

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The Effectiveness of Spirituality Counseling on Coping with Pregnancy and Quality of Life in First Time Pregnant Women

Protocol summary

Study aim

The Effectiveness of Spirituality Counseling on Coping with Pregnancy and Quality of Life in First Time Pregnant Women

Design

In A Randomized Clinical Trial With A Control Group, 60 of Eligible Pregnant Women will be Participated in The Study. The Intervention Group will be Received 8 Sessions Counseling and Control Group will be Received Routine Care . Both Groups will be Followed for Two Month. The Outcome of The Study will be Determined in Two Steps Before and Two Month After The Last Consultation.

Settings and conduct

Sampling will be Done From Three Health Centers of Zanjan City. Firstly, 60 Eligible Women will be Selected by Convenience Method and Then will be Allocated to The Intervention and Control Groups based on The Four Blocks That are Extracted by Statistical Software. We do not have Blindness in This Study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Include: Desire to Participate in The Study; Planned Pregnancy; First Time Pregnancy; Gestational Age 20-24 Weeks; Lack of History of Known Mental and Physical Illnesses; Low Risk and Uncomplicated Pregnancy; Singleton Pregnancy; Getting Score From 18 to 36 by Cohen Perceived Stress Questionnaire; Getting Score Lower Than 10 by Edinburgh Depression Inventory. Exclusion Criteria Include: Unwilling to Participate in The Study; The Absence of More Than Two Sessions

Intervention groups

The intervention group, in addition to the Pregnancy Preparation classes, will receive group counseling for the spirituality-centered and control groups only for the preparation of maternity wards.

Main outcome variables

Quality of Life and Coping with First Pregnancy

General information

Reason for update

Hello, The Start Date of sampling has been Incorrectly Entered and The Status of The Code has been Retrospective. Please Help to Resolve the problem.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N12**
Registration date: **2018-11-06, 1397/08/15**
Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**

Update count: **1**

Registration date

2018-11-06, 1397/08/15

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3345 4264

Email address

malekia@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-02-22, 1397/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Spirituality Counseling on Coping with Pregnancy and Quality of Life in First Time Pregnant Women

Public title

The Effectiveness of Spirituality Counseling on Coping with Pregnancy and Quality of Life in First Time Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Desire to Participate in The Study Planned Pregnancy First Time Pregnancy Gestational Age 20-24 Weeks Lack of History of Known Mental and Physical Illnesses Low Risk and Uncomplicated Pregnancy Singleton Pregnancy Getting Score From 18 to 36 by Cohen Perceived Stress Questionnaire Getting Score Lower Than 10 by Edinburgh Depression Inventory

Exclusion criteria:

Unwilling to Participate in The Study The Absence of More Than Two Sessions consultaion

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible Women will be Selected Using The Convenience Sampling Method and They will be Randomly Allocated to The Intervention and The Control Groups using Statistical software Randomized 4-Block method.

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 Zanjan University of Medical Sciences

Street address

Azadi Blvd, Zanjan University of Medical Sciences, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.ZUMS.REC.1397.024

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

Quality of Life, Coping With Pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Quality of life

Timepoint

Before and Two Months After The Last Session of Consultation

Method of measurement

Quality of Life Questionnaire

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

Copy With Pregnancy

Timepoint

Before and Two Months After The Last Session of Consultation

Method of measurement

Coping With Pregnancy Questionnaire

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

Participants in the intervention group will receive 8 group counseling sessions based on bipartite duality and 45 minutes per session for routine nursing care. The length of a one-month period and the content of the sessions include titles of forgiveness, repentance, meditation, the effect of the Qur'an, and authority on the birth and the fetus.

Category

Prevention

2**Description**

Control group: Control group: The control group is the first 30 pregnant women attending routine childbirth classes, and no intervention by the investigator is applied to this group.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Childbirth Preparing Class at Ayatollah Mousavi Hospital

Full name of responsible person

Masome Monfared Kashki

Street address

Gavazang Road, Ayatollah Mousavi Hospital

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Fax**Email**

sanammonfared@gmail.com

2**Recruitment center****Name of recruitment center**

Childbirth Preparing Class at Imam Hussein Hospital of Zanjan

Full name of responsible person

Masome Monfared Kashki

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The Beginning of The Coy Farhangh, Imam Hussein Hospital, Zanjan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Masome Monfared Kashki

Position

Msc Student in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Maleki Azam

Position

PhD in Maternal & Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Maleki Azam

Position

PhD in Maternal & Child Health

Latest degree

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Other areas of specialty/work

Midwifery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Dissatisfaction participants

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available