The effect of education about pain on illness perceptions in patients with fibromyalgia: a randomised clinical trial with a six-month follow up

Submission date	Recruitment status	Prospectively registered
20/03/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/04/2008	Completed	Results
Last Edited	Condition category	Individual participant data
30/04/2008	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Miriam van Ittersum

Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

Does giving written information about pain and the sensitisation model influence illness perceptions and health status in patients with fibromyalgia?

Hypothesis:

Educating patients about pain physiology is effective in changing patients' negative and catastrophising perceptions about their pain and possibly has an indirect de-sensitising effect on the central nervous system.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of University Hospital Antwerpen (Belgium) in October 2007.

Study design

Multicentre randomised single-blind controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Fibromyalgia syndrome, chronic pain, patient education

Interventions

Participants in the intervention group receive written information about pain (aetiology, physiology) and central sensitisation, either by email or postal. After two weeks every participant gets a phone call from one of the investigators to ask if the participant received and read the information, to motivate to do so when necessary and to give the participant the possibility to ask questions about the written information. Besides this phone call, every participant can ask questions to the investigators (electronic or by post) about interpretation of the written information and about how to apply this in daily living, with a maximum of two times of contacting the investigators. Patients get a fixed number of weeks (six) to read and absorb the information, to ask questions about it and to incorporate it in their daily lives.

Participants in the control group receive written information about the possible effects of relaxation exercise and education about how to perform such exercises. The procedures for participants in the control group are exactly the same as for those in the intervention group (one phone call, maximum of two times asking questions, six weeks to read and absorb the information and to ask questions).

Measures:

- 1. Fibromyalgia Impact Questionnaire (FIQ)
- 2. Pain Catastrophising Scale (PCS)
- 3. Revised Illness Perception Questionnaire (IPQ-R)

The intervention starts after three weeks and lasts for six weeks.

Joint sponsor/affiliation:
University of Applied Sciences Groningen (The Netherlands)
c/o Miriam van Ittersum
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The Netherlands

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. The 'rumination' subscale of the PCS
- 2. The 'consequences' and the 'psychological attributions' subscales of the IPQ-R

All outcomes will be measured at the same times: at the start of the study, after three weeks, six weeks, and six months.

Key secondary outcome(s))

- 1. The FIQ total score
- 2. The 'magnification' and 'helplessness' subscales of the PCS
- 3. The 'identity, 'timeline', 'personal control', 'treatment control', 'illness coherence', 'timeline cyclical', 'emotional representations', 'risk factor attribution', 'immune attribution', 'chance attribution' and 'fibromyalgia specific attribution' subscales of the IPQ-R

All outcomes will be measured at the same times: at the start of the study, after three weeks, six weeks, and six months.

Completion date

30/06/2008

Eligibility

Kev inclusion criteria

Patients with fibromyalgia according to the diagnostic criteria by the American College of Rheumatology, both men and women.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

ΔII

Key exclusion criteria

- 1. Age under 18 or over 65 years
- 2. Non-Dutch speaking
- 3. Pregnant during study period

Date of first enrolment 20/10/2007

Date of final enrolment 30/06/2008

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre Eyssoniusplein 18 Groningen Netherlands 9714 CE

Sponsor information

Organisation

University of Antwerp (Belgium)

ROR

https://ror.org/008x57b05

Funder(s)

Funder type

University/education

Funder Name

Hanze University Groningen (The Netherlands)

Funder Name

University of Antwerp (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes