Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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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Urmia
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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

Fariba Hosseinzadegan

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Imam Khomeini University Hospital-Ershad Ave-Modarres Blvd-Urmia-Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Golizadeh

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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

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Fariba Hosseinzadegan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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 Midwifery mail:hosseinzadegan.f@umsu.ac.ir tell:09144710551

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

Submission of request, check by recipient, sending response

Comments