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Efficacy of operant- and cognitive-behavioral treatments in fibromyalgia syndrome: analysis of psychophysiological reactivity (Th 899/2-1) and analysis of psychophysiological reactivity in fibromyalgia-syndrome after operant- or cognitive-behavioral pain therapy in fibromyalgia-syndrome (Th 899/2-2)

Submission date
17/02/2006

Registration date
20/02/2006

Last Edited
28/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Th 899/2-1, Th 899/2-2

Study information

Scientific Title

Acronym
CBTOBTFMS

Study objectives
1. Cognitive-Behavioral Therapy (CBT) and Operant-Behavioral Therapy (OBT) will produce significant improvements in pain, physical functioning, and emotional distress in Fibromyalgia Syndrome (FMS) patients
2. CBT and OBT will produce significantly greater improvements in pain, physical functioning, and emotional distress than the Attention Placebo (AP) treatment
3. CBT will produce significantly greater effects than the OBT and AP groups on coping and catastrophizing responses. Since the OBT indirectly focuses on inappropriate beliefs, it will produce significantly greater improvements on coping and catastrophizing than the AP group.
4. OBT will produce significantly greater reductions in pain, behaviors, physical therapy, and medication than CBT or AP treatments. Since CBT indirectly focuses on maladaptive behaviors, it will produce significantly greater improvements in pain behaviors than the AP group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Charite, Humboldt-University, Berlin, Germany on 01/02/2000, reference number 1270/2000

Study design
Randomized, placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Fibromyalgia syndrome

Interventions
The operant- and cognitive-behavioral pain therapy were compared to an attention placebo group (a social discussion group), a physiotherapy and a wait-list control group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain
2. Physical impairment
3. Affective distress

Secondary outcome measures
1. Coping
2. Catastrophizing
3. Pain behaviour
4. Number of physician visits
5. Spouse behavior

Overall study start date
01/04/2000

Completion date
01/04/2005

Eligibility

Key inclusion criteria
1. Participants must suffer from FMS as validated by a rheumatologist
2. They must meet the American College of Rheumatology (ACR) criteria for FMS
3. Pain for a period of at least six months
4. Married, and must show willingness of the spouse to be involved
5. Ability to complete the questionnaires and understand the treatment components

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Inflammatory rheumatic diseases
2. Acute episode of carcinoma
3. Psychotic episode
4. Opioid abuse

Date of first enrolment
01/04/2000

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
Germany

United States of America

Study participating centre
1959 NE Pacific Street
Washington
United States of America
98195-6540

Sponsor information

Organisation
German Research Council (Deutsche Forschungsgemeinschaft) (DFG)

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Sponsor type
Research organisation

Website
http://www.dfg.de

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Charity

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft) (DFG)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2006		Yes	No