Check for updates

Received: 23 July 2020 | Revised: 24 August 2020 | Accepted: 25 August 2020

DOI: 10.1002/msc.1509

RESEARCH ARTICLE

WILEY

A feasibility randomised controlled trial of a fibromyalgia self-management programme in a community setting with a nested qualitative study (FALCON): Study protocol

Jennifer Pearson[1,2] | Jessica Coggins[1] | Erik Lenguerrand[3] | Sandi Derham[2] | Julie Russell[2] | Nicola E. Walsh[1] | Fiona Cramp[1]

[1]Faculty of Health and Applied Sciences, University of the West of England, Bristol, Bristol, UK

[2]Therapy Department, Royal United Hospitals Bath NHS Foundation Trust, Bath, UK

[3]Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

Correspondence
Jen Pearson and Jessica Coggins, University of the West of England, Glenside Campus, Bristol BS16 1DD, UK.
Email: jen.pearson@uwe.ac.uk; jessica.coggins@uwe.ac.uk

Funding information
Chartered Society of Physiotherapy Charitable Trust, Grant/Award Number: PRF/17/A29

Abstract

Background: Fibromyalgia (FM) is a complex long-term condition associated with chronic widespread pain, fatigue, sleep problems, memory and concentration difficulties and irritable bowel syndrome. Current guidelines for the treatment of FM recommend nonpharmacological interventions.

The Fibromyalgia Self-Management Programme (FSMP) is a nonpharmacological, multidisciplinary exercise and education group intervention. It aims to provide education and teach core skills, enabling those affected by FM to self-manage. The FSMP is currently codelivered by a multidisciplinary team within a secondary care service. The aim of this feasibility randomised controlled trial (RCT) is to determine the practicality and acceptability of delivering the FSMP in a community setting, informing a future RCT of effectiveness.

Methods: The feasibility RCT aims to recruit 70 people with FM. Participants will be randomised to either a community FSMP or control arm. All participants will be asked to complete six patient-reported outcome measures and one health economics questionnaire on three occasions; baseline, 6 weeks (end of the intervention) and 6 months. Between 12 and 16 participants and four therapists delivering the FSMP will be invited to take part in a semi-structured interview to explore their experiences of the FSMP. Patient participants will be purposively selected based upon key characteristics.

Analysis: Quantitative data will be analysed descriptively to summarise recruitment and attendance, participant reported outcomes and health economic data. Semi-structured interviews will be transcribed, anonymised and inductively coded. The codes will be grouped into categories and theoretically thematically analysed, comparing the results to existing literature.

Trial registration: The trial is registered with ISRCTN registry and was assigned on 29th of April 2020. The registration number is ISRCTN10824225.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.
© 2020 The Authors. Musculoskeletal Care published by John Wiley & Sons Ltd

KEYWORDS
community, feasibility randomised controlled trial, fibromyalgia, self-management

1 | INTRODUCTION

Fibromyalgia (FM) is a complex long-term condition affecting up to 5.4% of the U.K. population (Fayaz, Croft, Langford, Donaldson, & Jones, 2016; Jones et al., 2015). Common symptoms include chronic widespread pain, fatigue, stiffness, sleep problems, cognitive dysfunction and psychological distress (Arnold et al., 2019; Bennett, 2009). FM is associated with high levels of disability, frequent use of healthcare resources and loss of workdays (Boonen et al., 2005; Hughes, Martinez, Myon, Taïeb, & Wessely, 2006; Soni et al., 2019).

There is limited robust evidence for the effectiveness of pharmacological treatments for FM (Eich et al., 2012). Current guidelines for the treatment of FM all recommend nonpharmacological interventions, of which cognitive behaviour therapy (CBT), aerobic exercise, warm water therapy, relaxation and patient education are best evidenced (Fitzcharles et al., 2013; Hughes et al., 2006; Macfarlane et al., 2017; Nüesch, Häuser, Bernardy, Barth, & Jüni, 2013). In combination with the pharmacological and nonpharmacological interventions to treat FM, a common patient goal is to develop the knowledge and skills needed to independently self-manage their condition.

The evidence for self-management interventions are compelling. They have been shown to improve both physical symptoms and function, participant engagement, self-efficacy and mood and reduce health service costs in a number of long-term conditions (Kennedy et al., 2007; Newman, Steed, & Mulligan, 2004; Schulman-Green, Jaser, Park, & Whittemore, 2016). Previous research on FM self-management within a community setting found short-term improvement in severity of FM symptoms, improvement in self-efficacy to manage symptoms of pain, decreased fatigue and a reduction in General Practitioner (GP) FM related contacts (Hammond & Freeman, 2006).

Allied health professionals at the Royal National Hospital for Rheumatic Diseases, Royal United Hospitals Bath NHS Foundation Trust (RUHB), designed the Fibromyalgia Self-Management Programme (FSMP), a nonpharmacological, multidisciplinary exercise and education group intervention. The FSMP has been delivered by the RUHB for over 10 years. The patient attendees are regularly asked for feedback to inform service improvements. The main aims of the FSMP are to provide condition-specific, patient-centred, education and exercise advice and to support the development of core self-management skills for those affected by FM. The FSMP comprises one 2.5-hour weekly session over six consecutive weeks. Core components include education about FM, sleep hygiene, goal setting, pacing, hydrotherapy and dietary advice. Participants can access an FM specific gym group upon completion of the programme.

A recent study (Pearson et al., 2020) mapped the FSMP to Behaviour Change Taxonomy (Michie et al., 2013) through non-participatory observation, review of patient and trainer manuals and semi-structured interviews with patients and health professionals. The FSMP mapped on to 22 discrete behaviour change techniques, covering 12 of the 16 main behaviour change areas. Patients reported making significant changes to their behaviour in terms of exercise, pacing and sleep and felt more empowered and knowledgeable in relation to FM. Along with FM education, patient focused goal setting with active involvement from a therapist in planning to meet identified goals appeared to be key factors that facilitated behaviour change. The delivery of the intervention in a group setting was also beneficial with patients sharing, with others, their experiences of diagnosis and symptom management (Pearson et al., 2020). The findings also align with the Capability, Opportunity, Motivation and Behaviour (COM-B) model (Michie, van Stralen, & West, 2011) which provides an overall theoretical framework to explain how the intervention works in practice.

To date, the delivery of the FSMP has been within an acute hospital setting by a team of specialist Rheumatology Occupational Therapists (OTs) and Physiotherapists (PTs). However, government plans recommended that the care of adults affected by long-term conditions is, where possible, transferred from acute hospital environments to the community, with an increased investment in community care (NHS England, 2014; NHS England, 2019). Transferring delivery of the FSMP to a community setting presents opportunities to offer specialised care closer to home and determine the clinical and cost effectiveness of this. Patient partners have been involved and consulted on all aspect of delivering the FSMP in the community. It is also possible that the programme and training of healthcare professionals will need to be modified for delivery in the community. For example, Band 6/7 nonspecialist therapists delivering the programme may not have a rheumatology background and are likely to have additional training needs.

2 | OBJECTIVES

The aim of this feasibility trial is to determine the practicality and acceptability of conducting a randomised controlled trial (RCT) to deliver the FSMP in the community to inform a future trial to test cost effectiveness. The research question is whether it is feasible to conduct an RCT of a community-based FSMP. The specific objectives of this research are the following:

- explore the ability to train Band 6 PTs and OTs to deliver the FSMP in the community;
- explore the ability to recruit adults with FM to the trial from primary care;
- assess feasibility of collecting a range of outcome data and identify the primary outcome for a future full trial;
- assess the feasibility and acceptability of collecting health economic data;

- determine recruitment rate and sample size calculations to inform a full trial; and
- understand patient and health professional acceptability of delivering the FSMP in the community through qualitative interviews.

3 | METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

3.1 | Trial design

The feasibility study will be a multicentre study with a nested qualitative evaluation. Participants will be randomly allocated to either the FSMP or the control arm using a parallel 1:1 study design. The randomised sequences list will be conducted by the Research and Development (R&D) team at the RUHB. To preserve concealment, for each cohort, a list of nonidentifiable participant ID numbers will be sent to the R&D team who will allocate participants to either the intervention or the control arm of the feasibility trial according to the randomisation sequence associated with the ID. Randomisation will be stratified by sites. The R&D team will not have any contact with the participants and no access to confidential and clinical data. Following randomisation, the R&D team will inform the research team and the research associate (RA) will inform participants of their allocation.

Participants in the intervention arm will be attending the FSMP and therefore participant blinding is not possible. The therapists directly involved with delivering the FSMP are also unblinded. Outcomes will be participant self-reported; however, the quantitative data analyst will be blinded to participant allocation.

Participants will be entitled to withdraw from the intervention at any point, and this will not affect their future care.

3.2 | Trial population

The feasibility trial will be conducted across two community provider sites in the United Kingdom.

Inclusion criteria are adults aged 18 years and over with a confirmed diagnosis of FM according to the American College of Rheumatology (2016) diagnostic criteria (Wolfe et al., 2016), willing to take part in a group-based intervention and able to travel to attend the group sessions. Exclusion criteria are those under 18 years of age, diagnosed with rheumatoid arthritis, Generalised Anxiety Disorder Questionnaire (GAD-7) score above 15, previously attended the RUHB FSMP or pain management programme, needs a carer to attend the FSMP in the community or needs an interpreter to communicate in English.

3.3 | Identification of potential participants and recruitment

In the trial set-up period, selected general practices will be sent a study information pack which will provide an overview of the study and trial processes. The practice manager at consenting sites will be asked to conduct a database search for patients diagnosed with FM using pre-identified codes. Once the practice has identified potential trial participants, a member of the practice team will screen for those participants who are not eligible or unsuitable (for example, recently bereaved or under investigation). To invite the identified participants to take part in the study, the research team will supply the participating GP sites with a patient information pack.

The pack will include an invitation letter from the GP, a detailed participant information leaflet (PIL), the contact details of the research team, a reply slip and prepaid return envelope. The GP team will send out invitations by letter to identified potential participants. Those participants who respond and are willing to participate in the feasibility trial will be asked to return a reply slip in a prepaid envelope or alternatively they can telephone or e-mail the research team. They will then be screened over the telephone by the chief investigator (CI) (JP) for further eligibility criteria including GAD score, previous attendance at the RUHB FSMP or pain management programme and requirement of a carer to enable attendance at the FSMP or an interpreter to communicate in English.

Once eligibility to the study has been established, the CI will discuss the PIL with the potential participant to ensure they fully understand the study and verbal consent to take part in the trial will be obtained. Full written consent will be obtained when the participant sends their signed consent form to the research team. The consent form will detail the intent to publish any findings.

In order to refine the delivery and fidelity of the intervention, four courses will be delivered at two selected community sites in Bristol and Wiltshire (two courses per site) and include eight to 12 patients on each course. The trial aims to recruit a total sample size of 70 participants, 35 in each arm, to account for loss-to-follow, missing data and estimate parameters such as the participation or completion rates and those required to derive the sample size for the main trial, with enough precision (Figure 1).

3.4 | Interventions

3.4.1 | Fibromyalgia Self-Management Programme

The intervention consists of a 6-week, condition-specific, group programme delivered by a PT and an OT. The FSMP comprises one 2.5-hour weekly group session over six consecutive weeks. Each week the course will focus on supporting the development of individual self-management skills by increasing knowledge and understanding of the condition, medication, goal setting, pacing, dietary advice, sleep hygiene, relaxation and exercise advice. The gentle exercise sessions are optional; participants can partake or observe. Participants will receive a booklet containing information on the content of the programme, links to relevant resources and worksheets. The participants can take notes, complete the worksheets and keep the booklet when the programme finishes. Participants in the intervention arm will continue to receive usual care from their GP throughout the trial.

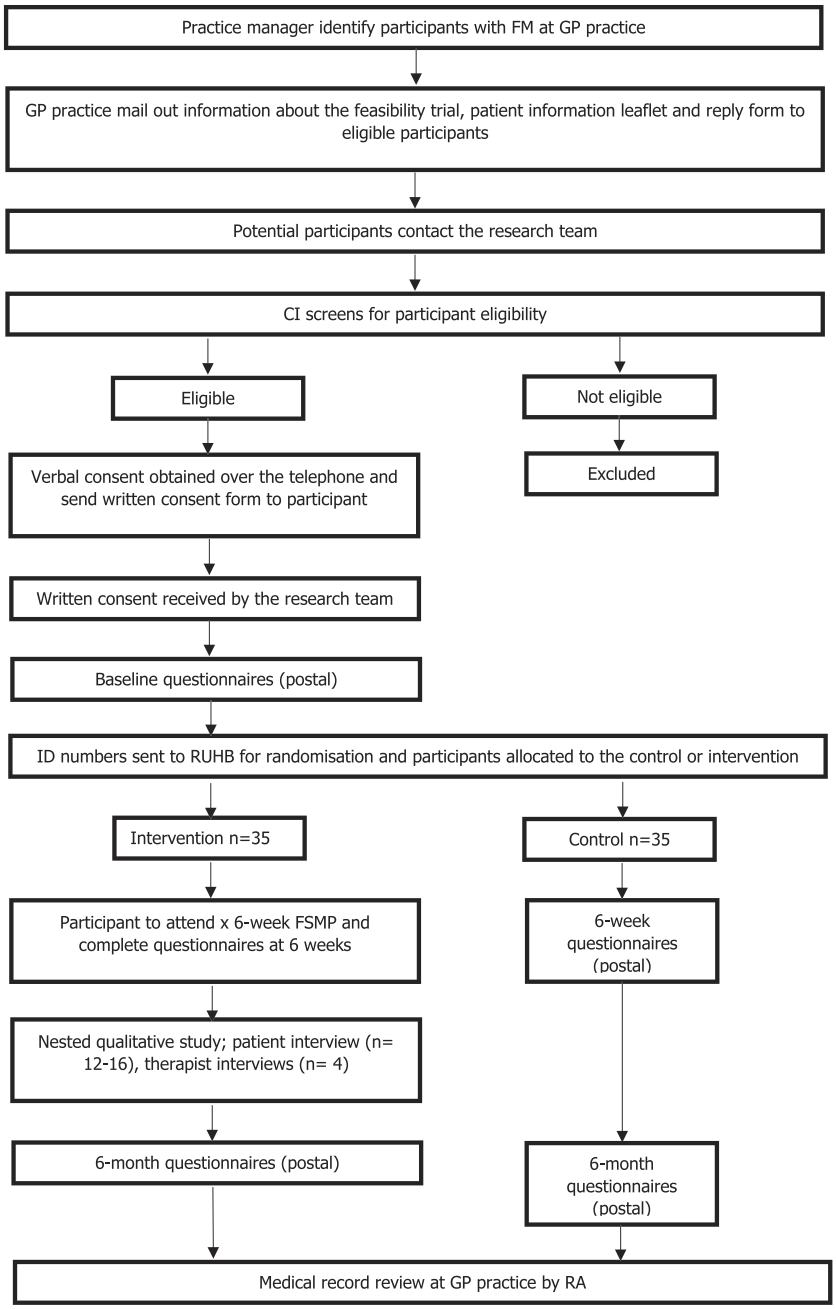

FIGURE 1 Participant timeline

3.4.2 | Control arm

Participants allocated to the control arm will continue to receive usual care from their GP. Once data collection is complete, participants randomised to the control arm will be sent out an FM information leaflet. The leaflet will provide information on FM, current treatments and information about local support groups.

Any adverse events that occur will be reported to the CI and recorded. Any serious adverse events will be reported within 24 h of discovery and to the Research Ethics Committee where appropriate. The CI must also notify the sponsor and provide a summary report to the Steering Group Committees.

3.5 | Data collection

Several different outcomes will be investigated in this feasibility study; those that are relevant to the feasibility study and additional measures needed to design a future definitive trial. All clinical outcome measures will be patient-reported. Participants randomised to the intervention arm will return the outcome measures by post at baseline and 6 months but complete the 6-week outcome measures on-site at the end of the 6-week intervention. Those in the control arm will be sent the outcome measures by post for all three timepoints. Following advice from patient partners, data will not be collected at additional time points to minimise participant burden.

The primary outcomes that are of particular relevance for feasibility of a future trial include number of patients coded as FM in primary care, percentage of FM patients deemed eligible, recruitment to the feasibility trial as a percentage of those contacted, number of analysable completed patient-reported questionnaires, attendance at the FSMP and number of patients who drop out of the FSMP.

To identify a suitable and feasible primary outcome measure for the definitive trial, the research team will collect a range of FM symptom based, quality of life (QoL) and self-management specific outcome measures. To assess the impact of FM symptoms, the Revised Fibromyalgia Impact Questionnaire (FIQR), a validated outcome measure to evaluate FM, will be included (Bennett et al., 2009).

As fatigue is a significant symptom that people affected by FM find burdensome (Humphrey et al., 2010; Wolfe, Hawley, & Wilson, 1996) the Chalder Fatigue Questionnaire will be used (Chalder et al., 1993), which has previously been used in the FM population (Naschitz et al., 2005). To monitor changes to QoL, the SF-36 will be used which has been validated for use in Primary Care (Brazier et al., 1992). The EQ-5D-5L will also be used to measure QoL (Herdman et al., 2011).

As self-efficacy can predict changes in self-management related health behaviours and increased levels of self-efficacy are closely linked with effective self-management of FM (Beal, Stuifbergen, & Brown, 2009; Burckhardt, 2005), arthritis self-efficacy outcome data will also be collected (Lorig, Chastain, Ung, Shoor, & Holman, 1989). The Arthritis Self-Efficacy Scale-8 (AES-8) will be used as it is a reliable and valid measure for FM (Brady, 2011; Mueller, Hartmann, Mueller, & Eich, 2003). To see whether any changes in sleep occur, Jenkins Sleep Scale data will be collected (Jenkins, Stanton, Niemcryk, & Rose, 1988; Crawford, Piault, Lai, & Sarzi-Puttini, 2010).

