Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Transcendental Medicine Educational Intervention (Based on Spiritual Meditation) on Improving Stress, Anxiety, Depression, and Optimism in Women with Spontaneous Abortion Referring to Comprehensive Health Centers

Protocol summary

Study aim

The Effect of Transcendental Medicine Educational Intervention (Based on Spiritual Meditation) on Improving Stress, Anxiety, Depression, and Optimism in Women with Spontaneous Abortion Referring to Comprehensive Health Centers of Shiraz

Design

The educational intervention in this study will be conducted on women with spontaneous abortion in Shiraz in 2026 (50 participants in the Transcendental Medicine-based intervention training group). These sessions will be administered by the researcher and supervised by the thesis supervisor and project advisors. The intervention program will consist of 8 sessions over two months, with two sessions per week, conducted in person.

Settings and conduct

A randomized, two-arm, unblinded (open-label) clinical trial with a control group was conducted on 50 women with spontaneous abortion. A table of random numbers was used for randomization.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include women aged 20 to 45 years (reproductive age), having experienced at least one spontaneous abortion (at least one within the past 6 months), absence of severe or chronic psychiatric disorders requiring active pharmacological treatment (e.g., schizophrenia or bipolar disorder). The exclusion criteria include experiencing other severe stressful events (e.g., death of close relatives) that could confound the results, and absence from more than two training sessions.

Intervention groups

Eligible participants were allocated into two groups (Transcendental Medicine based on spiritual meditation and control) through simple randomization using a table of random numbers, whereby even numbers were assigned to the intervention group and odd numbers to the control group.

Main outcome variables

mean scores of stress, anxiety, depression, and optimism.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260615069802N2**
Registration date: **2026-06-25, 1405/04/04**
Registration timing: **prospective**

Last update: **2026-06-25, 1405/04/04**
Update count: **0**

Registration date

2026-06-25, 1405/04/04

Registrant information

Name
Samira Taravatmanesh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 912 917 7516
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-01, 1405/04/10

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Transcendental Medicine Educational Intervention (Based on Spiritual Meditation) on Improving Stress, Anxiety, Depression, and Optimism in Women with Spontaneous Abortion Referring to Comprehensive Health Centers

Public title

The Effect of Transcendental Medicine Educational Intervention (Based on Spiritual Meditation) on Improving Stress, Anxiety, Depression, and Optimism in Women with Spontaneous Abortion

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20 to 45 years (reproductive age). Having experienced at least one spontaneous abortion (at least one spontaneous abortion within the past 6 months). Absence of severe or chronic psychiatric disorders requiring active pharmacological treatment (e.g., schizophrenia or bipolar disorder). No participation in similar psychological or spiritual meditation interventions within the past 6 months.

Exclusion criteria:

Recent use of psychotropic or antidepressant medications (within the past 3 months). Current pregnancy or active attempts to conceive that would hinder attendance at the sessions. Experiencing other severe stressful events (e.g., death of close relatives) that could confound the results. Absence from more than two training sessions.

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were allocated to the groups through simple randomization using a table of random numbers. To achieve this, the numbers were read from top to bottom, with the predetermined rule that even numbers would be assigned to the intervention group and odd numbers to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building, Shiraz University of Medical Sciences, Zand St., Opposite Palestine St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2026-03-14, 1404/12/23

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1404.141

Health conditions studied

1

Description of health condition studied

Stress, anxiety, depression, and optimism.

ICD-10 code

No specifi

ICD-10 code description

No specific ICD-10 code

Primary outcomes

1

Description

The mean scores of stress, anxiety, depression, and optimism.

Timepoint

Prior to the start of the educational intervention and two months after the start of the educational intervention.

Method of measurement

Based on the standard DASS-21 (Depression, Anxiety, and Stress Scale) questionnaire and the Scheier and Carver Optimism Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women with spontaneous abortion referring to comprehensive health centers of Shiraz in 2026 (50 participants in the Transcendental Medicine-based intervention training group). The intervention will be conducted through a series of sessions, which will be administered by the researcher and supervised by the thesis supervisor and project advisors. The intervention program will consist of the Transcendental Medicine-based intervention, comprising 8 sessions over two months, with two sessions per week, conducted in person.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
مراکز جامعه سلامت شهر شیراز در سال 1405

Full name of responsible person
Samira Taravatmanesh

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Shiraz, Zand Street, Opposite Palestine Street, Central Building of Shiraz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

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Central Building, Shiraz University of Medical Sciences, Zand St., Opposite Palestine St., Shiraz, Iran

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info@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Tayebeh Rakhshani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
It will be published as an article titled "The Effect of Transcendental Medicine Educational Intervention (Based on Spiritual Meditation) on Improving Stress, Anxiety, Depression, and Optimism in Women with Spontaneous Abortion Referring to Comprehensive Health Centers of Shiraz in 2025–2026".
When the data will become available and for how long
2026
To whom data/document is available
All People
Under which criteria data/document could be used
For healthcare teams (including physicians, nurses, and social workers) to become familiar with the implementation of this educational intervention.
From where data/document is obtainable
To obtain the document, please refer to the principal investigator of the study, Dr. Tayyebeh Rakhshani.
What processes are involved for a request to access data/document
To obtain information, please refer to the thesis supervisor, Dr. Tayyebeh Rakhshani, or the researcher, Dr. Samira Taravatmanesh.
Comments