Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effects of mindfulness interventions based on stress reduction and cognitive behavioral therapy on emotional self-regulation, sleep quality, and self-efficacy in women with type 2 diabetes

Protocol summary

Study aim

Comparing the effects of mindfulness interventions based on stress reduction and cognitive behavioral therapy on emotional self-regulation, sleep quality, and self-efficacy in women with type 2 diabetes

Design

sample size is 15 people in each group They will be selected by purposive sampling and randomly assigned by lottery without replacement to two experimental groups, experimental group 1 (cognitive behavioral therapy) (15 people), experimental group 2 (mindfulness-based stress reduction) (15 people), and a control group (15 people).

Settings and conduct

The present study is a quasi-experimental study with a pretest-posttest design with a control group. First, through a call and medical records, eligible individuals were identified based on the inclusion criteria (female, age 40 to 60 years, confirmed type 2 diabetes, minimum educational qualification of a high school diploma). Interventions in each group are implemented by a trained researcher during 8 90-minute weekly sessions. The study used a single-blind design.The location of the study is Semnan city.

Participants/Inclusion and exclusion criteria

The inclusion criteria 1. Female gender 2. Diagnosis of type 2 diabetes based on expert opinion 3. Age range between 40 and 60 years. 4. Having at least a high school diploma. The exclusion criteria 1. Not undergoing other treatment at the same time 2. Not taking psychiatric medications 3. Missing more than two treatment sessions

Intervention groups

Experimental group 1: receiving cognitive behavioral therapy (CBT) Experimental group 2: receiving mindfulness-based stress reduction (MBSR) Control group: no intervention.

Main outcome variables

In this study, the main outcomes include: Improvement of emotional self-regulation،Increase in sleep quality،f self-efficacy

General information

Reason for update

Acronym

WD

IRCT registration information

IRCT registration number: **IRCT20250519065797N1**
Registration date: **2025-06-25, 1404/04/04**
Registration timing: **retrospective**

Last update: **2025-06-25, 1404/04/04**
Update count: **0**

Registration date

2025-06-25, 1404/04/04

Registrant information

Name

Zahra Mirhaj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 935 276 4613

Email address

noormirhajz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-30, 1404/03/09

Expected recruitment end date

2025-07-31, 1404/05/09

Actual recruitment start date
2025-04-24, 1404/02/04
Actual recruitment end date
2025-05-25, 1404/03/04
Trial completion date
empty

Scientific title
Comparing the effects of mindfulness interventions based on stress reduction and cognitive behavioral therapy on emotional self-regulation, sleep quality, and self-efficacy in women with type 2 diabetes

Public title
Comparing the effects of mindfulness interventions based on stress reduction and cognitive behavioral therapy on emotional self-regulation, sleep quality, and self-efficacy in women with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of type 2 diabetes based on expert opinion Age range between 40 and 60 years. Having at least a high school diploma
Exclusion criteria:
Diagnosis of severe psychiatric disorders (e.g., schizophrenia, bipolar I disorder, or major depressive disorder with suicidal ideation) Ongoing or recent participation (within the past 3 months) in structured psychological interventions, including CBT or mindfulness-based therapies Concurrent enrollment in another interventional clinical study Presence of severe chronic medical conditions (e.g., end-stage renal disease, active cancer, or serious cardiovascular disease) Lack of informed consent or unwillingness to voluntarily participate in the study
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In experimental research, the minimum sample size is 15 people in each group (Delaware, 2009). In this regard, G power software was used to obtain the sample size, which is estimated to be 45 people, considering the effect size of 0.1 (Ashworm and Rankel, 2006, Lin, 2011), alpha of 0.05, and statistical power of 0.8. They will be selected by purposive sampling and randomly assigned by lottery without replacement to two experimental groups, experimental group 1 (cognitive behavioral therapy) (15 people), experimental group 2 (mindfulness-based stress reduction) (15 people), and a control group (15 people). Training sessions will be conducted by a researcher who has completed mindfulness-based stress reduction and cognitive behavioral courses and has received the necessary training to provide the intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
To reduce bias due to participants' awareness of their assigned group, the study was designed as a single-blind study, in which participants were unaware of the ultimate goal of the study and the type of intervention they would receive (cognitive-behavioral therapy or mindfulness-based stress reduction). To this end, participants were only informed that they were participating in one of the diabetes-related interventions, without being told which specific intervention they would receive. Also, the information provided in the introductory session was designed to avoid obvious differences between the intervention groups and to reduce participants' subjective expectations regarding the effects of the intervention.
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 of Medical Sciences
Street address
Unit 72, First Floor, Phoenix Tower, Imam Ali Square, Semnan
City
Semnan
Province
Semnan
Postal code
۳۵۱۹۷۷۳۰۵۳
Approval date
2025-03-12, 1403/12/22
Ethics committee reference number
IR.IAU.SEMNAN.REC.1404.010

Health conditions studied

1

Description of health condition studied
Women with Type 2 Diabetes experiencing difficulties in emotional regulation, sleep quality, and psychological

self-efficacy

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Emotional self-regulation is considered the primary outcome variable of this study. It refers to the individual’s ability to identify, control, and manage their emotions effectively and adaptively. This variable will be measured using validated psychometric questionnaires. The main goal of the study is to assess changes in emotional self-regulation levels following mindfulness-based stress reduction and cognitive-behavioral therapy interventions.

Timepoint

Baseline (Pre-intervention):Farvardin 1404 (April 2025)Post-intervention: First week of Khordad 1404 (May 2025)

Method of measurement

The emotional self-regulation variable will be measured using the Emotion Regulation Questionnaire (ERQ) developed by Gross & John. This tool includes 10 items assessing two emotional regulation strategies: cognitive reappraisal and expressive suppression. Participants respond using a 5-point Likert scale ranging from "strongly disagree" to "strongly agree."The ERQ has demonstrated good validity and reliability in both international and local studies. Total scores indicate the degree of use of emotion regulation strategies. Data will be collected at two time points (pre-test, post-test) and analyzed

2

Description

Sleep Quality

Timepoint

Baseline (Pre-intervention):Farvardin 1404 (April 2025)Post-intervention: First week of Khordad 1404 (May 2025)

Method of measurement

Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI). This standardized self-report instrument includes 19 items that measure seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The total score ranges from 0 to 21, with higher scores indicating poorer sleep quality.The PSQI has demonstrated high validity and reliability in both international and Iranian studies. Data will be collected at two time points: pre-test, post-test, and follow-up.

3

Description

self efficacy

Timepoint

Baseline (Pre-intervention):Farvardin 1404 (April 2025)Post-intervention: First week of Khordad 1404 (May 2025)

Method of measurement

Self-efficacy will be assessed using the General Self-Efficacy Scale (GSE) developed by Sherer and Maddux. This scale includes 10 items designed to evaluate an individual's belief in their ability to cope with a variety of demanding situations. Responses are rated on a 4-point Likert scale ranging from “Not at all true” to “Exactly true.”The GSE is one of the most widely used and validated instruments for measuring general self-efficacy and has demonstrated strong reliability and validity in both international and Iranian studies. The total score indicates the individual’s perceived self-efficacy level. This variable will be measured at two time points: pre-test, post test

Secondary outcomes

empty

Intervention groups

1

Description

The present study is a quasi-experimental study with a pretest-posttest design with a control group. First, through a call and medical records, eligible individuals were identified based on the inclusion criteria (female, age 40 to 60 years, confirmed type 2 diabetes, minimum educational qualification of a high school diploma). Interventions in each group are implemented by a trained researcher during 8 90-minute weekly sessions. The study used a single-blind design.The location of the study is Semnan city.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital, Semnan

Full name of responsible person

Zahra mirhaj

Street address

Semnan, Golestan Town, Power Plant Square

City

Semnan

Province

Semnan

Postal code

۳۵۱۹۷۷۳۰۵۳

Phone

+98 935 276 4613

Email

noormirhajz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra mirhaj
Street address
Unit 72, First Floor, Phoenix Tower, Imam Ali Square, Semnan
City
Semnan
Province
Semnan
Postal code
۳۵۱۹۷۷۳۰۵۳
Phone
+98 935 276 4613
Email
noormirhajz@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Me
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra mirhaj
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Unit 72, First Floor, Phoenix Tower, Imam Ali Square, Semnan
City
Semnan
Province
Semnan
Postal code
۳۵۱۹۷۷۳۰۵۳
Phone
+98 935 276 4613
Email
noormirhajz@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra mirhaj
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Unit 72, First Floor, Phoenix Tower, Imam Ali Square, Semnan
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Province
Semnan
Postal code
۳۵۱۹۷۷۳۰۵۳
Phone
+98 935 276 4613
Email
noormirhajz@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra mirhaj
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Unit 72, First Floor, Phoenix Tower, Imam Ali Square, Semnan
City
Semnan
Province
Semnan
Postal code
۳۵۱۹۷۷۳۰۵۳
Phone
+98 935 276 4613
Email
noormirhajz@gmail.com

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The findings of this study, titled "Comparison of the Effectiveness of Mindfulness-Based Stress Reduction and Cognitive Behavioral Interventions on Emotion Regulation, Sleep Quality, and Self-Efficacy in Women with Type 2 Diabetes", will be published as a peer-reviewed research article in a reputable scientific journal indexed in Scopus or PubMed. Additionally, the summarized results will be included in the final thesis report submitted to the Iranian Research Institute for Information Science and Technology (IranDoc) and will be available through the university library. Upon acceptance of the article, the DOI and publication link will be provided in future updates. A summary of the results will also be shared with the study participants upon request.

When the data will become available and for how long

Since the implementation of the study is scheduled between late April and June 2025 (Farvardin to Khordad 1404), the data and related documents will be available after the completion of statistical analysis and report writing, starting from August 2025 (Mordad 1404). The summarized results will be published as part of a scientific article and master's thesis. Upon request, anonymized data may be shared for research purposes.

To whom data/document is available

Access to the data and documents of this study will be limited to the research team, including the principal investigator, academic supervisor, and scientific advisors. In case of a formal request and approval by the ethics committee, anonymized data may be shared with qualified researchers for scientific purposes. Public access to summary results will be provided through the publication of a scientific article.

Under which criteria data/document could be used

The data and documents of this study are intended to be used solely for scientific and research purposes. Their use should aim to advance knowledge in the field of psychological interventions for patients with type 2 diabetes and must not be used for commercial or personal purposes. Access will be granted only under the following conditions: a formal written request, approval by a relevant ethics committee, and strict adherence to participant confidentiality and data anonymization. Any use of the data must include appropriate citation of the original study.

From where data/document is obtainable

o request access to the data and documents of this study, an official request should be submitted to the responsible investigator. Contact information is as follows: Name:Zahra Mirhaj Academic Title: Student of Psychology Affiliation: Semnan Islamic Azad University Email:noormirhajz@gmail.com

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

Any request for access to the data or documents of this study must be made through a formal written request submitted to the principal investigator or academic supervisor. The request should include the applicant's identity, institutional affiliation, purpose of use, type of data requested, and confidentiality protection measures. Upon receipt, the following process will be followed: Verification of the applicant's academic background and institutional affiliation Evaluation of the request's alignment with ethical standards and scientific objectives Final approval by the principal investigator and, if necessary, the university's ethics committee If approved, the requested data will be provided in an anonymized and limited format, suitable for scientific use. Any use of the data must respect participant confidentiality and include proper citation of the original study.

Comments