Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of mindfulness based cognitive therapy (MBCT) on stress and life expectancy in infertile women undergoing acupuncture treatment

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based cognitive therapy (MBCT) on stress and life expectancy in infertile women undergoing acupuncture treatment.

Design
A randomized, double-blind, experimental and control clinical trial was conducted on 60 infertile women undergoing acupuncture treatment.

Settings and conduct
This research is conducted in the acupuncture clinic of Dr. Abbas Ansari in Tehran. Infertile women are enrolled in the study under acupuncture treatment. Considering that the women do not know about the group allocation, therefore, a blind strain study is performed. Then we will place them in two groups of 30 people randomly.

Participants/Inclusion and exclusion criteria
Entry criteria: infertile women aged between 20 and 40 years, diagnosed with infertility by a specialist doctor, receiving acupuncture treatment for infertility, ability and willingness to participate in a treatment intervention program, not having severe mental disorders. Exclusion criteria: presence of severe physical problems, use of psychotropic or antidepressant drugs, pregnancy or planning to become pregnant during the study period, and unwillingness to continue acupuncture treatment during the study period.

Intervention groups
The experimental group consists of infertile women undergoing acupuncture treatment who participate in the MBCT intervention program. The intervention consists of 8 90-minute group therapy sessions. Sessions are designed based on MBCT techniques, which include mindfulness exercises, meditation, and training to pay attention to current experiences. The control group receives no specific intervention and only uses standard acupuncture care. This group serves as a comparison group to evaluate the effects of MBCT intervention and its combination with relaxation exercises.

Main outcome variables
Stress and life expectancy in infertile women under acupuncture treatment.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240623062228N1**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date
2024-07-25, 1403/05/04

Registrant information

Name
Arezou Nouri shafie
Name of organization / entity
Islamic Azad University, Semnan branch
Country
Iran (Islamic Republic of)
Phone
+98 21 3611 1111
Email address
arezounoori66@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-27, 1403/05/06
Expected recruitment end date
2024-08-27, 1403/06/06

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of mindfulness based cognitive therapy (MBCT) on stress and life expectancy in infertile women undergoing acupuncture treatment

Public title
Investigating the effectiveness of mindfulness based cognitive therapy (MBCT) on stress and life expectancy in infertile women undergoing acupuncture treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with an age range of 20 to 40 years. Diagnosis of infertility by a specialist doctor. Receiving acupuncture treatment for infertility. Ability and willingness to participate in 8 cognitive therapy intervention sessions based on mindfulness. Not having diagnosed severe mental disorders (such as schizophrenia, bipolar disorder). Ability to read and write in order to fill out questionnaires and do homework. Written consent to participate in the study and follow the research instructions.
Exclusion criteria:
Existence of severe physical problems that prevent regular attendance at meetings. Currently taking psychotropic or antidepressant medications. Pregnancy or planning to become pregnant during the study period. History of participating in similar cognitive therapy programs based on mindfulness in the past year. Unwillingness to continue acupuncture treatment during the study period. Inability to do mindfulness exercises due to cognitive or physical problems. Any other condition that the researcher considers to be an obstacle to effective participation in the study.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, randomization method is used to assign infertile women to intervention and control groups. First, each participant receives a unique ID. These IDs are randomly written on cards and the cards are thrown into a large container. Then, the cards are shuffled and taken out in turn. Each ID is randomly assigned to different groups. To determine the intervention and control groups, the set of cards is divided into two groups and each group is randomly assigned to one of the groups. This process ensures that the allocation of participants to groups is done without prejudice and randomly, which reduces the possibility of bias in the research results.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this research, blinding is done in one way. In this way, the participants do not know the type of intervention they are receiving. For this purpose, all participants attend therapy sessions that are identical in appearance and physical environment. Therapists, aware of the type of intervention (MBCT or acupuncture alone), consistently administered the same modality for all groups, and there were no apparent differences between sessions for participants. In order to maintain blinding, information about the exact type of intervention is not provided to the participants. They are only informed that they are participating in a study to investigate the effectiveness of mindfulness-based cognitive therapy. Any additional explanation about the details of the treatments will not be given to the participants until the end of the study in order to reduce bias effects. This method helps to evaluate the obtained results without bias and more accurately.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Semnan Azad University
Street address
Islamic Azad University, University Town, Semnan
City
Semnan
Province
Semnan
Postal code
3513137111
Approval date
2024-05-01, 1403/02/12
Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.039

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Stress score

Timepoint

Before the start of the intervention (pre-test), after completing 8 sessions of the intervention (post-test), one month after the end of the intervention (follow-up).

