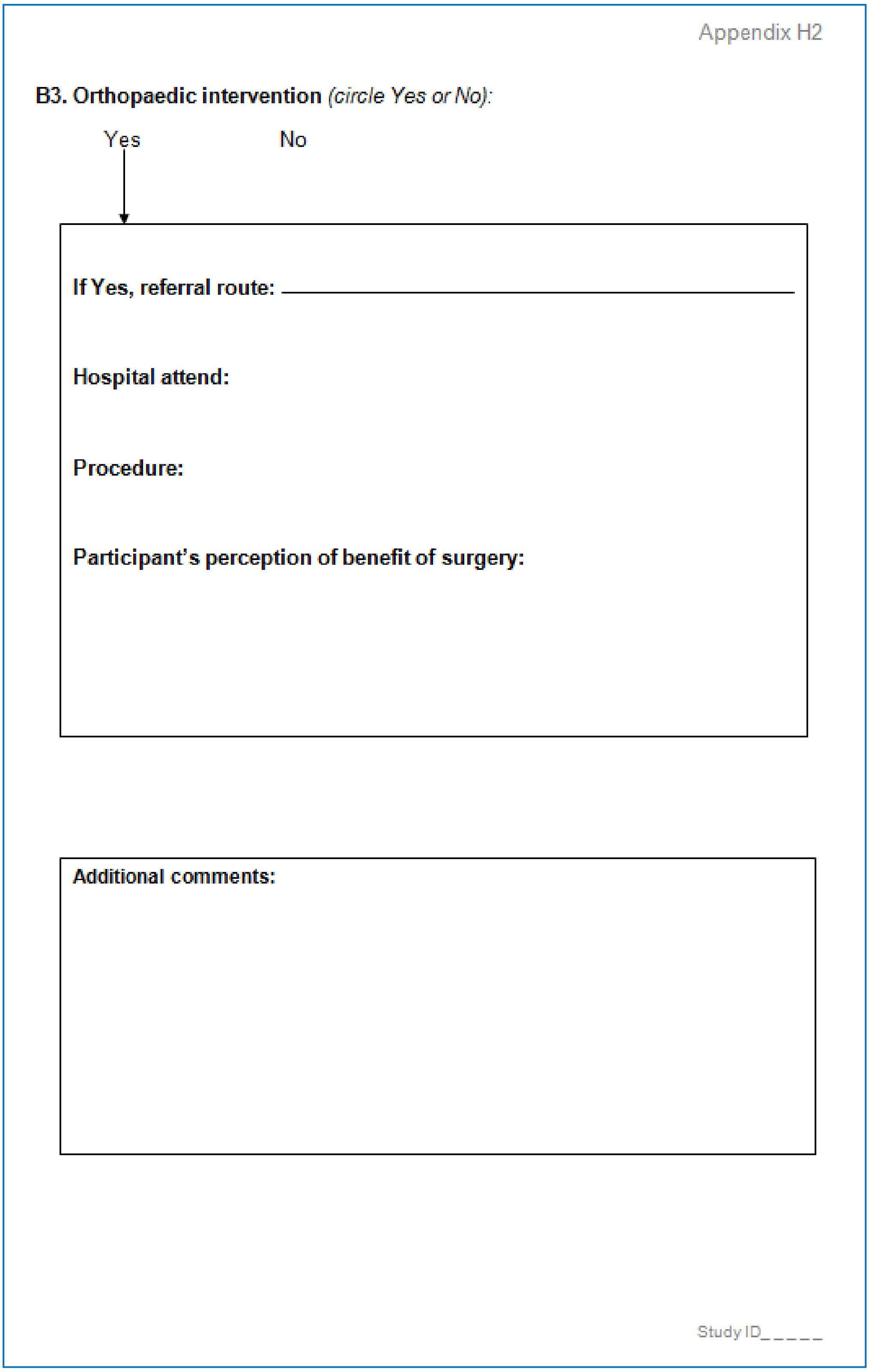
Prescribed footwear (PF) *(tick answer)*

Stock ☐ modular ☐ bespoke ☐

Using PF? Tick answer

Yes ☐ No ☐

If no, participant's reasons for not using PF.



Appendix H2

B3. Orthopaedic intervention *(circle Yes or No):*

Yes No

If Yes, referral route: ________________________________

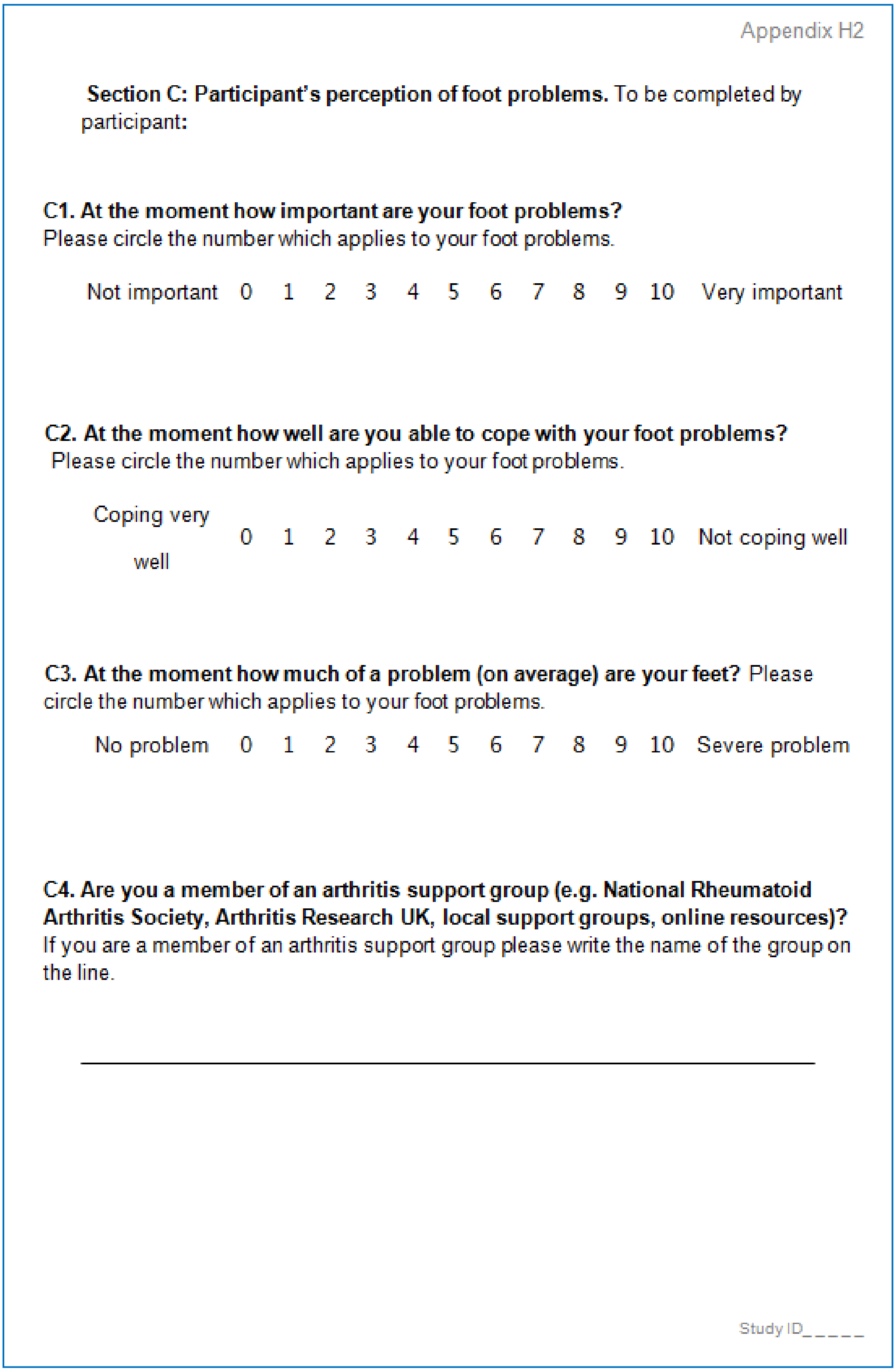
Hospital attend:

Procedure:

Participant's perception of benefit of surgery:

Additional comments:

Study ID_ _ _ _ _



Section C: Participant's perception of foot problems. To be completed by participant:

C1. At the moment how important are your foot problems?
Please circle the number which applies to your foot problems.