To assess the feasibility of collecting health economic data, the Client Service Receipt Inventory (CSRI) will be adapted for FM to collect health and social care use (Beecham & Knapp, 2001; Curtis & Burns, 2018). In addition, a comprehensive medical records review will be conducted. This health economic data will be collected by the RA who will attend each participating GP practice and perform an electronic medical record review of consultations, prescriptions and onward referrals to other services in the last 6 months (Table 1).

TABLE 1 Patient-reported outcome measures included in FALCON

Patient-reported outcome measure	Domain
Revised Fibromyalgia Impact Questionnaire (FIQR)	Evaluate the impact of fibromyalgia symptoms
Arthritis Self-Efficacy Scale-8 (AES-8)	Self-efficacy to self-manage FM symptoms
Chalder Fatigue Questionnaire	To assess disabling fatigue in hospital and community settings
SF-36	Quality of life
EQ-5D-5L	Quality of life
Jenkins Sleep Scale	Sleep quality

Between 12 and 16 patient participants and four therapists delivering the programme will be invited to take part in semi-structured interviews to share their experiences of the FMSP. Patient participants will be purposively selected based upon key characteristics including trial site, age, gender, severity of FM and attendance at the FSMP. The semi-structured interviews will be transcribed, anonymised and inductively coded. The codes will be grouped into categories and theoretically thematically analysed, comparing the results to existing literature.

3.6 | Data management

The CI will ensure confidentiality of participants and ensure the study adheres to the Data Protection Act (2018). Self-reported questionnaires and data regarding subjects will be physically kept in the CI's office in a locked filing cabinet on secure premises at UWE, accessed by digitally locked corridors and a key-locked door. Access will only be granted to members of the research team. Electronic identifiable participant information will be kept on UWE secure password protected computers and stored securely within an NHS therapy office at the study sites. Once the intervention has been completed at the trial sites, the research team will ensure that any participant identifiable information will be electronically deleted, and hard copies shredded in accordance with NHS policy. Qualitative data will be anonymised and managed by the research team. Patient information and all appropriate documentation will be stored for a minimum of six years after the completion of the study, in accordance with the Data Protection Act (2018).

All members of the research team will be trained to the appropriate level of good clinical practice standards, to ensure the collection of good quality data and that the protocol data collection processes will be followed. The collected quantitative data will be inputted by the RA, and 10% of the data will be double-checked by another member of the research team. The RA will contact research participants for any missing data. However, to ensure that participants are not overburdened, they will be contacted a maximum of three times at each data collection time point.

4 | ANALYSIS

The collected data will be analysed using qualitative and quantitative methods.

4.1 | Quantitative data analysis

Quantitative descriptive analysis will include the number and percentages of participants approached, recruited and retained in the study and the completion of the intervention with outcome data.

The final data will also include reasons for nonparticipation, loss to follow-up, withdrawal, missing data and noncompliance with the protocol which will be described, with the emphasis on how these may impact on the full-scale trial. These rates will be also presented by trial arms to investigate any differences requiring particular attention in the design of the main trial. Deviations from the protocol will be recorded and reported by relevant categories to identify areas requiring particular attention during the design of the main trial.

Descriptive statistics, including means and standard deviations, will be used to analyse the patient-reported outcome measures. No comparison between arms will be conducted. The data completeness of the different outcomes to identify those with the highest completion rate and candidate measures for the main trial will also be reported. Health economic data will also be analysed descriptively. The results will inform the selection of the primary outcome measure and sample size needed for an appropriately powered full RCT.

No sub-group analyses will be conducted and there will be no interim analysis.

4.2 | Qualitative data analysis

The qualitative research is underpinned by a qualitative description approach (Bradshaw, Atkinson, & Doody, 2017). All interviews will be audio recorded and transcribed verbatim. Each patient participant and therapist involved in the qualitative study will be given a unique ID and pseudonym. All transcripts will be read, checked for accuracy and anonymised for name and place. The qualitative data will then be transferred and uploaded to NVIVO software (QSR International Pty Ltd, 2018) where the transcripts will be inductively coded. A selection of the transcripts will then be doubled coded by two members of the research team and disagreements recorded. The codes will be grouped into categories to be theoretically thematically analysed (Braun & Clarke, 2006; Braun & Clarke, 2019) which will then be compared to existing literature in order to develop a comprehensive understanding of the acceptability of the intervention in the community, feasibility of the RCT and identification of important clinical outcomes.

A proportion of the FSMP sessions will be recorded for fidelity purposes. The audio files will be listened to but not transcribed. A coding framework will be developed by the research team and will be used as a fidelity assessment tool (Ritchie & Lewis, 2003). The coding framework will map key areas of the course and the therapist's manuals, and the raw audio files will then be coded to the framework. Data will be analysed exploring whether the therapists delivered the course in comparison to what is delivered at the RUHB. The results will help to refine the delivery of the FSMP intervention in the feasibility trial and help to further develop a training package for a full RCT.

5 | STUDY MONITORING

The overall responsibility for the project will be held by the CI (JP). Day to day responsibility for the trial will be held by the CI (JP) and the RA (JC), and a monthly research meeting will occur.

A project steering group meeting will be held four times per year and will be chaired by the CI (JP). The meeting will be attended by the full research team, including the patient partners, and will discuss issues relating to the trial focusing upon recruitment, protocol adherence, data quality, milestones, deliverables and budget.

To ensure the successful delivery of the feasibility trial, an independent trial steering group meeting will be held biannually. The purpose of these meetings is to ensure that the trial is achieving agreed milestones, deliverables, is on budget and that there are no protocol violations.

6 | ETHICAL APPROVAL AND DISSEMINATION

The protection of human subjects in research is of great importance. This study will adhere to the principles defined in the Declaration of Helsinki 2008 (Williams, 2008). This study has been reviewed and approved by Yorkshire & The Humber—South Yorkshire Research Ethics Committee (18/YH02/63).

To facilitate the impact of this research in practice, it will be important to provide timely feedback to the stakeholders and research partners. All stakeholders involved in this trial will receive a relevant summary of the findings. The results will be disseminated to academics and clinical leaders locally, and presentations will be given at local research events, within the local NHS trusts and at internal seminar series at UWE and the University of Bristol. The research team intends to present at national conferences, alongside disseminating results nationally using social media platforms. The quantitative and qualitative results will be submitted to peer-reviewed journals.

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank the patient partners Sophie Moss and Sarah Moden for their contribution to the design of the study.

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

SOURCES OF FUNDING

The study was funded by the Chartered Society of Physiotherapy Charitable Trust (reference: PRF/17/A29). The funder was not involved in the design of the study, collection, analysis and interpretation of data and writing the manuscript.

ORCID

Jennifer Pearson https://orcid.org/0000-0002-5754-2762
Jessica Coggins https://orcid.org/0000-0002-6663-6816
Erik Lenguerrand https://orcid.org/0000-0002-0371-731X
Sandi Derham https://orcid.org/0000-0003-4163-5697
Nicola E. Walsh https://orcid.org/0000-0002-0499-4829
Fiona Cramp https://orcid.org/0000-0001-8035-9758

REFERENCES

Arnold, L. M., Bennett, R. M., Crofford, L. J., Dean, L. E., Clauw, D. J., Goldenberg, D. L., … Buskila, D. (2019). AAPT diagnostic criteria for fibromyalgia. *The Journal of Pain*, *20*(6), 611–628. https://doi.org/10.1016/j.jpain.2018.10.008

Beal, C. C., Stuifbergen, A. K., & Brown, A. (2009). Predictors of a health promoting lifestyle in women with fibromyalgia syndrome. *Psychology, Health & Medicine*, *14*(3), 343–353. https://doi.org/10.1080/13548500902730093

Beecham, J., & Knapp, M. (2001). Costing psychiatric interventions. In G. Thornicroft (Ed.), *Measuring mental health needs* (2nd ed.) (pp. 200–224).

Bennett, R. M. (2009). Clinical manifestations and diagnosis of fibromyalgia. *Rheumatic Disease Clinics of North America*, *35*(2), 215–232. https://doi.org/10.1016/j.rdc.2009.05.009

Bennett, R. M., Friend, R., Jones, K. D., Ward, R., Han, B. K., & Ross, R. L. (2009). The revised fibromyalgia impact questionnaire (FIQR): Validation and psychometric properties. *Arthritis Research & Therapy*, *11*(4), R120. https://doi.org/10.1186/ar2783

Boonen, A., van den Heuvel, R., van Tubergen, A., Goossens, M., Severens, J. L., van der Heijde, D., & van der Linden, S. (2005). Large differences in cost of illness and wellbeing between patients with fibromyalgia, chronic low back pain, or ankylosing spondylitis. *Annals of the Rheumatic Diseases*, *64*(3), 396–402. https://doi.org/10.1136/ard.2003.019711

Bradshaw, C., Atkinson, S., & Doody, O. (2017). Employing a qualitative description approach in health care research. *Global Qualitative Nursing Research*, *4*. https://doi.org/10.1177/2333393617742282

Brady, T. J. (2011). Measures of self-efficacy: Arthritis Self-Efficacy Scale (ASES), Arthritis Self-Efficacy Scale-8 Item (ASES-8), Children's Arthritis Self-Efficacy Scale (CASE), Chronic Disease Self-Efficacy Scale (CDSES), Parent's Arthritis Self-Efficacy Scale (PASE), and Rheumatoid Arthritis Self-Efficacy Scale (RASE). *Arthritis Care & Research*, *63*(S11), S473–S485. https://doi.org/10.1002/acr.20567

