

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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)

Sponsor details

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