Not important 0 1 2 3 4 5 6 7 8 9 10 Very important

C2. At the moment how well are you able to cope with your foot problems?
Please circle the number which applies to your foot problems.

Coping very well 0 1 2 3 4 5 6 7 8 9 10 Not coping well

C3. At the moment how much of a problem (on average) are your feet? Please circle the number which applies to your foot problems.

No problem 0 1 2 3 4 5 6 7 8 9 10 Severe problem

C4. Are you a member of an arthritis support group (e.g. National Rheumatoid Arthritis Society, Arthritis Research UK, local support groups, online resources)?
If you are a member of an arthritis support group please write the name of the group on the line.

____

Study ID_____

Followed by FIS (as in Appendix F2).

Followed by HAQ (as in Appendix D2).

Appendix I: Supplementary data

Table 1: Frequency of co-morbidity categories according to foot care service accessed Study 2

	Type of co-morbidity	Podiatry (n=204) in this category Number (%)	Orthotics (n=192) in this category Number (%)	Orthopaedics (n=92) in this category Number (%)
Diabetes Thyroid disease Paget's disease Osteopinia	Endocrine	39 (19.1)	34 (17.7)	13 (14.1)
Myocardial infarction Cerebrovascular accident Hypertension Arrythmia Deep vein thrombosis Raynaud's Peripheral vascular disease Hypercholesterolemia	Cardiovascular disease	84 (41.2)	67 (34.9)	34 (37.0)
Asthma Chronic obstructive pulmonary disease Brochiectasis Sleep apnoea	Pulmonary disease	30 (14.7)	26 (13.5)	12 (13.0)
Anxiety Depression Schizophrenia	Mental health	3 (1.5)	8 (4.2)	1 (1.1)
Eczema Psoriasis Herpes simplex Urticaria	Dermatology	7 (3.4)	5 (2.6)	3 (3.3)
Glaucoma Retinopathy Ocular toscocariasis	Eye	4 (2.0)	5 (2.6)	2 (2.2)
Basal cell carcinoma Breast cancer Prostate cancer	Cancer	3 (1.5)	3 (1.6)	1 (1.1)
Anaemia Thrombocytopenia	Haematology	3 (1.5)	4 (2.1)	2 (2.2)
Ulcerative colitis Crohn's disease Hiatus hernia Oesophageal reflux	Gastrointestinal	10 (4.9)	9 (4.7)	3 (3.3)
Multiple sclerosis Dystonia	Neurology	0 (0)	0 (0)	0 (0)
Ankylosing spondylitis Juvenile idiopathic arthritis Gout Osteoarthritis Giant cell arteritis Systemic lupus erythematosus Sarcoidosis Sjogrens	Other rheumatological diagnosis	17 (8.3)	18 (9.3)	6 (6.5)
Osteoporosis Spinal stenosis Sciatica Degeneration of spine	Back problems	13 (6.4)	15 (7.8)	11 (12.0)
Fibromyalgia	Chronic pain	2 (1.0)	4 (2.1)	1 (1.1)

	Type of co-morbidity	**Podiatry (n=204) in this category Number (%)**	**Orthotics (n=192) in this category Number (%)**	**Orthopaedics (n=92) in this category Number (%)**
Primary bilary cirrhosis	Heptology	1 (0.5)	0 (0)	0 (0)
Tendinopathy Fracture Foot deformity not RA related	Other MSK	2 (1.0)	0 (0)	1 (1.1)
Chronic kidney disease	Renal disease	3 (1.5)	0 (0)	0 (0)
	Any category	145 (71.1)	99 (51.6)	66 (71.7)