Method of measurement

Newton et al. stress test (1999)

2

Description

Life expectancy score

Timepoint

Before the start of the intervention (pre-test), after completing 8 sessions of the intervention (post-test), one month after the end of the intervention (follow-up).

Method of measurement

Miller's Life Expectancy Test (1988)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8 intervention sessions will be implemented based on the treatment plan of Williams et al (1952). This intervention consists of eight one-and-a-half-hour weekly group sessions. The main focus of this treatment is mindfulness exercises and paying attention to consciousness. Different mindfulness techniques are taught in each session and participants are asked to practice these techniques to learn them well. Also, home exercises are provided between sessions to help stabilize the treatment better. All questions and doubts of the participants will be answered between the sessions. This treatment period lasts for a total of two months and its purpose is to reduce stress and increase the life expectancy of these women.

Category

Treatment - Other

2

Description

Control group: It usually receives no intervention and serves as a comparison group. In other words, the control group will only receive the usual and standard care and will not benefit from the MBCT treatment program.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Abbas Ansari Acupuncture Clinic

Full name of responsible person

Abbas Ansari

Street address

Unit 1, First floor, No. 2526 (Building 790), In front of 10th South Gandhi Street, Above Hemet Bridge, Valiasr Street.

City

Tehran

Province

Tehran

Postal code

1435674511

Phone

+98 21 2676 7205

Email

info@doctoransari.ir

Web page address

https://doctoransari.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Semnan branch

Full name of responsible person

Shahab Moradi

Street address

Islamic Azad University, University Town, Semnan

City

Semnan

Province

Semnan

Postal code

3513137111

Phone

+98 23 3365 4040

Email

shahabmoradi66@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Semnan branch

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

Islamic Azad University, Semnan branch

Full name of responsible person

Arezou Nouri shafie

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

1st floor, No. 31, South Ofogh Alley, 20 meters of Dolat St.

City

Varamin

Province

Tehran

Postal code

3371965635

Phone

+98 21 3611 1111

Email

arezounoori66@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Semnan branch

Full name of responsible person

Maryam Salehyan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Islamic Azad University, University Town, Semnan

City

Semnan

Province

Semnan

Postal code

3513137111

Phone

+98 23 3365 4040

Email

arezounoori66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Semnan branch

Full name of responsible person

Arezou Nouri shafie

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

1st floor, No. 31, South Ofogh Alley, 20 meters of Dolat St.

City

Varamin

Province

Tehran

Postal code

3371965635

Phone

+98 21 3611 1111

Email

arezounoori66@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Since the research plan is related to a thesis, only the study protocol, clinical study report, and study results will be published. The participant data file contains information about the participants, and due to the preservation of individuals' privacy it cannot be published.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The stages of the clinical study, such as the number of participants, the criteria for entering and exiting the research project, the sampling method, the treatment protocol, and the results of the study will be described in the thesis and article.

When the data will become available and for how long

Data can be made available 6 months after results are published.

To whom data/document is available

In research, access to data and documents is limited in

order to protect the privacy and confidentiality of the participants. People who are allowed to access data and documents are: principal researchers and research collaborators, ethical supervisors and ethics review committees, colleagues and specialized consultants, researchers in scientific and academic centers and legal supervisors (if the research requires approval or supervision legal, legal observers may have access to data and documents). To access data and documents, all these people must respect the principles of confidentiality and privacy of the participants and only have access to the data they need to perform their duties.

Under which criteria data/document could be used

Using data to analyze and review research results and answer research questions, writing scientific articles, reports and presentations in conferences and authoritative publications, improving research methods and processes in future research, supporting decisions at the policy level and implementing operational plans. Using data as educational resources to educate students and researchers while maintaining the privacy and confidentiality of research participants' information.

From where data/document is obtainable

If you need the data, write to arezounoori66@gmail.com.

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

After receiving the request and reviewing it by the main researcher, the data will be sent to the requester within a week, along with an undertaking that the data will not be published without the name of the main researcher and that the privacy and confidentiality of the research participants will be preserved.

Comments