

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effectiveness of mindful-self compassion program on distress tolerance, emotion regulation, mindfulness and quality of life in high risk pregnant women

Protocol summary

Study aim

Investigating the effectiveness of mindful-self compassion program on distress tolerance, emotion regulation, mindfulness and quality of life in high risk pregnant women

Design

A clinical trial, single-blind, randomized clinical trial on 52 high-risk pregnant women.

Settings and conduct

At first, written consent is obtained from high-risk pregnant women referring to Hospital, and necessary explanations are given regarding the current research (number of sessions, length of each session), confidentiality of information and the right to withdraw from the research at any time. In the current research, randomization and blinding will be done. Then, among the high-risk pregnant women referred to the hospital who have been diagnosed by obstetricians, 52 people will be randomly selected and 26 people will be randomly placed in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gynecologist's diagnosis of high-risk pregnancy (pregnancies under 18 and over 40, history of frequent abortions, suspected premature birth, etc.) Not undergoing psychotherapy currently or in the past 6 months exclusion criteria:

Intervention groups

Intervention group: Consists of 26 high-risk pregnant women who, after completing the therapeutic intervention research questionnaires, will participate in 8 sessions held once a week for 1 hour. After completing the therapy sessions, participants will be provided with the research questionnaires again for completion. Control group: Consists of 26 high-risk pregnant women who will receive the research questionnaires in two stages without undergoing any therapeutic intervention.

Main outcome variables

distress tolerance; emotion regulation; mindfulness; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230713058767N1**

Registration date: **2023-11-05, 1402/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-05, 1402/08/14**

Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

Name

Mahsa Abdollahpur Kahriz

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-22, 1402/04/31

Expected recruitment end date

2024-01-19, 1402/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of mindful-self compassion program on distress tolerance, emotion regulation, mindfulness and quality of life in high risk pregnant women

Public title
Investigating the effectiveness of mindful-self compassion program in high risk pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Gynecologist's diagnosis of high-risk pregnancy (Pregnancies under the age of 18 and over 40, A history of repeated miscarriages, Suspected premature birth, diabetes, etc) Not undergoing psychotherapy now or in the last 6 months
Exclusion criteria:
Non-pregnant women Having certain physical diseases such as cancer Foreign nationals (non-Iranians)

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be simple randomization method. the random unit is individuals. 52 high risk pregnant will be divided into intervention and control groups by Microsoft Excel software using Rand function. in this way, a table of random numbers will be prepared and the Randbetween function will be created and the high risk will be divided into two groups of 26 people respectively.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the current research, only the statistical analyst will not be involved in the type of intervention.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Department of Clinical Psychology, Yas building, 4th floor, Ayatollah Taleghani Hospital, Arabi street, velenjak street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-07-22, 1402/04/31

Ethics committee reference number

IR.SBMU.MSP.REC.1402.182

Health conditions studied

1

Description of health condition studied

High risk pregnant

ICD-10 code

Z35.2

ICD-10 code description

Supervision of pregnancy with other poor reproductive or obstetric history

Primary outcomes

1

Description

Distress tolerance Being able to handle difficult emotions can help a person more quickly return to a state of equilibrium when new stressors arise.

Timepoint

The duration of the intervention is 8 sessions and one session per week, which lasts approximately 2 months.

Method of measurement

Simmons and Gaher Distress Tolerance Questionnaire

2

Description

Emotion regulation is a term generally used to describe a person's ability to effectively manage and respond to an emotional experience.

Timepoint

The duration of the intervention is 8 sessions and one session per week, which lasts approximately 2 months.

Method of measurement

Gertz and Romer emotion regulation questionnaire

3

Description

Mindfulness is a type of meditation in which you focus on being intensely aware of what you're sensing and feeling in the moment, without interpretation or judgment.

Timepoint

The duration of the intervention is 8 sessions and one session per week, which lasts approximately 2 months.

Method of measurement

Baer's five-facet questionnaire of self-awareness

4

Description

Quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Timepoint

The duration of the intervention is 8 sessions and one session per week, which lasts approximately 2 months.

Method of measurement

Ware's Quality of life short form questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindful self compassion: education will be 8 sessions in 8 weeks for 2 groups. Each session lasts 45-60 minutes. mindful self compassion therapy includes two parts: mindfulness techniques to reduce rumination and worries about the future, and self-compassion, which includes techniques for behaving and speaking kindly to yourself.

Category

Treatment - Other

2

Description

Control group: High-risk pregnant women without intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdia Gynecology and Obstetrics Hospital

Full name of responsible person

Afshin Zarghi

Street address

Department of Clinical Psychology, Yas building, 4th

floor, Ayatollah Taleghani Hospital, Arabi street, Velenjak street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Street address

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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

50

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

Afshin Zarghi

Position

PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Kristin Neff and Dr Christopher Germer

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

In the current study, except for the confidential information of the clients, including the name and surname, all information including age, occupation, education, language, and social and economic status will be shared.

When the data will become available and for how long

The time to access information and data will be one week after the results are published.

To whom data/document is available

The results of the present study can be available to all people, including workers and researchers in this field and even other fields and the general public.

Under which criteria data/document could be used

Researchers and workers in this and other fields can access the results of this study without any restrictions.

From where data/document is obtainable

To access the results of this study, they can refer to the following website. m.abdollahpur1373@gmail.com

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

After the publish of the results of this study, all the results will be available to the requestors of the results without any time limit.

Comments