

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the effectiveness of mindfulness-based intervention on the feeling of decreased fetal movements in the third trimester of pregnancy outcomes and number of referrals in Niknafs maternity hospital in Rafsanjan in 2023.

Protocol summary

Study aim

Determining the effect of psychological intervention based on mother's mindfulness on the feeling of reduced fetal movements in the third trimester of pregnancy, pregnancy outcomes and the number of referrals to Nik Nafs maternity hospital in Rafsanjan in 2023

Design

The current study is a semi-experimental study of an intervention type with a pre-test, post-test and control group design. Sampling is pilot and the number of samples is 30 people. The samples will be divided into two control and intervention groups as a block of four.

Settings and conduct

Pregnant women in the intervention group will undergo individual psychological counseling based on mindfulness for 45 minutes. Audio and video files are sent. A pregnant woman can ask the consultant questions related to counseling and movements of her fetus until the end of her pregnancy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age less than 35 years old; absence of oligohydraminos and polyhydraminos; no smoking and any opioids; absence of anterior placenta; absence of SGA fetus; singleton pregnancy. Exclusion criteria: not attending more than two sessions; participating in other counseling sessions.

Intervention groups

Pregnant women who feel a decrease in fetal movements between 28-30 weeks of gestation, after consulting and confirming the health of the fetus, immediately on the bed, undergo individual psychological counseling based on mindfulness for 45 minutes, and then once every three days and in 5 counseling sessions from It is carried out remotely (telephone and virtual space). Pregnant women can also ask their questions through communication channels. The control group will not

receive any counseling except pregnancy routine.

Main outcome variables

Number of referrals; pregnancy outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230826059260N1**

Registration date: **2023-09-09, 1402/06/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-09, 1402/06/18**

Update count: **0**

Registration date

2023-09-09, 1402/06/18

Registrant information

Name

Faezeh Ghasemirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3426 7649

Email address

f.ghasemirad74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-02, 1402/06/11

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of mindfulness-based intervention on the feeling of decreased fetal movements in the third trimester of pregnancy outcomes and number of referrals in Niknafs maternity hospital in Rafsanjan in 2023.

Public title

The effect of psychological intervention based on mother's mindfulness on the feeling of decreased fetal movements in the third trimester of pregnancy, pregnancy outcomes and the number of referrals

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 35 years old
Absence of oligohydramnios and polyhydramnios
Absence of smoking and any opioids
Absence of anterior placenta
Absence of SGA fetus
Singleton pregnancy

Exclusion criteria:

Failure to attend more than two sessions
Participation in other counseling sessions

Age

To 35 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Kerman University of Medical Sciences

Street address

Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.KMU.REC.1402.122

Health conditions studied**1****Description of health condition studied**

Abnormal pregnancy

ICD-10 code

O36.9

ICD-10 code description

Maternal care for fetal problem, unspecified

Primary outcomes**1****Description**

The number of visits to the mother due to the feeling of decreased fetal movements

Timepoint

Throughout pregnancy

Method of measurement

Self-made questionnaire

Secondary outcomes**1****Description**

Pregnancy outcomes include: Apgar <7 in the first 5 minutes of birth, Apgar <4 in the first 5 minutes of birth, birth weight less than 10%, birth weight <2 SD, NICU admission, fetal death (stillbirth), premature delivery (less than 37 weeks), age Pregnancy at birth > 6+41, spontaneous onset of labor, induction of labor, cesarean section

Timepoint

Postpartum

Method of measurement

Self-made questionnaire

Intervention groups**1****Description**

Intervention group: Intervention group: The research population is pregnant women with decreased fetal movements in the gestational age range of 28-30 weeks who have visited Nik Nafs maternity hospital for the first time. After obtaining informed consent from the pregnant parents and if they meet the entry criteria, the pregnant mother will enter the study with the doctor's confirmation that there is no problem and the health of the fetus. The samples will be divided into two control and intervention groups. Pregnant women in the intervention group are immediately placed on the bed, undergoing individual psychological counseling based on mindfulness for 45 minutes. After discharge, once every three days and in 5 times, remote counseling is done, which includes three components: 1) a short phone call of 5 minutes 2) immediately after the phone call, audio files And a video is sent to women as a part of the consultation via WhatsApp, Telegram or Skype. 3) A pregnant woman can ask the counselor questions related to counseling and fetal movements in phone consultations and in between through WhatsApp, Telegram or Skype until the end of her pregnancy.

Category

Other

2

Description

Control group:Control group: This group does not receive any counseling and only prenatal care is performed and is evaluated through a self-made questionnaire: fetal movements, pregnancy outcome and the number of referrals.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs maternity hospital in Rafsanjan

Full name of responsible person

zahrahashemi

Street address

Shohada St

City

Rafsanjan

Province

Kerman

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7715633863

Phone

+98 34 3425 9040

Email

f.ghasemirad74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abedin Iranpour

Street address

Kerman University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis

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Phone

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Email

a.iranpour@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Firozeh Mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Firozeh Mirzaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Ph.D.

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the information related to the main consequences is possible to share.

When the data will become available and for how long

The access period starts six months after the announcement of the results

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

To investigate additional research and other parameters

From where data/document is obtainable

via email F_mirzaee@gmail.com

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

The request should be sent via e-mail, and after checking and approval, it will be sent within a period of one month

Comments