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Fibromyalgia community self-management feasibility trial

Submission date
05/04/2019

Recruitment status
No longer recruiting

Registration date
29/04/2019

Overall study status
Completed

Last Edited
13/07/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
77

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
United Kingdom

England

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
SN15 2AJ

Sponsor information

Organisation
University of the West of England

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

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/07/2022	13/07/2022	Yes	No
Protocol article	protocol	01/03/2021	07/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes