

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effectiveness of mindfulness based on cognitive therapy on attitude to life, quality of work life, resilience and happiness in employees

Protocol summary

Study aim

Determining the effectiveness of mindfulness based on cognitive therapy on attitude to life, quality of work life, resilience and happiness in employees.

Design

The current study is a randomized clinical trial. The study will be conducted as a pre-test-post-test with a random control group. The sample size is 60 people, 30 people are in the test group and 30 people are in the control group.

Settings and conduct

Study samples will be selected from among the employees of Tehran University of Medical Sciences. First, the examinees are invited to study through a call. In order to maintain blinding, this random sequence will be provided to the main researcher and then based on the created sequence, each group will be identified and placed in dark envelopes designed for this purpose, and each envelope will be numbered and envelope will be closed. The person who will be in charge of sampling will open the envelopes based on the number of employees and will perform the intervention based on the group inside the envelope.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are employees working at the headquarters of Tehran University of Medical Sciences, having at least a bachelor's degree, not having a history of mental illness, and the criteria for leaving the study are not participating in more than three sessions and not agreeing to participate in the research.

Intervention groups

Employees of Tehran University of Medical Sciences

Main outcome variables

attitude to life, quality of work life, resilience and happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231118060094N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

Fariba Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8163 3615

Email address

fakbari@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness based on cognitive therapy on attitude to life, quality of work life, resilience and happiness in employees

Public title

The effectiveness of mindfulness based on cognitive therapy on attitude to life, quality of work life, resilience and happiness

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Employees working in the headquarters of Tehran University of Medical Sciences Have at least a bachelor's degree No history of mental illness

Exclusion criteria:

Not attending more than three sessions Not agreeing to participate in the research

Age

From **22 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the method of random blocks with size 4 will be used, and the random sequence will be generated by the statistician and by the software. In order to maintain blinding, this random sequence will be chosen by the main researcher and then based on the created sequence, each specific group will be placed in envelopes designed for this purpose, and each envelope will have a reported number and a closed envelope. becomes will be. Before starting the study, all participants (control and intervention groups) will complete the pre-test questionnaire. The experimental group will receive cognitive therapy training based on mindfulness for 8 sessions of 120 minutes, while the control group will not receive any training. One month after training the intervention group, all participants in the study will complete the post-test questionnaire.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to maintain blinding, the random sequence will be provided to the main researcher and then based on the created sequence, each group will be identified and placed in dark envelopes designed for this purpose.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

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1419733171

Approval date

2023-10-15, 1402/07/23

Ethics committee reference number

IR.TUMS.FNM.REC.1402.156

Health conditions studied**1****Description of health condition studied**

attitude to life

ICD-10 code

Y98

ICD-10 code description

Lifestyle-related condition

2**Description of health condition studied**

quality of work life

ICD-10 code

Y96

ICD-10 code description

Work-related condition

3**Description of health condition studied**

resilience

ICD-10 code

Z72.8

ICD-10 code description

Other problems related to lifestyle/ Self-damaging behaviour

4**Description of health condition studied**

happiness

ICD-10 code

F34.8

ICD-10 code description

Other persistent mood [affective] disorders

Primary outcomes

1

Description

attitude to life, quality of work life, resilience and happiness

Timepoint

At the beginning of the study, after the intervention

Method of measurement

Batista LRI Life Attitude Questionnaire, Oxford Happiness Questionnaire, Quality of Work Life Questionnaire (QWL), Freiburg Resilience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the supplemental pre-test questionnaire will be started, then for 8 sessions of 120 minutes, they will receive the intervention therapy training about mindfulness, after the session, the post-test training will be completed.

Category

Behavior

2

Description

Control group: In the control group, the pre-test questionnaire will be completed first, after two months, the post-test questionnaire will be completed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

University headquarters

Full name of responsible person

Fariba Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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?

No

Title of funding source

Personal credit

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fariba Akbari

Position

the expert

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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