

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	☐ Prospectively registered
Registration date 20/02/2006	Overall study status Completed	☐ Protocol
Last Edited 28/10/2008	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kati Thieme

Contact details
1959 NE Pacific Street
Box 356540
Seattle
Washington
United States of America
98195-6540
+1 206 685 2082
thiemek@u.washington.edu

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

1. Pain
2. Physical impairment
3. Affective distress

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Charity

Funder Name

German Research Council (Deutsche Forschungsgemeinschaft) (DFG)

Results and Publications

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