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Improved management of patients with fibromyalgia: Implementation and evaluation of an integrated care model

Submission date
12/07/2016

Recruitment status
No longer recruiting

Registration date
12/07/2016

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Musculoskeletal Diseases

[X] 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 common long-term condition, which causes widespread muscle and joint pain all over the body. The exact cause of FM is unknown, but it is thought that a variety of physical, mental and emotional factors are responsible. Current treatments for FM typically involve a combination of pain killers, talking therapies and lifestyle changes. In addition, exercise has also been found to be an effective treatment, including helping to reduce pain. The aim of this study is to find out whether a multi-component rehabilitation programme can help to improve FM patients overall wellbeing, reduce their symptoms of pain, fatigue and sleep disturbances, and increase their physical activity and work ability.

Who can participate?
Adults aged between 20 and 50 who have fibromyalgia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a rehabilitation program in their community. This involves a 10 sessions of a mindfulness training programme called the Vitality Training Programme, VTP (which helps people to become more aware and accepting of their feelings and bodily sensations) over four months, followed by eight weeks of individually tailored physical activity counselling provided by a physiotherapist at a Healthy Living Centre. Those in the second group continue to receive treatment as usual for the duration of the study, but are given the chance to take part in the rehabilitation programme once the study is over. At the start of the study, after the VTP is complete (four months) and then after 12 months, participants in both groups complete a range of questionnaires in order to find out if their overall wellbeing, pain symptoms, sleep and ability to work and take part in physical activity have improved.

What are the possible benefits and risks of participating?
Participants who take part in the rehabilitation programme may benefit from improvements to their overall wellbeing, pain symptoms, sleep and ability to work and take part in physical activity. There are no notable risks involved with participating.

Where is the study run from?
The study is run by the National Advisory Unit on Rehabilitation in Rheumatology and takes place in two districts in the City of Oslo and six other municipalities in South-Eastern Norway (Norway)

When is the study starting and how long is it expected to run for?
March 2016 to May 2020

Who is funding the study?
South-Eastern Norway Regional Health Authority (Norway)

Who is the main contact?
Dr Heidi A. Zangi
heidi.zangi@diakonsyk.no

Contact information

Type(s)
Scientific

Contact name
Dr Heidi A. Zangi

ORCID ID
http://orcid.org/0000-0001-6882-221X

Contact details
National Advisory Unit on Rehabilitation in Rheumatology
PO Box 23 Vinderen
Oslo
Norway
0319
+47 (0)93054517
heidi.zangi@diakonsyk.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016015

Study information

Scientific Title

Evaluation of a multicomponent rehabilitation program for patients with fibromyalgia in primary health care compared to treatment as usual combined with a short patient education program: Effects on patient global impression of change, disease related symptoms, physical activity and work ability

Study objectives
The integrated care model will improve fibromyalgia patients' overall wellbeing, pain, fatigue, sleep disturbances, physical activity and work ability at one-year follow-up compared to patients receiving 'treatment as usual'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committees for Medical and Health Research Ethics, 04/02/2016, ref: 2015/2447

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, only available in Norwegian

Health condition(s) or problem(s) studied
Fibromyalgia/widespread musculoskeletal pain

Interventions
Participants will be randomised one of two groups:

Intervention group: Participants take part in a multicomponent rehabilitation programme in their home municipality. The programme comprises a 10-session mindfulness-based Vitality Training Programme (VTP) followed by 8 weeks tailored physical exercise supervised by a physiotherapist at a Healthy Life Center.

Control group: Participants will receive treatment as usual in primary care, i.e. GP consultations and any physical activity as usual. They will be offered the VTP after completion of the last data collection, i.e. one year after inclusion.

Participants in both groups are followed up at 4 months (end of VTP) and 12 months post-randomisation.

Intervention Type
Behavioural

Primary outcome measure
Patient global impression of change (PGIC) measured by a 7-point self-reported Likert scale ranging from 1 (“I feel very much worse”) through 4 (“no change”) to 7 (“I feel very much better”) one year after inclusion. Scores of 6 and 7 are considered clinically relevant improvement. The primary outcome will be measured after completion of the VTP (4 months) and at 12 months follow-up.

Secondary outcome measures
All outcomes will be measured at baseline (before randomisation), at 4 months and 12 months:
1. Pain measured by Numeric Rating Scale (NRS, 0-10)
2. Fatigue measured by Numeric Rating Scale (NRS, 0-10)
3. Sleep quality measured by Numeric Rating Scale (NRS, 0-10)
4. Psychological distress measured by General Health Questionnaire-12 (GHQ-12)
5. Physical activity measured by 4 questions from the Norwegian HUNT-study
6. Work ability measured by the Work Productivity and Activity Impairment Questionnaire (WPAI)

Added 04/05/2021:
7. Tendency to be mindful measured using the Five Facet Mindfulness Questionnaire (FFMQ) at baseline (before randomisation), at 4 months and 12 months
8. Motivation and barriers to physical activity measured using the Exercise Beliefs and Exercise Habits questionnaire at baseline (before randomisation), at 4 months and 12 months
9. Health-related quality of life measured using the EuroQol (EQ-5D-5L) at baseline (before randomisation), at 4 months and 12 months

Overall study start date
01/03/2016

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Rheumatologist confirmed diagnosis of fibromyalgia according to the American College of Rheumatology 2011 criteria
2. Aged between 20 and 50

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
140

Total final enrolment
170

Key exclusion criteria
1. Comorbid inflammatory rheumatic disease
2. Serious psychiatric disorder
3. Other disease impeding physical activity
4. Not at all been working during the last two years because of disease
5. Not able to understand and speak Norwegian

Date of first enrolment
01/11/2016

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Norway

Study participating centre
National Advisory Unit on Rehabilitation in Rheumatology
Dept. of Rheumatology
Diakonhjemmet Hospital
PO Box 23 Vinderen
Oslo
Norway
0319

Study participating centre
Eidsvoll Municipality
Rådhusgata 1
Eidsvoll
Norway
2080

Study participating centre
Hurdal Municipality
Minneåsvegen 3

Hurdal
Norway
2090

Study participating centre
Gjerdrum Municipality
Gjerivegen 1
Gjerdrum
Norway
2022

Study participating centre
Nannestad Municipality
Teiealleen 31
Nannestad
Norway
2030

Study participating centre
Nes Municipality
Rådhusgata 2
Årnes
Norway
2150

Study participating centre
Ullensaker Municipality
Furusethgt. 12
Jessheim
Norway
2050

Study participating centre
Frogner District
Sommerrogata 1
Oslo
Norway
0201

Study participating centre
Ullern District
Hoffsveien 48
0377
Norway
0377

Sponsor information

Organisation
National Advisory Unit on Rehabilitation in Rheumatology

Sponsor details
PO Box 23 Vinderen
Oslo
Norway
0319
+47 (0)22451500
postmottak@diakonsyk.no

Sponsor type
Hospital/treatment centre

Website
http://diakonhjemmetsykehus.no

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Government

Funder Name
South-Eastern Norway Regional Health Authority

Results and Publications

Publication and dissemination plan
The results from the study will be published in a high-impact peer reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Heidi A. Zangi (heidi.zangi@diakonsyk.no).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/06/2018		Yes	No
Results article		29/06/2021	01/07/2021	Yes	No
Results article		07/01/2025	10/01/2025	Yes	No