

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 21 6105 4214

Email address

r_masoumi@sina.tums.ac.ir

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 women with 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 Raziye Masoumi

Street address

Qotbe Ravadi bulvar

City

Kashan

Province

Isfahan

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87159/81151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Raziye masoumi

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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

Raziye Maasoumi

Position

assistant proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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 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. Raziye 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