Use of guided imagery in patients with fibromyalgia: effects on pain, self-efficacy and functional status

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The primary objective is to gain insight into the effects of guided imagery on pain intensity in people with fibromyalgia. Secondary objective is to gain insight into the effects on self efficacy and functional status.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON35696

Source
ToetsingOnline

Brief title
Use of guided imagery in patients with fibromyalgia

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
fibromyalgia, fibromyalgia syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Selecteer
Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd door

Fonds NutsOhra

Intervention

Keyword: fibromyalgia, functional status, pain, self efficacy

Outcome measures

Primary outcome

The primary outcome of the study is pain intensity.

Secondary outcome

Secundary outcomes are self efficacy and functional status.

Study description

Background summary

The cause of fibromyalgia is unknown, and no specific medical treatment exists. Therefore it is important that people with fibromyalgia learn to manage their complaints by themselves.
It is expected that the use of guided imagery techniques provides an opportunity for self management of complaints. Guided imagery is a relaxation intervention, in which the care provider guides the patient in visualising a pleasant, relaxing situation (e.g. walking in a forest, lying on the beach). The care provider asks the patient about his sensory impressions (e.g. temperature, noises), and by doing so the patient's ability to visualise the pleasant situation can be improved, and the intended purpose (e.g. pain reduction) may be reached.

There is already a lot of evidence regarding the effectiveness of guided imagery on for instance pain and well-being in oncological patients (see the meta-review van Luebbert et al., 2001).
About the effects of guided imagery in people with fibromyalgia less is known. So far there are only a few studies published in this area (Fors en Götestam, 2000; Fors et al., 2002; Menzies et al., 2006; Menzies en Kim, 2008). These four studies provide insufficient evidence, particularly because the results are not in all regards unequivocal. Therefore, more research is needed on the effects of guided imagery in this specific patient group. The proposed project will provide more insight into the effectiveness of guided imagery with regard to pain intensity, self efficacy and functional status of people with

fibromyalgia.

Study objective

The primary objective is to gain insight into the effects of guided imagery on pain intensity in people with fibromyalgia. Secondary objective is to gain insight into the effects on self efficacy and functional status.

Study design

This study has a randomised pretest posttest control group design. The experimental condition consists of 2 group meetings supervised by a specialised reumatology nurse in combination with instruction and use of guided imagery. In the control condition patients also have 2 group meetings, but they are not instructed about guided imagery.

Intervention

The experimental condition consists of group support (2 meetings) in combination with instruction about and use of guided imagery techniques. Participants in the experimental condition receive a CD with guided imagery exercises and they are requested to use these exercises at a daily base at home.
In the control condition there are two group meetings as well, but no instruction on guided imagery is provided.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
The burden for patients is very limited and concerns:
* participation in 2 group meetings of 1,5 hrs each, guided by a specialised rheumatology nurse
* filling in a set of questionnaires about pain, self efficacy and functional status at 3 measurement points, which will take about 0,5 hrs/measurement
* writing a pain diary during 4 weeks (between group meeting 1 and 2), which will take 5 minutes/day.

Participation involves no risks for the patients. The lack of risks, the limited research burden and the expected benefits of the intervention, justify the research.

Contacts

Public
Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- having a diagnosis of fibromyalgia for less than 6 years, proved by a (copy of a) diagnosis by a reumatologist based on the classification criteria of the American College of Rheumatology
- being able to travel to the group meetings in Utrecht
- being able to sit down for about 1,5 hrs, during the groups meetings
- sufficient hearing abilities for hearing the exercises

Exclusion criteria

- having a psychiatric disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2009
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23507
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28451.041.09
OMON	NL-OMON23507