

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effectiveness of compassion-focused therapy on psychological symptoms of women with recurrent spontaneous abortion

Protocol summary

Study aim

Investigating the effectiveness of compassion-focused therapy on psychological symptoms of women with recurrent spontaneous abortion

Design

A randomized controlled group with parallel-group, unblinded, on 52 patients. The online Randomly assign tool was used for randomization.

Settings and conduct

Clinical trial with repeated measures, parallel-group, single-blinded, randomized on 52 patients, random list generator app used for randomization

Participants/Inclusion and exclusion criteria

Age above 18: History of recurrent spontaneous abortion (having at least 2 miscarriages): Not participating in psychological interventions during the last year: In case of taking psychiatric drugs, no change in the drugs during the last 6 months.

Intervention groups

In group one participants will undergo ten 60-minute psychotherapy sessions utilizing a compassion-focused treatment approach. The group two will consist of participants on a waiting list, who will not receive any intervention until the end of the first group's sessions.

Main outcome variables

Depression score: Anxiety score: Resilience score: Body image concern score: Internalized shame score: Perinatal grief score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230924059503N1**

Registration date: **2023-11-29, 1402/09/08**

Registration timing: **retrospective**

Last update: **2023-11-29, 1402/09/08**

Update count: **0**

Registration date

2023-11-29, 1402/09/08

Registrant information

Name

Mohammadreza Norouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9770

Email address

mnorouzi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-26, 1402/07/04

Expected recruitment end date

2023-10-26, 1402/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of compassion-focused therapy on psychological symptoms of women with recurrent spontaneous abortion

Public title

compassion-focused therapy for women with recurrent spontaneous abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age above 18 History of recurrent spontaneous abortion (having at least 2 miscarriages)

Exclusion criteria:
participating in psychological interventions during the last year In case of taking psychiatric drugs, change in the drugs during the last 6 months

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
All the people who entered the study were given a code, then these codes were entered into the Randomly assign online software (<https://www.graphpad.com/quickcalcs/randomize1.cfm>) and the software randomly assigned each code to a group.

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

Ethics committe of Shahid Beheshti University of Medical Science

Street address

Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2023-08-29, 1402/06/07

Ethics committee reference number

IR.SBMU.MSP.REC.1402.288

Health conditions studied

1

Description of health condition studied

recurrent pregnancy loss

ICD-10 code

N96

ICD-10 code description

Recurrent pregnancy loss

Primary outcomes

1

Description

Depression score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

Beck depression inventory

2

Description

Anxiety score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

Beck anxiety inventory

3

Description

Resilience score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

Connor-Davidson Resilience Scale

4

Description

Body image concern score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

The Body Image Concern Inventory

5

Description

Internalized shame score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

Internalized Shame Scale

6

Description

Perinatal grief score

Timepoint

before treatment, after the treatment, and 6 month after treatment

Method of measurement

Perinatal Grief Scale

Secondary outcomes

empty

Intervention groups

1

Description

This group underwent ten 60-minute weekly sessions of compassion-focused psychotherapy, aimed at developing a positive therapeutic relationship that facilitates the process of engaging with one's challenges and development of skills to deal with them, developing non-blaming compassionate understandings into the nature of suffering, developing the ability to experience and cultivate compassionate attributes and developing the feeling of compassion for others, being open to compassion from others, and developing self-compassion.

Category

Treatment - Other

2

Description

Control group: This was a waiting list, and clients in this group did not receive any therapy until the end of the therapy of the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Mohammadreza Norouzi

Street address

Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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taleghanihospital@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

mohammadreza Norouzi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

There is no further information

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