

# Fibromyalgia community self-management feasibility trial

<b>Submission date</b> 05/04/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/07/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Fibromyalgia (FM) is a complex long-term condition affecting up to 5.4% of the UK population. It is associated with chronic widespread pain, fatigue, stiffness, sleep problems, memory and concentration difficulties, and irritable bowel syndrome. FM can cause high levels of disability, with individuals making frequent use of healthcare resources and experiencing loss of workdays. There is limited robust evidence for the effectiveness of drug treatments for FM. Current guidelines for the treatment of FM all recommend non-drug treatments, of which cognitive behaviour therapy (CBT), aerobic exercise, hydrotherapy, relaxation and patient education are the best evidenced. In combination with the drug and non-drug treatments to treat FM, a common patient goal is to develop the skills needed to independently self-manage their condition. The evidence for self- management interventions are compelling and have been shown to improve both physical symptoms and function, participant engagement, self-efficacy, mood, and reduce health service costs in a number of long-term conditions. 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 GP FM-related contacts.

Allied health professionals at the Royal National Hospital for Rheumatic Diseases, Royal United Hospitals Bath NHS Foundation Trust (RUHB), have designed the Fibromyalgia Self-Management Programme (FSMP), a non-drug, multidisciplinary exercise and education group intervention. The main aims of the FSMP are to provide condition-specific patient-centred education and exercise advice, supporting 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. Local audits suggest that the FSMP improves patients' self-efficacy in managing FM symptoms, reduces healthcare utilisation costs and has high levels of patient satisfaction. To date, the delivery of the FSMP has been within an acute hospital setting by a team of specialist Rheumatology occupational therapists and physiotherapists. However, recent government plans recommended that the care of adults affected by long-term conditions is transferred from acute hospital environments to the community. Transferring the delivery of FSMP to a community setting presents an opportunity to determine the clinical and cost effectiveness of the programme. 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 non-specialist therapists delivering the programme may not have a rheumatology background and are likely to have additional training needs.

The aim of this feasibility study is to determine the practicality and acceptability of conducting a full trial to deliver the FSMP in the community.

**Who can participate?**

Adults aged 18 and over with FM

**What does the study involve?**

Participants are randomly allocated to either the FSMP or the GP management group (control group). Those in the GP management group continue under the normal care of their GP, but are asked to complete the questionnaires. Those in the education programme group attend six education classes over a six-week period. Each class is run by a physiotherapist and occupational therapist, consists of 8-12 people and lasts for about 2.5 hours. During this time they participate in education sessions which may help them to manage their fibromyalgia. The classes consist of information about FM and chronic pain, pacing activities, sleep, medication, relaxation, diet and exercise. They also receive information on how to set goals, plan activities and participate in optional gentle exercise sessions.

**What are the possible benefits and risks of participating?**

Participants may be at risk of increased fatigue after the sessions, but as this is self-management intervention the risk to patients is low. The clinical teams at the RUHB have been delivering the FSMP intervention for over 10 years and are not aware of any issues raised by patients.

Participants are informed of self-management techniques and this may subsequently improve their quality of life. The results of this study will also impact how fibromyalgia treatment is managed.

**Where is the study run from?**

The trial team are based within the University of the West of England or within the Royal National Hospital for Rheumatic Diseases (Royal United Hospitals Bath NHS Trust). The trial sites are:

1. Chippenham Community Hospital
2. Charlotte Keel Medical Practice

**When is the study starting and how long is it expected to run for?**

January 2019 to April 2021 (updated 02/12/2020, previously: December 2020)

**Who is funding the study?**

Chartered Society of Physiotherapy Charitable Trust (UK)

**Who is the main contact?**

Dr Jen Pearson

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## **Contact information**

**Type(s)**

Public

**Contact name**

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Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

HAS.18.8.015; 39058

**Study information****Scientific Title**

A feasibility randomised controlled trial (RCT) of a fibromyalgia self-management programme (FSMP) in a community setting

**Acronym**

FALCON

### **Study objectives**

The research question is whether it is feasible to conduct an RCT of a community-based Fibromyalgia Self Management Programme (FSMP).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 09/08/2018, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 1048091; Email: nrescommittee.yorkandhumber-southyorks@nhs.net), IRAS project ID: 246892

### **Study design**

Feasibility randomised control trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Community

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

### **Health condition(s) or problem(s) studied**

Fibromyalgia

### **Interventions**

Patient participants will be randomised to either usual care or referred to one of two local community sites where the 6-week FSMP intervention will be delivered. A range of outcome data including fibromyalgia symptoms, quality of life and self-efficacy to manage their FM symptoms will be collected at baseline, 6 weeks and 6 months. To explore the acceptability of the FSMP within a community setting a qualitative study, consisting of semi-structured interviews with patient participants and health professionals (physiotherapists and occupational therapists delivering the FSMP), will be nested within the feasibility RCT. Quantitative outcomes will be analysed descriptively and qualitative data will be analysed thematically to inform a future RCT.

