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Identifying prognostic factors in fibromyalgia

Submission date
21/07/2017

Recruitment status
No longer recruiting

Registration date
06/08/2017

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People with fibromyalgia (FM) are managed in both primary and secondary care, but its diagnosis and management remain a challenge for patients and healthcare professionals. Currently, there is no evidence of the outcome of treatment and rehabilitation of FM in Norway, or whether patient characteristics and content of the rehabilitation program influences patients' health outcome. Consequently, there is currently no attempt to target the rehabilitation practice to patient characteristics. The aim of this study is to examine three different aspects of rehabilitation for FM in Norway.

Who can participate?
Adults aged 18 to 70 who have FM

What does the study involve?
Participants are asked to complete a questionnaire about their current and planned rehabilitation, their general health and other information. This is completed before they receive rehabilitation, as well as six and 12 months after the end of rehabilitation.
What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
This study is being run by Norwegian National Advisory Unit on Rehabilitation in Rheumatology (Norway) and takes place in three regional coordination units for rehabilitation in Western, South-Eastern and Central Norway

When is the study starting and how long is it expected to run for?
April 2017 to June 2018

Who is funding the study?
Norwegian National Advisory Unit on Rehabilitation in Rheumatology (Norway)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n/a

Study information

Scientific Title
Development and validation of a fibromyalgia rehabilitation screening tool

Acronym
FiRST

Study objectives
The aim of this study is to examine three distinct but inter-related aspects of rehabilitation for fibromyalgia (FM) including:
1. The course of FM in the context of the nature and quality of current at Norwegian rehabilitation institutions
2. Identification of specific factors that is associated with prognosis of FM in this context
3. Development and validation of a statistical model that can predict individual risk of a future outcome for patients with FM

Ethics approval required

Old ethics approval format

Ethics approval(s)
Norwegian Regional Committee for Medical Research Ethics (REK South-East), 22/02/2017, ref: 2016/2032

Study design
Multi-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
When consent has been provided, a unique identifier for each participant is generated and registered in an online data collection tool. The participants receive an email or SMS with a unique link to the questionnaire, and asked to complete sections on general demographic information, current and planned treatment and rehabilitation, information about symptoms and possible prognostic factors for FM.

The questionnaires are completed one to three weeks before rehabilitation, and six and 12 months after inclusion.

Intervention Type
Mixed

Primary outcome measure
Patient global impression of change (PGCI) is measured using the seven point self-reported Likert scale at six and 12 months

Secondary outcome measures
Work productivity and activity impairment is measured using the Work Productivity and Activity Impairment (WPAI) questionnaire at six and 12 months

Overall study start date
15/04/2016

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Patients with Fibromyalgia referred to rehabilitation by their general practitioner
2. Men and women between 18 and 70 years of age admitted to the participating centre

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
986

Key exclusion criteria
Inability to understand and speak Norwegian.

Date of first enrolment
01/04/2017

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
Norway

Study participating centre
Regional Coordination Unit for rehabilitation in South-Eastern Norway Regional Health Authority
Nesodden
Norway
N-1450 Nesoddtangen

Study participating centre
Regional Coordination Unit for rehabilitation in Western Norway Regional Health Authority
Bergen
Norway
N-5021 Bergen

Study participating centre
Regional Coordination Unit for rehabilitation in Central Norway Regional Health Authority
Levanger
Norway
N-7601 Levanger

Sponsor information

Organisation
Norwegian National Advisory Unit on Rehabilitation in Rheumatology

Sponsor details
PO Box 23 Vinderen
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Norwegian National Advisory Unit on Rehabilitation in Rheumatology

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Additional documentation is available upon request. Planned publication of the study protocol.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2022	16/08/2022	Yes	No