ISRCTN86684957 https://doi.org/10.1186/ISRCTN86684957

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
20/03/2008

Recruitment status
No longer recruiting

Registration date
30/04/2008

Overall study status
Completed

Last Edited
30/04/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Eyssoniusplein 18
Groningen
Netherlands
9714 CE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

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 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
Eyssoniusplein 18
9714 CE Groningen
The Netherlands

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
20/10/2007

Completion date

30/06/2008

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200 participants in total, 100 in the intervention group (information about sensitisation) and 100 in the control group (information about relaxation)

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)

Sponsor details
c/o Jo Nijs
Keizerstraat 15
Antwerpen
Belgium
2000

Sponsor type
University/education

Website
http://www.ua.ac.be/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration