Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 attended 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)
Phone
+98 17 3243 0360
Email address
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 an 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 Rajaee Ave, Gorgan Health Center, Gorgan Town

City
Gorgan

Province
Golestan

Postal code
4919689631

Phone
+98 17 3242 0710

Fax
+98 17 3242 9645

Email
ebrahimi1059@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Honarvar

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

City
Gorgan

Province
Golestan

Postal code
4915767446

Phone
+98 17 3245 1354

Fax

Email
erahimi1059@yahoo.com

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

Street address
Reproductive health and midwifery counsultant cometee- second floor- faculty of nursing and midwifery- falsafi complex- Golestan university of medical sciences- Shast kola Ave, Hirkan Blvd

City
Gorgan

Province
Golestan

Postal code
4934174515

Phone
+98 17 3242 1660

Fax
+98 17 3242 1657

Email
ebrahimi1059@yahoo.com

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

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

City
Gorgan

Province
Golestan

Postal code
4913815739

Phone
+98 17 3245 6900

Fax
+98 17 3242 5171

Email
a-baniaghil@yahoo.com

Web page address

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

City
Gorgan

Province
Golestan

Postal code
4934174515

Phone
+98 17 3242 1660

Fax
+98 17 3242 1657

Email
Ebrahimi1059@yahoo.com

Web page address

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