

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the Impact of Mindfulness-Based Cognitive Therapy on the Quality of Life of Burn Survivors

Protocol summary

Study aim

Determining the impact of mindfulness-based cognitive therapy on the quality of life of burn survivors

Design

A randomized, double-blind clinical trial with a control group, convenience sampling and then random allocation, conducting a study on 60 patients, the lottery method is used for randomization.

Settings and conduct

The intervention (cognitive therapy training based on mindfulness) will be held during 8 two-hour sessions for the intervention group. Mindfulness-based cognitive therapy training will be conducted in groups (three groups of 10 people) between 10 and 12 am on Thursdays, based on Kabatzin's mindfulness-based cognitive therapy program in Imam khomeini hospital in Urmia. This type of cognitive therapy includes various meditations, body scan exercises, yoga, and several cognitive therapy exercises that reflect the relationship between mood, thoughts, feelings, and body sensations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People between the age group of 18-45 years, Having a burn level between 15-45%, Passing at least six months since the burn, Ability to speak Persian, Having at least a high school diploma, Willingness to participate in the study. The conditions for not entering the study include having a confirmed mental illness and self-immolation and having burns on the face, neck, and genital areas.

Intervention groups

The samples in this research are selected by available sampling method, then 30 people are assigned to the control group and 30 people to the intervention group(cognitive therapy based on mindfulness).

Main outcome variables

Promotion of quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181206041867N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Fariba Hosseinzadegan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3275 4961

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Mindfulness-Based Cognitive Therapy on the Quality of Life of Burn Survivors

Public title

Investigating the Impact of Mindfulness-Based Cognitive Therapy on Burns

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are between the age group of 18-45 years. Patients Suffering from second-degree burns. Having a burn level between 15-45%. It has been at least six months since the burn. Having at least a high school diploma. Having the willingness to participate in the study. Having the ability to speak Persian.

Exclusion criteria:

Confirmed mental illness and self-immolation Having burns in the face, neck, and genital areas

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, samples are selected by the convenience sampling method, then randomly by the lottery method, 30 people are allocated to the control group and 30 people to the intervention group. So we put the names of all the people on paper and in a box, and then we take the papers out individually (without replacing them) until the sample size of the intervention group is completed, and the rest of the names left in the box are in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the knowledge that the participants were in the intervention or control group could affect the results of the study, the study groups were blinded. So after the first session provides explanations about the purpose of the study and other points and informed consent, in the next step, the participant does not know whether he is in the intervention or control group, but to solve the moral problem of the work, the training package is also provided to the control group at the end of the study to benefit from its benefits. Also, given that the data analyzer also knows about groups, it may affect the analysis and results, the data analyzer will also be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

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West Azarbaijan

Postal code

5714783734

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.UMSU.REC.1402.209

Health conditions studied

1

Description of health condition studied

Quality of life of burn patients

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

Primary outcomes

1

Description

Improving the quality of life

Timepoint

The quality of life assessment will be conducted at the beginning of the study (pre-intervention), after intervention and 30 days after intervention.

Method of measurement

The Burn Specific Health Brief Scale (BSHBS).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention (mindfulness-based

cognitive therapy training) will be held within 8 two-hour sessions for the intervention group. This approach increases the flexibility of cognitive activities and reduces intellectual rumination, hypertonicity, and self-critical assessments, and increases cognitive processes such as non-judgmental observation of mental content. Mindfulness-based cognitive therapy training will be conducted in groups (three groups of 10 people) and between 10 and 12 a.m. on Thursdays, based on the Kabatzin Mindfulness-Based Cognitive Therapy Program. Session one: introduction of the program (explanation of Sessions and objectives), automatic guidance, training and practice of breathing and eating twin with conscious attention, presentation of assignments; session two: review of completed assignments, explanations related to mechanisms and reactions, description of the results of some recent research on the effectiveness of MBCT, sitting meditation (breathing, listening to sound, paying attention to thoughts and feelings in a sitting position), breathing practice and walking twin with conscious attention, presentation of assignments; session three: review of completed assignments training in body scanning techniques, training in conscious attention, training in stop techniques, one-minute breathing space, presenting assignments, session four.: Review of completed assignments, the practice of yoga movements and exercises, the practice of body scanning and yoga meditation, presentation of assignments; session five: a review of completed assignments, explain the importance of thoughts in the manifestation of emotions, the practice of sitting yoga meditation, presentation of assignments; session six: a review of completed assignments, training, and practice of pond and Mountain meditation, presentation of assignments; session seven: review of completed assignments, training and practice of compassion meditation, presentation of assignments; session eight: Reviewing assignments, receiving feedback from Group members on the principles taught, summarizing past content, using conscious attention techniques (conscious attention walking, conscious attention eating, and so on...) In life and its generalization to the whole flow of life.

Category
Behavior

2

Description

Control group: no intervention will be done on the control group and they will only receive routine treatments. At the end of the study, the training given to the intervention group will be given to the control group in the form of a booklet.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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

Oroumia University of Medical Sciences

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

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic data and main outcome results of the study can be shared after de-identifying people

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Available for researchers working in scientific and academic institutions

Under which criteria data/document could be used

Further statistical analysis

From where data/document is obtainable

Fariba Hossein Zadegan, Assistant Professor, Urmia University of Medical Sciences, Faculty of Nursing and

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

Submission of request, check by recipient, sending response

Comments