Table 2 Co-morbidity condition categories Study 3

Co-morbidity condition	Type of co-morbidity	Total selected patients n=110 (%)	AFC n=65 (%)	NAFC n=45 (%)
Diabetes Thyroid disease Paget’s disease Osteopinia	Endocrine	8 (7)	5 (8)	3 (7)
Myocardial infarction Cerebrovascular accident Hypertension Arrythmia Peripheral vascular disease	Cardiovascular disease	26 (24)	17 (26)	9 (20)
Asthma Chronic obstructive pulmonary disease Bronchiectasis Sleep apnoea	Pulmonary disease	12 (11)	7 (11)	5 (11)
Anxiety Depression Schizophrenia	Mental health	4 (4)	3 (5)	1 (2)
Eczema Psoriasis Herpes simplex Urticaria	Dermatology	2 (2)	2 (3)	0 (0)
Glaucoma Retinopathy Ocular toscocariasis	Eye	1 (1)	0 (0)	1 (2)
Basal cell carcinoma Breast cancer Prostate cancer	Cancer	1 (1)	1 (2)	0 (0)
Anaemia Thrombocytopenia	Haematology	0 (0)	0 (0)	0 (0)
Ulcerative colitis Crohn’s disease Hiatus hernia Oesophageal reflux	Gastrointestinal	4 (4)	3 (5)	1 (2)
Multiple sclerosis Dystonia	Neurology	0 (0)	0 (0)	0 (0)
Ankylosing spondylitis Juvenile idiopathic arthritis Gout Osteoarthritis Osteoporosis Psoriatic arthritis Systemic lupus erythematosus	Other rheumatological diagnosis	33 (30)	24 (37)	9 (20)
Spinal stenosis Sciatica Degeneration of spine	Back problems	11 (10)	8 (12)	3 (7)
Fibromyalgia	Chronic pain	1 (1)	1 (2)	0 (0)
Primary bilary cirrhosis	Heptology	1(1)	1 (2)	0 (0)
Tendonopathy Fracture Foot deformity not RA related	Other MSK	21 (19)	11 (17)	10 (22)
Chronic kidney disease	Renal disease	3 (3)	3 (5)	0 (0)
	Any category	79 (72)	48 (74)	31 (69)

Appendix J1: Abstract British Society for Rheumatology conference 2012 and Society of Chiropodists and Podiatrists conference 2012

Wilson, O., Kirwan, J., Dure, E., Quest, E.,& Hewlett, S. (2012a). "Just do something about my feet": Foot problems and access to foot care in people with rheumatoid arthritis [abstract] *Rheumatology, 51* (Suppl. 3), iii53-iii54.

and

Wilson, O., Kirwan, J., Dure, E., Quest, E.,& Hewlett, S. (2012b). "Just do something about my feet": Foot problems and access to foot care in people with rheumatoid arthritis [abstract] Society of Chiropodists and Podiatrists Annual Conference. Glasgow 2012.

Background: The foot is often involved in RA but the impact of foot involvement in patients with RA and patients' beliefs regarding access to and efficacy of foot care services are unknown.

Objective: To explore patients with RA experiences of foot problems and their access to foot care provision.

Methods: Inductive thematic analysis of the transcripts from semi structured face-to-face interviews with patients purposively sampled for self-reported foot problems and a range of personal/disease characteristics. Themes were identified within and across data sets. Analysis was by OW with a subset independently analysed (SH, ED and patient partner EQ). Emerging themes were discussed and agreed by all authors.

Results: 12 patients (7F); aged 29-72 yrs (mean 56.8); 42% accessed foot care services; disease duration 2-27 yrs (mean 12); with 92% on DMARDs; 42% on biologics; HAQ 0-2.875 (mean 1.58); and global opinion numerical scale 0-9 (mean 5.9). An overarching theme of Access to Foot Care was identified, comprising three themes.

