Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness Therapy on Emotion Regulation and Psychological Pain in Women with Experience of Spousal Infidelity

Protocol summary

Study aim

Determining the Effectiveness of Mindfulness Therapy on Emotion Regulation and Psychological Pain in Women with Experience of Spousal Infidelity

Design

This study is a randomized clinical trial with two parallel groups and double blinding that is conducted in phase II on 30 participants (15 in each group). The allocation of samples is carried out using a simple randomization method with the RAND function in Excel; first, each individual receives an identification code and, based on the random number, they are ordered and divided into two groups of 15 participants.

Settings and conduct

This study will be conducted in counseling centers in the city of Ahvaz among women affected by spousal infidelity. The experimental group will receive mindfulness training, while the control group will receive no intervention. The study is designed as a double-blind trial, in which the evaluators, clinical caregivers, and data analysts will not be aware of the group allocations.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Be between 20 and 50 years old. Having at least three years of marital life At least six months have passed since the disclosure of the spouse's infidelity Exclusion Criteria: Having a physical illness that interferes with the treatment process Use of psychiatric medications

Intervention groups

Intervention group: Mindfulness training: This intervention is an educational–therapeutic approach based on increasing awareness of the present moment, non-judgmental observation of experiences, and acceptance of thoughts and feelings, which is implemented based on the protocol of Bowen et al. (2011; cited in Akbarpour et al., 2023) in 8 sessions of 120 minutes for the experimental group. Control group: They receive no intervention.

Main outcome variables

Emotion Regulation; Psychological Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260511069347N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**
Update count: **0**

Registration date

2026-05-17, 1405/02/27

Registrant information

Name

Neda Fasihizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 303 2689

Email address

ndafsyhyzadh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effectiveness of Mindfulness Therapy on Emotion Regulation and Psychological Pain in Women with Experience of Spousal Infidelity

Public title
The Effectiveness of Mindfulness Therapy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be between 20 and 50 years old. Having at least a high school diploma Having at least three years of marital life At least six months have passed since the disclosure of the spouse's infidelity Applying for divorce due to the spouse's infidelity

Exclusion criteria:
Having a physical illness that interferes with the treatment process Use of psychiatric medications

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method was used to allocate participants to the experimental and control groups. The unit of randomization in this study was women referring to the counseling center. First, a complete list of applicants who were selected based on the study inclusion criteria was prepared. Then, a unique numerical identification code was assigned to each individual. These codes were entered into the Random Number Generator software and a random number was generated for each person. After generating these numbers, individuals were arranged in ascending order based on the value of the random number. Then, participants were allocated to the two groups; sequentially, the first 15 individuals on the list were assigned to the experimental group and the next 15 individuals to the control group. With this method, the order of entry into the study and the researcher's familiarity with the participants had no role in group selection. To ensure allocation concealment, the person responsible for entering the data into the software was independent from the individuals performing the clinical procedures and could not be aware of or change the allocation process. Furthermore, identification codes were kept confidential and stored separately from the other participants' information. Therefore, it was not possible to predict the group assigned to each individual before the randomization process was carried out.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the clinical assessor, outcome evaluator, and data analyst were blinded to the allocation of the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of Ahvaz

Street address
Islamic Azad University of Ahvaz, Farhang Shahr

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Approval date
2026-04-15, 1405/01/26

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.034

Health conditions studied

1

Description of health condition studied
Marital Infidelity

ICD-10 code
Z63.0

ICD-10 code description
Problems in relationship with spouse or partner

Primary outcomes

1

Description
Emotion Regulation

Timepoint
before performing the intervention and two weeks after completion of the intervention

Method of measurement
Cognitive Emotion Regulation Questionnaire (Garnefski et al., 2001)

2

Description
Psychological Pain
Timepoint
before performing the intervention and two weeks after completion of the intervention
Method of measurement
Psychological Pain Questionnaire (Orbach et al., 2003)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The mindfulness training intervention includes 8 sessions of 120 minutes that are designed with the aim of increasing awareness of the present moment, non-judgmental observation of experiences, and acceptance of thoughts and emotions. This program is implemented based on the protocol of Bowen et al. (2011; cited in Akbarpour et al., 2023). In the first session, participants become familiar with each other and the structure of the sessions is introduced, and exercises such as mindful raisin eating and body scan meditation are conducted to experience mindful attention. In the second session, awareness of thoughts and emotions and the way of managing intrusive thoughts are taught and sitting meditation is practiced. The third session is devoted to strengthening non-judgmental observation through mindful seeing and listening exercises, the three-minute breathing space practice, and mindful body movements. In the fourth session, participants become familiar with ways of responding to difficult situations and perform exercises such as sitting meditation and mindful walking. In the fifth session, sitting meditation and mindful body movements are reinforced and the application of mindfulness in daily activities is strengthened. The sixth session is devoted to awareness of thoughts and experiencing them as merely thoughts and learning skillful ways of coping with problematic thoughts. In the seventh session, the focus is on self-care, identifying pleasant and unpleasant events, and planning to increase positive experiences in life. In the eighth session, all the learned skills are reviewed and integrated and strategies for continuing
Category
Behavior

2

Description
Control group: They do not receive any intervention or treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rayan Consulting Center
Full name of responsible person
Neda Fasihizadeh
Street address
1st floor, Mahtab Complex, between East 4th and 5th Streets, Kianpars.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan egdernezhad
Street address
Islamic Azad University of Ahvaz, Farhang Shahr.
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6134937333
Phone
+98 61 3334 8421
Email
a_eigder@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Neda Fasihizadeh

Position
Master’s student

Latest degree
Bachelor

Other areas of specialty/work
Counseling

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Unit 3, Apadana Complex, No. 145, 5th Gharbi St., Phase 3, Kianpars

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participant data is completely confidential and I do not intend to publish it.

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

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available