Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Faezeh Ghasemirad

Name of organization / entity

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Iran (Islamic Republic of)

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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 oligohydraminosis and polyhydraminosis 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

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7715633863

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abedin Iranpour

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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

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 updating data

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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