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2019). Reflecting on reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*, *11*(4), 589–597. https://doi.org/10.1080/2159676X.2019.1628806

Brazier, J. E., Harper, R., Jones, N. M., O'cathain, A., Thomas, K. J., Usherwood, T., & Westlake, L. (1992). Validating the SF-36 health survey questionnaire: New outcome measure for primary care. *BMJ*, *305*(6846), 160–164. https://doi.org/10.1136/bmj.305.6846.160

Burckhardt, C. S. (2005). Educating patients: Self-management approaches. *Disability and Rehabilitation*, *27*(12), 703–709. https://doi.org/10.1080/09638280400009097

Chalder, T., Berelowitz, G., Pawlikowska, T., Watts, L., Wessely, S., Wright, D., & Wallace, E. P. (1993). Development of a fatigue scale. *Journal of Psychosomatic Research*, *37*(2), 147–153. https://doi.org/10.1016/0022-3999(93)90081-p

Crawford, B. K., Piault, E. C., Lai, C., & Sarzi-Puttini, P. (2010). Assessing sleep in fibromyalgia: Investigation of an alternative scoring method for the Jenkins Sleep Scale based on data from randomised controlled studies. *Clinical and Experimental Rheumatology-Incl Supplements*, *28*(6), S100.

Curtis, L., & Burns, A. (2018). *Unit costs of health and social care 2019, personal social services research unit*. Canterbury: University of Kent. https://doi.org/10.22024/UniKent/01.02.79286

Eich, W., Häuser, W., Arnold, B., Bernardy, K., Brückle, W., Eidmann, U., … Settan, M. (2012). Fibromyalgia syndrome. General principles and coordination of clinical care and patient education. *Schmerz*, *26*(3), 268–275. https://doi.org/10.1007/s00482-012-1167-z

Fayaz, A., Croft, P., Langford, R. M., Donaldson, L. J., & Jones, G. T. (2016). Prevalence of chronic pain in the UK: A systematic review and meta-analysis of population studies. *BMJ Open*, *6*(6), e010364. https://doi.org/10.1136/bmjopen-2015-010364

Fitzcharles, M. A., Ste-Marie, P. A., Goldenberg, D. L., Pereira, J. X., Abbey, S., Choinière, M., … Shir, Y. (2013). 2012 Canadian guidelines for the diagnosis and management of fibromyalgia syndrome: Executive summary. *Pain Research and Management*, *18*(3), 119–126. https://doi.org/10.1155/2013/918216

Hammond, A., & Freeman, K. (2006). Community patient education and exercise for people with fibromyalgia: A parallel group randomized controlled trial. *Clinical Rehabilitation*, *20*(10), 835–846. https://doi.org/10.1177/0269215506072173

Herdman, M., Gudex, C., Lloyd, A., Janssen, M. F., Kind, P., Parkin, D., … Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research*, *20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Hughes, G., Martinez, C., Myon, E., Taïeb, C., & Wessely, S. (2006). The impact of a diagnosis of fibromyalgia on health care resource use by primary care patients in the UK: An observational study based on clinical practice. *Arthritis & Rheumatology*, *54*(1), 177–183. https://doi.org/10.1002/art.21545

Humphrey, L., Arbuckle, R., Mease, P., Williams, D. A., Samsoe, B. D., & Gilbert, C. (2010). Fatigue in fibromyalgia: A conceptual model informed by patient interviews. *BMC Musculoskeletal Disorders*, *11*(1), 216. https://doi.org/10.1186/1471-2474-11-216

Jenkins, C. D., Stanton, B. A., Niemcryk, S. J., & Rose, R. M. (1988). A scale for the estimation of sleep problems in clinical research. *Journal of Clinical Epidemiology*, *41*(4), 313–321. https://doi.org/10.1016/0895-4356(88)90138-2

Jones, G. T., Atzeni, F., Beasley, M., Flüß, E., Sarzi-Puttini, P., & Macfarlane, G. J. (2015). The prevalence of fibromyalgia in the general population: A comparison of the American College of Rheumatology 1990, 2010, and modified 2010 classification criteria. *Arthritis & Rheumatology*, *67*(2), 568–575. https://doi.org/10.1002/art.38905

Kennedy, A., Reeves, D., Bower, P., Lee, V., Middleton, E., Richardson, G., … Rogers, A. (2007). The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: A pragmatic randomised controlled trial. *Journal of Epidemiology & Community Health*, *61*(3), 254–261. https://doi.org/10.1136/jech.2006.053538

