Guided imagery in patients with fibromyalgia.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23507

Source
NTR

Health condition

fibromyalgie; fibromyalgia

Sponsors and support

Primary sponsor: NIVEL (Utrecht), Aveant (Utrecht), Van Praag Instituut (Utrecht), F.E.S. (Amsterdam)
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Source(s) of monetary or material Support: Fonds NutsOhra (Amsterdam)

Intervention

Outcome measures

Primary outcome

Daily pain (VAS).

Secondary outcome

1. Self-efficacy (Chronic Pain Self-Efficacy Scale);

2. Functional status (Fibromyalgia Impact Questionnaire).

Study description

Background summary

Objectives:
To investigate the effects of a 4-week intervention of guided imagery on pain level, functional status, and self-efficacy in persons with fibromyalgia.

Design:
Longitudinal, prospective, randomized controlled clinical trial.

Setting and subjects:
The sample includes people diagnosed with fibromyalgia ≤6 years (American College of Rheumatology) who are able to travel, sit 1,5 hours and have sufficient hearing.

Intervention:
Participants randomized to Guided Imagery (GI) receive two 1,5 hour group sessions, including: group conversation, a set of four guided imagery exercises on cd and instructions how to use at least one exercise daily for 4 weeks. Participants randomized to the control groups receive two 1,5 hour group sessions with group conversation.

Measures:
All participants complete daily pain VAS-scales. The Chronic Pain Self-Efficacy Scale and the

Fibromyalgia Impact Questionnaire are completed at baseline, 4, and 10 weeks.

Study objective

Guided imagery will have positive effects on pain, self-efficacy and functional status of patients diagnosed with fibromyalgia.

Study design

1. Pain: daily during 4 weeks;

2. Self-efficacy and functional status:

A. Pre-intervention (pre-test);

B. After 4 weeks (post-test);

C. After 10 weeks (follow-up).

Intervention

EXPERIMENTAL

1. Two 1,5 hour group sessions: group conversation, instruction about Guided Imagery (GI), distribution of cd with GI exercises;

2. 1 or 2 GI exercises per day during 4 weeks.

CONTROL

Two 1,5 hour group sessions: group conversation.

Guided Imagery has been defined as a dynamic, psychophysiologic process in which a person is guided to imagine, and experience, an internal reality in the absence of external stimuli. A person who uses imagery may experience an affective, behavioural or physiologic (i.e., psychophysiologic) response without a real stimulus event. In this way mental imagery may be used to alter one's physiologic process, mental state, self-image, performance, or behavior.

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Eligibility criteria

Inclusion criteria

1. Diagnosed fibromyalgia (American College of Rheumatology: Wolfe et al., 1990);

2. Being able to travel;

3. Being able to sit 1,5 hours;

4. Sufficient hearing.

Exclusion criteria

A comorbid psychiatric disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2009
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-01-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35696
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2055
NTR-old	NTR2172
CCMO	NL28451.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35696

Study results

Summary results
N/A