

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of effect of group counseling based on Mindfulness on pregnancy's worries and stress in nulliparous pregnant women

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of group counseling based on Mindfulness on pregnancy's worries and stress.

Design

A trial with a control group, randomized allocation classified, and a sample size of 102 pregnant women.

Settings and conduct

At first, by using available sampling, samples are selected in all health centers of city of Gorgan. Then, they are categorized by random allocation based on the score of the questionnaire into two groups of control and intervention. The intervention group is invited to 8 weekly counseling sessions on Mindfulness, while the control group does not receive any counseling. In the case of statistical analyzer, there is blindness and they do not know about the intervention and control of the codes.

Participants/Inclusion and exclusion criteria

Pregnant women with pregnancy's worries and stresses with the first pregnancy and the gestational ages between 12 to 20 weeks.

Intervention groups

The experimental group will attend in 8 weeks group sessions on mindfulness based group counseling. Every session will last 120-150 minutes. The control group does not receive the sessions. Participants will complete the Pregnancy's Worries and Stress Questionnaire before and after the end of the intervention.

Main outcome variables

Worries and stresses

General information

Reason for update

Acronym

MBCT= شناخت درمانی مبتنی بر ذهن آگاهی. MBSR= شناخت درمانی مبتنی بر کاهش استرس

IRCT registration information

IRCT registration number: **IRCT20171026037015N4**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Houri Alijani

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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alijani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences, Faculty of Nursing, Midwifery of Boyeh

Expected recruitment start date

2017-11-18, 1396/08/27

Expected recruitment end date

2018-09-18, 1397/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of group counseling based on Mindfulness on pregnancy's worries and stress in

nulliparous pregnant women

Public title

Evaluation of effect of group counseling based on Mindfulness on pregnancy's worries and stress

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant nulliparous women Aged 18 to 35 years old
Gestational age 12 to 20 weeks
The desire to participate in the study
The Pregnancy's Worries and Stress Questionnaire Score higher than 10
A low risk pregnancy

Exclusion criteria:

Having a degree of university education in medical sciences, psychology or counseling courses.
Severe family disputes in the week leading up to the study
Woman or her husband with a known psychological illness, Use of psychiatric medications or physical illnesses (such as cancers) and chronic illnesses during the past two months
Drug, psychotropic or alcohol abuse of woman or his husband in the past two months
Experience of formal mental health treatment before
Experience of severe stressful events during the past 3 months (a car crash or death of one of first grad relatives)

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

It has been randomized by using the minimization method, which is a non-randomized method in allocating samples to groups and it is based on scores of the questionnaires. In this way, each of the two scores close to each other choose randomly based on throwing a coin in an intervention or control group. we will have two groups of 12 people in every steps for control and intervention groups. This action continues to reach the sample of 51 people in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyzer is not informed about intervention and control groups.

Placebo

Not used

Assignment

Parallel

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

Hirkan Blvd, The Shast kola Ave, Deputy of Research and Technology, Golestan University of Medical Sciences, Gorgan Town

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2017-09-19, 1396/06/28

Ethics committee reference number

IR.GOUMS.REC.1396.141

Health conditions studied

1

Description of health condition studied

pregnancy's stress and worries

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Pregnancy's worries and Stresses score

Timepoint

Pregnancy Worries Score Measurement before the beginning of the first Mindfulness Consultation session and immediately after the last session.

Method of measurement

pregnancy's Stresses and Worries Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive Mindfulness based group counseling at 8 weekly sessions of 120-150

minutes, which will be held in groups of 6 to 12 people. By participating in Mindfulness counseling sessions, subjects will be able to relinquish their thoughts and control their thoughts through formal and informal practices of Mindfulness. They will learn the way of living in the body and the environment (instead of life in mind), which ultimately reduces the number of thoughts and the severity of their beliefs in them and creates mental relaxation.

Category

Behavior

2**Description**

Control group: No intervention received

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health Centers of the city of Gorgan

Full name of responsible person

Fateme Ebrahimi

Street address

Kalantari 13, Shahid Rajaei Ave, Gorgan Health Center, Gorgan Town

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

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Shast kola Ave., Hirkan Blvd., Deputy of research and technology., Golestan University of Medical Sciences., Gorgan Town

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Web page address**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

fateme ebrahimi

Position

Master's student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Web page address**Person responsible for scientific**

inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Asie sadat Baniaghil

Position

Professor Assistant and Faculty Member of Golestan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Service Management

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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

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

Information on the main outcome or the like can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academic and academic institutions.

Under which criteria data/document could be used

The data will be available for scientific research with reference to the research. In order to access the data, they can reply to the person's e-mail address.

From where data/document is obtainable

En responsible person's email address:
Ebrahimi@yahoo.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Fateme Ebrahimi

Position

Master's student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shast kola Ave, Hirkan Blvd, Faculty of Nursing Midwifery, Golestan University of Medical Sciences, Gorgan Town

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