Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effect of spiritual self-care program on anxiety in pregnant women with preterm labor pain: a randomized clinical trial

Protocol summary

Study aim
determining the effect of spiritual self-care program on anxiety in pregnant women with preterm labor pain
Design
Non blind randomized clinical trial
Settings and conduct
Seventy eligible pregnant women who refer to Shahid Beheshti hospital, Kashan, Iran, will enroll to the study. Intervention will be done through five integrative educational sessions; two face to face and group educational sessions and three mobile-based educational sessions. content of education is adopted by the Kajbaf etal's spiritual care package.
Participants/Inclusion and exclusion criteria
The inclusion criteria include age at least 18 years, education at least diploma status, having a android cell phone, primary parus, gestational age between 30 to 34 weeks; exclusion criteria include use of psychiatric drugs and drugs associated with thyroid disorders, positive history of well-known anxiety disorders, participation in religious ceremonies and undergraduate courses by a pregnant mother or her husband, absence of more than one session of educational classes in intervention group, preterm delivery during the intervention and unwilling to continue the cooperation in the research.
Intervention groups
the first group is the intervention group and the second group is control group
Main outcome variables
anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160808029255N2**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **registered_while_recruiting**
Last update: **2018-05-21, 1397/02/31**
Update count: **0**
Registration date
2018-05-21, 1397/02/31

Registrant information
Name
Raziyeh Maasoumi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 6105 4214
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2018-10-12, 1397/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of spiritual self-care program on anxiety in pregnant women with preterm labor pain: a randomized clinical trial

Public title
The effect of spiritual self-care program on anxiety in pregnancy
Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age at least 18 years education at least diploma status having android cell phone primary parus gestational age between 30 to 34 weeks

Exclusion criteria:

use of psychiatric drugs and drugs associated with thyroid disorders positive history of well-known anxiety disorders participation in the religious ceremonies and related undergraduate courses by pregnant mother or her husband

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are divided randomly into two groups; the first group as the intervention group and the second group as the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences Nursing and Midwifery Care Research Center

Street address

south Nosrat Ave., Towhid Sq., Tehran city

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4274

Health conditions studied

1

Description of health condition studied

on anxiety in pregnant womenwith preterm labor pain

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

Primary outcomes

1

Description

Pregnancy anxiety

Timepoint

Before intervention. Immediately after the end of the intervention. One month after the end of the intervention

Method of measurement

Pregnancy Related Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The method of work in the intervention group is a combination of in-person and virtual training. Two in-person sessions will be held by the researcher for 90 minutes based on spiritual therapy package,s Kajbaff et al. (37). So that these two sessions will be held within a week at intervals of five days (beginning and end of the week).Teaching is organized a group in a classroom and the researcher will use lecture and question and answer methods, as well as the teaching materials will include a panel, a marker and a brochure. Three training sessions will be held virtual and the content of each one will be available through the telegram program within five days and will be followed up by phone call with each participant to receive and study it.

Category

Behavior

2

Description

Control group: These persons will not receive any spiritual self-care education.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti hospital in the city of Kashan

Full name of responsible person
Dr Raziyeh Masoomi

Street address
Qotbe Ravadi bulvar

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Kashan

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Isfehan

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87159/81151

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r_masoumi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research and Technology of Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Raziyeh Maasoumi

Position
assisstant proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Dr. Raziyeh Maasoumi

Position
Pos.doc of Sexology, PhD of Reproductive Health,

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Other areas of specialty/work

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Web page address

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data of the study would be available after unrecognizable process of participants

When the data will become available and for how long

Six months after publication of findings

To whom data/document is available

Data of this research would be be available for academic researches

Under which criteria data/document could be used

Data of this study would be available only same research

From where data/document is obtainable

Dr. Raziyeh Maasoumi email: r_masoumi@sina.tums.ac.ir

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

Sending a request by email attendance to the office of corresponding of project presentation the reasons for similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in office of corresponding author

Comments