

Identifying prognostic factors in fibromyalgia

Submission date 21/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/08/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/08/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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