Access supported. "I'd put them [feet] top priority": This included proactive discussions of foot problems generated by patients and health care professionals ("He generally asks"); having feet examined ("Took my shoes and socks off and showed the woman"); previous positive experiences of foot care ("The podiatrist is keeping an eye on them"); and continuing access to foot care ("It helps").

***Access perceived unnecessary*.** "It's not where I want to go [prescribed footwear], another nail in the coffin": This included: fluctuating foot symptoms ("Some days I can't walk, then it goes"); general RA disease activity ("Just took it as part of the RA"); ability to self–manage foot problems ("I know how to look after my feet"); feet not being considered a major concern ("Not a big problem").

Access hindered. "It seems to be an area where medical staff don't know an awful lot do they?": This included patients' perceptions of feet being ignored in clinical practice ("Not on any RA form"); limited knowledge of how or when to access care foot care ("Didn't know you could access it on the NHS"); expectations that the rheumatology team would initiate access to foot care ("He will refer me");

assumptions that no treatment options were available (“I’ve just plodded on”); and previous negative experiences of foot care (“All they did was cut my nails”).

Conclusions: Patients who had accessed foot care services prioritised their foot problems as an important health care need. However, for others who would like foot care services, personal knowledge and values, and perceived barriers in clinical practice, appear to interact to inhibit foot care access. The extent which these interactions affect overall access to foot care in RA patients in general now needs to be quantified to help to inform and improve the effectiveness of the organisation and delivery of foot care.

Appendix J2: Abstract British Society for Rheumatology conference 2014 and Society of Chiropodists and Podiatrists conference 2014

Oonagh Wilson, Sarah Hewlett, Jon Pollock, James Woodburn, Enid Quest, Caroline Swales, John Kirwan (2014). Population survey of prevalence, impact and care of foot symptoms in people with rheumatoid arthritis. *Rheumatology.* 51 (suppl. 1): i42

and

Oonagh Wilson, Sarah Hewlett, Jon Pollock, James Woodburn, Enid Quest, Caroline Swales, John Kirwan (2015). Population survey of prevalence, impact and care of foot symptoms in people with rheumatoid arthritis. *Journal of Foot and Ankle Research*. 8 (Suppl 1): A9

Background: Foot symptoms in rheumatoid arthritis (RA) derive from a combination of inflammation, altered foot mechanics, deformity and secondary skin lesions. Guidelines recommend regular review of patients' feet, the extent to which the general population of RA patients report foot symptoms and access foot care has not been established.

Methods: All RA patients under hospital care in a defined geographical area (Bristol Community Health) were identified from relevant departmental records. A random sample was sent a postal survey (reminder after 3 weeks) about presence of symptoms, disability (HAQ) and patient characteristics (age, disease duration, arthritis medication and co-morbidities). Measures of impact (Foot Impact Scale (FIS)) with additional questions (numerical rating scales) related to importance, severity, coping and ability to work derived from a previous study. For each patient an Indices of Multiple Deprivation (IMD) score (a measure of socio-economic status) was derived from postcodes.

Results: Of 739 patients sent the survey, 413 (56%) replied. Responders and non responders were similar for age (63.5 vs.61.5 years), gender (74.1%F vs. 75.2%F) and socio-economic status (IMD highest deprivation quintiles 13.3% vs.15.9%). Responders' median (inter-quartile range) disease duration was 10 (5-20) years and HAQ score 1.5 (0.75-2.0). Most responders (394, 95.4 %) were taking arthritis medication and 273 (66.1%) reported additional medical conditions (including 28 (6.8%) with diabetes). Almost all (377) reported current foot symptoms (91.3%) or previous foot symptoms (6.3%), 10 (2.4%) reported never having foot symptoms. Current symptoms included: articular features 73.8%; extra-articular features 42.6%; cutaneous lesions 65.4%; structural deformity 57.6%; infection 7.5%. Median (IQR) FIS impairment footwear score 10/21 (6-14); and FIS activities participation score 16/30 (7-23). Median (IQR): importance was 6 (3-8); severity 6 (3-8); and coping 5 (3-7). Overall, 37.8% reported that foot symptoms affected their ability to work.
Of respondents, 69.5% had accessed foot care. This was similar for men and women (62.3%M vs. 72.0%F) (chi test p=0.80, NS), as were the proportions who accessed podiatry (42.1%M vs. 52.0%F), orthotics (39.3%M vs.49.2%F) and orthopaedics (15.0%M vs. 24.8%F). There was no difference in foot care access in relation to socio-economic status.

Conclusions: Unlike previous studies this was representative of all hospital patients with RA and almost all reported foot symptoms. Although FIS scores were slightly

lower than in previous studies based on patients recruited at hospital or foot care clinic appointments, nevertheless substantial impact was reported including affecting ability to work. In spite of this, 30% of patients had never accessed foot care. Further research is required to compare self-report of foot symptoms with clinical observations and explore the reasons why patients do and do not access foot care.

Appendix J3: Abstract European League Against Rheumatism conference 2015

Oonagh Wilson, Wendy Briggs, Sarah Hewlett, Jon Pollock, James Woodburn, Enid Quest, Caroline Swales, John Kirwan· (2105) DOES SELF-REPORT OF FOOT PROBLEMS AGREE WITH CLINICAL EXAMINATION IN PEOPLE WITH RHEUMATOID ARTHRITIS? Annals of the Rheumatic Diseases. 74 (Suppl 2): 106.2

Background: Data about the frequency of foot problems in rheumatoid arthritis (RA) can be obtained through self-report or clinical examination. The level of agreement between these two approaches has not been established in RA.

Objectives: Data about the frequency of foot problems in rheumatoid arthritis (RA) can be obtained through self-report or clinical examination. The level of agreement between these two approaches has not been established in RA.

Methods: A random sample of RA patients who had self-reported foot problems in a questionnaire underwent a structured foot examination and clinical interview conducted by a single observer (podiatrist). Data collected included: patient demographics and clinical characteristics; whether they had accessed foot care (AFC) services (podiatry, orthotics and / or orthopaedics); impact of foot problems (Foot Impact Scale: Impairment/Footwear (FIS_{IF}) and Activities/Participation (FIS_{AP}) subscales); and presence of foot problems on examination. Extent of agreement between self-report and clinical examination was measured by the kappa statistic (k).

Results: Of 235 patients invited to participate, 110 (47%) attended; 65 AFC (59%); 77 Female (70%); mean (SD) age 63.1 (11.2) years; median (IQR) disease duration 8.5 (1, 51) years; HAQ 1.25 (0.375, 2.00); FIS_{IF} 9 (5, 13); and FIS_{AP} 15 (3, 22).
The overall frequency of reported and examined foot problems were: toe deformities - 66% and 69%; hallux valgus - 35% and 33%; pes planus - 26% and 56%; callus - 56% and 53%; corns - 12% and 12%; blisters - 5% and 2%; thickened toe-nails - 57% and 45%: ingrown toe-nails - 16% and 15%; joint swelling - 28% and 65%; nodules - 23% and 16%; numbness - 27% and 19%.
High agreement occurred for: corns (98%, k=0.913); ingrown toe-nails (97%, k=0.893); and hallux valgus (98%, k= 0.959); nodules (92%, k=0.724); callus (84%, k=0.670); toe deformities (86%, k=0.67); and thickened toe nails (80%, K=0.606). Fair agreement was detected for numbness and pes planus (79%, k=0.418 and 76%, k=0.377) but only chance agreement for joint swelling (49%, k<0.01).

Conclusions: Overall, high levels of agreement were detected between self-report and clinical examination for many foot problems, suggesting self-report can be utilised with a high degree of confidence. However, levels of agreement for more complex foot problems (e.g. pes planus) were only fair and patients substantially under-reported features of disease activity (e.g. joint swelling), indicating that clinical examination is required for these features.