

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effectiveness of mindfulness-based cognitive therapy separately and combined with TDCS on Worry, Emotion regulation, Pain severity and quality of life in Fibromyalgia patients

Protocol summary

Study aim

Effectiveness of mindfulness-based cognitive therapy separately and combined with transcranial Direct Current Stimulation (TDCS) on Worry, Emotion regulation, Pain severity and quality of life in Fibromyalgia patients

Design

Randomised - consists of control group- three experimental group- each group consists of 12 people.

Settings and conduct

The research has been done on patients referred to rouyan clinic in Tehran. Fibromyalgia patients divided into three experimental and one control group and gone under treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Fibromyalgia disorder. Pain period: at least 6 months. Pain is not related to another disease such as cancer or MS. Ability to attend treatment sessions and not attended in any psychological treatment program during last 6 months. Exclusion criteria: suffering from a Rheumatologic or acute psychological disorder which lead to pain. have past epilepsy, seizure disease, Traumatic Brain Injury, brain tumor and brain implant and Mental retardation. acute heart patients using drug pump. Pregnant people. Substance abuse and addicted patients.

Intervention groups

Mindfulness Based Cognitive Therapy Group - tDCS
Group - Combination (MBCT and tDCS) Group - Control Group

Main outcome variables

Worry: Emotion regulation: Pain severity: quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201004048920N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Maryam Akbarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8873 7529

Email address

m_akbarzadeh@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of mindfulness-based cognitive therapy separately and combined with TDCS on Worry, Emotion regulation, Pain severity and quality of life in

Fibromyalgia patients

Public title
Effectiveness of mindfulness-based cognitive therapy separately and combined with TDCS (device treatment) on Worry, Emotion regulation, Pain severity and quality of life in Chronic muscle pain patients.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Fibromyalgia disorder. Pain period: at least 6 months. Pain is not related to another disease such as cancer or MS. Ability to attend treatment sessions and not attended in any psychological treatment program during last 6 months
Exclusion criteria:
suffering from a Rheumatologic or acute psychological disorder which lead to pain. have past epilepsy, seizure disease, Traumatic Brain Injury, brain tumor and brain implant and Mental retardation. Acute heart patients using drug pump. Pregnant people. Substance abuse and addicted patients.

Age
From **30 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be used. unit of randomization: individual. randomization tool: random number table. A random number table is a series of digits (0 to 9) arranged randomly in rows and columns. The table usually contains 5-digit numbers, arranged in rows and columns, for ease of reading. Typically, a full table may extend over as many as four or more pages. we have a population of 48 patients and each patient has been assigned a number from 1 to 48. we wish to sample 12 patients to out for each group. Since 48 is a two-digit number, we need to use the first two digits of the numbers listed on the random table. We close our eyes and randomly point to a spot on the table. For this example, we will assume that we selected 50631 in the first column. We interpret that number as 50 (first two digits). Since we don't have a member of our population with that number, we go down to the next number 29 (29990). We choose this number as 1st sample for first group. Continuing down the chart to select other 11 subjects for the first group. After completing the first group, start this procedure to select next 12 samples for the next group and in this way, we select members of all four sample groups. (during this process, we will ignore duplicate numbers)

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Darband Blvd., Mahdishahr.
City
Semnan
Province
Semnan
Postal code
9591900000
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.SEMUMS.REC.1399.195

Health conditions studied

1
Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1
Description
Worry
Timepoint
Before treatment, Maximum a week after treatment, two months after treatment
Method of measurement
Pennsylvania State Worry Questionnaire

2
Description
Emotion regulation
Timepoint
Before treatment, Maximum a week after treatment, two months after treatment

Method of measurement

Cognitive Emotion Regulation Questionnaire

3

Description

Pain severity

Timepoint

Before treatment, Maximum a week after treatment, two months after treatment

Method of measurement

Short-form McGill Pain Questionnaire

4

Description

Quality of life

Timepoint

Before treatment, Maximum a week after treatment, two months after treatment

Method of measurement

Short-Form 36 (SF-36) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-Based Cognitive Therapy (MBCT): Accomplished in groups of 12 people in 2 hours sessions per week. (2 sessions per week) during 1 month on 12 patients. Training includes both formal exercises (e.g. body checkout, sitting meditation, walking meditation and yoga) and informal exercises (such as bringing present awareness to daily activities), Cognitive - behavioral technics such as education, activity supervision and planning, negative spontaneous thoughts recognition and planning response prevention program.

Category

Treatment - Other

2

Description

Intervention group: 8 Sessions tDCS treatment (3 sessions per week). 20 minutes each session. During treatment sessions, cathode electrode will be placed at FP2 area and anode electrode at F3 area. 2mA current will be used.

Category

Treatment - Devices

3

Description

Intervention group: Combination group (MBCT and tDCS)

Category

Treatment - Other

4

Description

Control group: Receive artificial stimulation: Electrode will be placed on patient's head. but as soon as sense of irritation, the device will be turned off and he/she will not receive any stimulation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Physiotherapy Clinic

Full name of responsible person

Maryam Akbarzadeh

Street address

2nd Floor, 75 Doctor's Building, Royan Alley, Keshavarz Blvd.

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Semnan

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Semnan
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Semnan
Full name of responsible person
Maryam Akbarzadeh
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data without any private information about attendees could be published.

When the data will become available and for how long
A year after publication.

To whom data/document is available
Scholars

Under which criteria data/document could be used
The data could be used just by source citation.

From where data/document is obtainable

m_akbarzadeh@semnan.ac.ir

What processes are involved for a request to access data/document

Send request and explain the reason.

Comments