Lorig, K., Chastain, R. L., Ung, E., Shoor, S., & Holman, H. R. (1989). Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis and Rheumatism*, *32*(1), 37–44. https://doi.org/10.1002/anr.1780320107

Macfarlane, G. J., Kronisch, C., Dean, L. E., Atzeni, F., Häuser, W., Fluß, E., … Jones, G. T. (2017). EULAR revised recommendations for the management of fibromyalgia. *Annals of the Rheumatic Diseases*, *76*(2), 318–328. https://doi.org/10.1136/annrheumdis-2016-209724

Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., … Wood, C. E. (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine*, *46*(1), 81–95. https://doi.org/10.1007/s12160-013-9486-6

Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science*, *6*(1), 42. https://doi.org/10.1186/1748-5908-6-42

Mueller, A., Hartmann, M., Mueller, K., & Eich, W. (2003). Validation of the arthritis self-efficacy short-form scale in German fibromyalgia patients. *European Journal of Pain*, *7*(2), 163–171. https://doi.org/10.1016/S1090-3801(02)00097-6

Naschitz, J. E., Rozenbaum, M., Fields, M. C., Enis, S., Manor, H., Dreyfuss, D., … Sabo, E. (2005). Cardiovascular reactivity in fibromyalgia: Evidence for pathogenic heterogeneity. *The Journal of Rheumatology*, *32*(2), 335–339.

Newman, S., Steed, L., & Mulligan, K. (2004). Self-management interventions for chronic illness. *The Lancet*, *364*(9444), 1523–1537. https://doi.org/10.1016/S0140-6736(04)17277-2

NHS England. (2014). Five year forward view. Retrieved from https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

NHS England. (2019). The NHS long term plan. Retrieved from https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf

Nüesch, E., Häuser, W., Bernardy, K., Barth, J., & Jüni, P. (2013). Comparative efficacy of pharmacological and non-pharmacological interventions in fibromyalgia syndrome: Network meta-analysis. *Annals of the Rheumatic Diseases*, *72*(6), 955–962. https://doi.org/10.1136/annrheumdis-2011-201249

Pearson, J., Whale, K., Walsh, N. E., Derham, S., Russell, J., & Cramp, F. (2020). Fibromyalgia self-management: Mapping the behaviour change techniques used in a practice-based programme[published online ahead of print, 2020 May 26]. *Musculoskeletal Care*. https://doi.org/10.1002/msc.1470

QSR International Pty Ltd. (2018). NVivo (Version 12) [software program]. Retrieved from https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home

Ritchie, J., & Lewis, J. (2003). *Qualitative research practice: A guide for social science students and researchers* (2nd ed.). London: Sage.

Schulman-Green, D., Jaser, S. S., Park, C., & Whittemore, R. (2016). A metasynthesis of factors affecting self-management of chronic illness. *Journal of Advanced Nursing*, *72*(7), 1469–1489. https://doi.org/10.1111/jan.12902

Soni, A., Santos-Paulo, S., Segerdahl, A., Javaid, M. K., Pinedo-Villanueva, R., & Tracey, I. (2019). Hospitalization in fibromyalgia: A cohort-level observational study of in-patient procedures, costs and geographical variation in England. *Rheumatology*Advanced Online Publication, *59*, 2074–2084. https://doi.org/10.1093/rheumatology/kez499

The Data Protection Act. 2018. Retrieved from: https://www.gov.uk/government/collections/data-protection-act-2018

Williams, J. R. (2008). The Declaration of Helsinki and public health. *Bulletin of the World Health Organization*, *86*(8), 650–652. https://doi.org/10.2471/blt.08.050955

Wolfe, F., Clauw, D. J., Fitzcharles, M. A., Goldenberg, D. L., Häuser, W., Katz, R. L., … Walitt, B. (2016). 2016 revisions to the 2010/2011 fibromyalgia diagnostic criteria. *Seminars in Arthritis and Rheumatis*, *46*(3), 319–329. https://doi.org/10.1016/j.semarthrit.2016.08.012

Wolfe, F., Hawley, D. J., & Wilson, K. (1996). The prevalence and meaning of fatigue in rheumatic disease. *The Journal of Rheumatology*, *23*(8), 1407–1417.

How to cite this article: Pearson J, Coggins J, Lenguerrand E, et al. A feasibility randomised controlled trial of a fibromyalgia self-management programme in a community setting with a nested qualitative study (FALCON): Study protocol. *Musculoskeletal Care*. 2021;19:59–66. https://doi.org/10.1002/msc.1509