

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of Mindfulness-Based Stress Reduction on depression, anxiety, and stress of women with the early loss of pregnancy

Protocol summary

Study aim

Determining the effectiveness of Mindfulness-Based Stress Reduction on depression, anxiety, and stress of women with the early loss of pregnancy

Design

A clinical trial with two intervention and control groups, without blinding, randomized based on a random allocation table, the intervention was conducted during 8 sessions on 53 people in the intervention group.

Settings and conduct

The study was conducted in Zainabiyah Hospital, Shiraz. After identifying the women with the termination of the first trimester of pregnancy, if they met the criteria for participation in the study, the purpose of the research was explained to them if they wished, and they signed written informed consent. People were randomly placed in two intervention and control groups according to the allocation table. Both groups completed the pre-test, and then eight mindfulness sessions were held for the intervention group for eight weeks; after the intervention, both groups completed the post-test.

Participants/Inclusion and exclusion criteria

Entry conditions: bleeding, gestational age under 20 weeks
Conditions of non-entry: unintended pregnancy, history of mental illness, use of neuropsychiatric drugs, recent great stress

Intervention groups

For the intervention group, 8 sessions of 2 to 2.5 hours of mindfulness group counseling were conducted in 8 weeks. The control group received usual post-pregnancy care

Main outcome variables

Reduce stress, reduce anxiety, reduce depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024866N17**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **retrospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Katayoun Alidousti

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

alidoosti@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

2020-07-31, 1399/05/10

Actual recruitment end date

2021-01-09, 1399/10/20

Trial completion date

2021-01-09, 1399/10/20

Scientific title

Effectiveness of Mindfulness-Based Stress Reduction on depression, anxiety, and stress of women with the early loss of pregnancy

Public title

The effect of mindfulness on psychological problems after abortion

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All women with bleeding in the first trimester of pregnancy that led to termination of pregnancy

Exclusion criteria:

The current pregnancy was unintended Have a history of mental illness She is currently taking psychiatric drugs He is currently undergoing psychological counseling She has suffered a major stressful event from two months before the study until now

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Actual sample size reached: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random Allocation table Randomization has been done by the block method. We considered the intervention group as "A" and the control group as "B", and then 27 blocks of 4 combinations of "A, B" were randomly selected using R version 3.2.1 statistical software. A sequence of letters A, B was produced, and each person who referred to the Zeinabieh hospital was placed in the intervention or control group based on the sequence produced

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Kerman University of Medical Sciences

Street address

Razi Nursing and Midwifery Faculty., Kerman University of Medical Sciences Campus., Haft Bagh

Alavi Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.KMU.REC.1398.217

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

Stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

2**Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3**Description of health condition studied**

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes**1****Description**

Stress score from the Depression- Anxiety- Stress Scale

Timepoint

Before intervention and after completion of counseling sessions

Method of measurement

Depression- Anxiety- Stress Scale

2**Description**

Anxiety score from the Depression- Anxiety- Stress Scale

Timepoint

Before intervention and after completion of counseling sessions

Method of measurement

Depression- Anxiety- Stress Scale

3

Description

Depression score from the Depression- Anxiety- Stress Scale

Timepoint

Before intervention and after completion of counseling sessions

Method of measurement

Depression- Anxiety- Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 8 sessions of 2 to 2.5 hours of mindfulness group counseling were conducted in 8 weeks.

Category

Behavior

2

Description

Control group: Routine post-abortion care was given.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Zeinabieh hospital

Full name of responsible person

Masumeh Nasrollahi

Street address

Zeinabieh hospital., Defae Mogadas squar

City

Shiraz

Province

Fars

Postal code

7134814336

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+98 71 3230 5410

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info@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Deputy of research and technology., Somayeh Crossroads

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vcr@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Katayoun Alidousti

Position

Instructor of the midwifery faculty

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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