### **Intervention Type**

Behavioural

**Primary outcome measure**

1. The ability to recruit adults with FM to the trial from primary care by 24 months
2. Attrition rate recorded as the number of participants that remain until the end of follow up at 6 months
3. Feasibility of collecting outcome data from patients recruited to the trial
4. Identify the primary outcome for a future full trial
5. Recruitment rate to inform a full trial
6. Sample size calculations to inform a full trial

**Secondary outcome measures**

Measured at baseline, 6 weeks and 6 months:

1. Self-efficacy to self-manage FMS symptoms assessed using Arthritis Self-Efficacy 8-item scale
2. Disabling fatigue in hospital and community settings assessed using Chalder fatigue scale
3. Health economic data collected using Client Service Receipt Inventory
4. Quality of life assessed using EQ-5D-5L Health Questionnaire
5. Impact of fibromyalgia symptoms assessed using revised fibromyalgia impact questionnaire (FIQR)
6. Sleep quality assessed using Jenkins Sleep Questionnaire
7. Quality of life assessed using SF-36 health survey questionnaire

**Overall study start date**

07/01/2019

**Completion date**

06/04/2021

**Eligibility****Key inclusion criteria**

1. Adults aged 18 and over with a confirmed diagnosis of FM according to ACR (2016) diagnostic criteria
2. Willingness to take part in a group based intervention
3. Ability to travel to attend the group sessions

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

70

**Total final enrolment**

**Key exclusion criteria**

1. Those under 18 years of age
2. Diagnosed with rheumatoid arthritis
3. Generalised Anxiety Disorder Questionnaire (GAD-7) score >15
4. Has previously attended the RUHB FSMP or pain management programme
5. Needs a carer to attend the FSMP
6. Needs an interpreter to communicate in English

**Date of first enrolment**

06/03/2019

**Date of final enrolment**

01/11/2019

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Bristol Community Health**

5th Floor South Plaza

Bristol

United Kingdom

BS1 3NX

**Study participating centre****Wiltshire Health and Care**

Chippenham Community Hospital

Rowden Hill

Chippenham

United Kingdom

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**Sponsor information****Organisation**

University of the West of England

**Sponsor details**

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**Sponsor type**

University/education

**Website**

[www.uwe.ac.uk](http://www.uwe.ac.uk)

**ROR**

<https://ror.org/02nwg5t34>

**Funder(s)****Funder type**

Charity

**Funder Name**

Chartered Society of Physiotherapy Charitable Trust

**Alternative Name(s)**

CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Results and Publications**

Publication and dissemination plan

To facilitate the impact of their research in practice the researchers recognise the importance of providing timely feedback from research to our stakeholders and research partners. They will ensure that all stakeholders involved in this research (patients, therapists at community sites, GPs and commissioners (involved in the MSK STP review) receive a relevant summary of the findings. In order to disseminate the results to academics and clinical leaders locally, the researchers will present their findings at local research events, internal seminar series at the University of the West of England (UWE) and University of Bristol (UoB) and within local NHS trusts. Nationally, they plan to present at three national conferences: Physiotherapy UK, Occupational Therapy Show and British Society of Rheumatology. They will provide links to the findings from their research across the UWE social media platforms. They aim to publish both the protocol and findings (quantitative and qualitative) papers in peer-reviewed journals.

### **Intention to publish date**

01/05/2022

### **Individual participant data (IPD) sharing plan**

The datasets generated during the current study are available in the University of the West of England Research Data Repository (<http://researchdata.uwe.ac.uk/657>)

### **IPD sharing plan summary**

Stored in publicly available repository

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol article</a>	protocol	01/03/2021	07/09/2020	Yes	No
<a href="#">Results article</a>	results	11/07/2022	13/07/2022	Yes	No