

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of performing technique emotionol relese on stress, anxiety and depression in women with recurrently miscarriage

Protocol summary

Study aim

Comparing the stress, anxiety, and depression levels of women with repeated abortions before, immediately after, and four weeks after the intervention

Design

The clinical trial has a control group, an intervention group, no blinding, and each group has 47 people. Randomized using www.random.org.

Settings and conduct

Iranian women aged 25-49 with a history of two consecutive miscarriages will be included in the study, according to Shahid Akbarabadi Hospital in Tehran. A pre-test will be administered to both experimental and control groups in this research, and then the experimental group will be trained for eight sessions, one two-hour session every week, on mind release techniques, which will be taught by the researcher for each subject.

Participants/Inclusion and exclusion criteria

Reading and writing skills,The spouse does not smoke,Having multiple sexual partners,there is no inflammation or pelvic mass,Not suffering from severe stress, anxiety, or depression,Has not participated in mind liberation classes in the past,The couple does not suffer from mental illness,The couple has not suffered any stressful events in the last three months, ,Not using medicinal,and non-medicinal methods to improve stress, anxiety, and depression in the period of 6 months before the study until the end of the study ,miscarriages in the early stages of pregnancy

Intervention groups

As part of this research, the control and intervention groups will participate in the pre-test. Then only the experimental group will receive eight sessions of mind liberation training, one session each week for two hours. The therapist performs this method on each patient.

Main outcome variables

Stress; anxiety; depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220822055777N1**

Registration date: **2022-12-06, 1401/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-06, 1401/09/15**

Update count: **0**

Registration date

2022-12-06, 1401/09/15

Registrant information

Name

Raana Mozafarifar

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of performing technique emotionol relese on stress, anxiety and depression in women with recurrently miscarriage	
Public title	effect of technique emotionol relese in women with recurrently miscarriage
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Reading and writing skills Having multiple sexual partners Recurrence of miscarriages in the early stages of pregnancy (more than two miscarriages) Exclusion criteria: From 6 months before the study to the end of the study, medicinal or non-medicinal methods were used to boost stress, anxiety or depression. In the last 3 months, the couple has experienced any stressful experiences, such as the death of a loved one The couple does suffer from mental illness having attended a mind liberation class in the past suffering from severe stress, anxiety, or depression At the time of entering the study, the attending physician diagnosed inflammation or pelvic masses. tobacco abuse by the spouse
Age	From 25 years old to 40 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 94
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is such that the participants were assigned to two control and intervention groups using the www.random.org site and through random block design with a block size of 4. Blocking was done by a person not involved in data sampling and analysis. The person is asked to write any number of 4-digit letters from the letters A and B, for example, AAAA, BBBB, etc. Then the researcher numbers these letters. The random site is used to assign random numbers. The output of this site is numbers. In order to hide the allocation, the type of intervention will be written on a sheet of paper and placed inside opaque envelopes numbered consecutively
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

0000000000

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.IUMS.REC.1401.604

Health conditions studied

1

Description of health condition studied

recurrently miscarriage

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

Primary outcomes

1

Description

stress

Timepoint

4 weeks after the educational intervention

Method of measurement

Stress, anxiety and depression questionnaire (DASS-21)

2

Description

anxiety

Timepoint

4 weeks after the educational intervention

Method of measurement

Stress, anxiety and depression questionnaire (DASS-21)

3

Description

depression

Timepoint

4 weeks after the educational intervention

Method of measurement

Stress, anxiety and depression questionnaire (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in this research, a pre-test will be taken from both the test and control groups, and after that, the experimental group will be trained in mind release techniques for 8 sessions, one two-hour session every week, and this method will be taught by the therapist. Individual subjects are executed. Training and implementation of the IFT technique will be done using Craig's instructions (2017) under the title "Golden Standard of IFT".

Category

Behavior

2

Description

Control group: they will take a pre-test at the beginning of the study. During the study and implementation of the intervention, they will not receive any training and after 4 weeks the post-test will take place. At the end of the study, after obtaining the results, during a 2-hour session for The control group is briefly explained about the technique of freeing the mind and its effects based on the obtained results.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Masoomeh Kheirkhah

Street address

School of Nursing & Midwifery, Rashid Yasemi st.,
Valiasr St., Tehran, 1996713883, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran 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?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masoomeh Kheirkhah

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results obtained from the research will be reflected to the University of Medical Sciences and the Vice-Chancellor of Health

When the data will become available and for how long

After printing the results

To whom data/document is available

Deputy health and research

Under which criteria data/document could be used

In order to be used in various educational, clinical, research and economic fields.

From where data/document is obtainable

Name: Masoomeh Kheirkhah Email: kheirkhah.m@iums.ac.ir
Name: Rana Moozafari Email: raanamoozafari@gmail.com

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

Contact the corresponding author by email and register the request

Comments