

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of mindfulness self-compassion training on the fear of childbirth among first time pregnant women

Protocol summary

Study aim

Determination of mindfulness self-compassion training effect on the fear of childbirth among primigravid women

Design

The clinical trial will be with an intervention group and a control group with a pretest and post-test design.

Settings and conduct

Sampling in the first stage is done by the convenience method and all primigravid women in Gorgan who are eligible to participate in the study will be selected. For this purpose, the researcher will extract the list of all primigravid women of Gorgan who eligible to enter the study will be called via telephone call after explaining of the research goal and obtaining oral informed consent. Intervention group will receive mindfulness self-compassion training during eight ninety-minute sessions Online or face-to-face group counseling and control group will not receive any training.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian, ability to read and write in Persian, gestational age of 14-20 weeks, willing to participate in the study, having a smartphone and being able to work with it . Exclusion criteria: mental disorders, history of suicide, history of taking psychiatric drugs, educated in medicine and para medicine and psychology, passing training courses including mindfulness, self-compassion and CBT

Intervention groups

women in the intervention group will receive mindfulness self-compassion training during eight 90-minute sessions in the form of 12-person group sessions, online or face-to-face.

Main outcome variables

fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231025059856N1**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

sareh ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3255 7845

Email address

ebrahimi.s@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mindfulness self-compassion training on the fear of childbirth among first time pregnant women

Public title

Investigating the effect of mindfulness self-compassion training on the fear of childbirth among first time pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Ability to read and write in Persian Gestational age 14-20 weeks Willingness to participate in the study Having a smart mobile and the ability to work with it

Exclusion criteria:

Psychopathy Having a history of suicide History of taking psychiatric drugs Educated in the fields of medicine, paramedicine and psychology Passing training courses including mindfulness, self-compassion and CBT

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 23

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible people will be randomly assigned to intervention and control groups. In order to randomize the study subjects, the randomization method using envelopes is used, so that first, sealed envelopes will be prepared for the number of eligible people, in half of them code A (intervention group) in half. Another code B (control group) is inserted, and therefore, for each selected sample, an envelope is randomly selected from among the envelopes, and after opening the envelope, the desired group is determined. In the next stage, another 22 qualified people will be selected and assigned to two control and intervention groups. Blinding is not considered in this study.

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 Golestan University of Medical Sciences

Street address

Farhang Shahr real estate consultant, upper floor, between Sayad 14 and 16.Sayadshirazi Blvd.

City

Gorgan

Province

Golestan

Postal code

4917964441

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.GOUMS.REC.1402.317

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the intervention

Method of measurement

Vijma version A fear of childbirth questionnaire and self-compassion questionnaire Long form (Neff et al., 2003)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mindfulness self-compassion training

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Gorgan city

Full name of responsible person

Narjes Sadat Borghei

Street address

Golestan University of Medical Sciences, Hyrcan
Boulevard, beginning of Shisht Kola Road, Deputy of
Research and Technology, Gorgan

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4934174515

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borghei2006@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Narges Begum Mir Behbahani

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Golestan University of Medical Sciences, Hyrcan
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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

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Narjes Sadat Borghei

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Golestan University of Medical Sciences, Hyrcan
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Narjes Sadat Borghei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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

Gorgan University of Medical Sciences

Full name of responsible person

Sare ebrahimi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For use in meta-analysis studies

From where data/document is obtainable

Corresponding Author

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

Correspondence by e-mail with the responsible author stating the reason for the need to review the documentation Sharing the topic by the responsible author with other authors Data sharing if members agree

Comments