

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The Effectiveness of Counseling With Spiritual Therapy Approach in Improving Breastfeeding Self-efficacy And Perceived Stress in Primipara Women

Protocol summary

Study aim

To Determine The Effect of Counseling With Spiritual Approach in Improving Breastfeeding Self-efficacy And Perceived Stress in Primipara Women

Design

The Present Study Is Phase 3 Of A Randomized Clinical Trial, Has A Control Group With Parallel Groups. That Will Be Performed On 60 Patients (30 Interventions And 30 Control Interventions). We Do Not Have Blinding. Eligible Women Will Be Selected By Convenience Sampling Method And Will Be Assigned To Two Intervention And Control Groups Using 4 Random Blocks.

Settings and conduct

The Research Setting Includes Preparation Classes For Childbirth Of Ardabil City. Using A Randomized Block Method The Eligible Pregnant Women Will Be Divided Into Two Intervention And Control Groups. We Do Not Have Blinding. For The Intervention Group, 8 Sessions Counseling With Spiritual Approach Will Be Held. The Control Group Will Be Received Routine Prenatal Care.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having The Score Of Breastfeeding Self-efficacy Lower Than Median; Having The Score Of Perceived Stress 18-36 Based On Cohen Questionnaire; First Time Pregnancy; Wanted Pregnancy. Exclusion Criteria: Twin Pregnancy; Breastfeeding Contraindication; Having Psychological Disease

Intervention groups

The Intervention Group Will Be Receive Counseling With A Spiritual Approach At 32 To 36 Weeks Of Gestation. Spiritual Group Counseling Will Be Held In 8 Sessions, Twice Per A Week, Each Session For 45 To 60 Minutes. The Content Of The Sessions Includes Breastfeeding Self-Efficacy, Factors Affecting Self-Efficacy, Emotion Management In Dealing With Stressors Related To Breastfeeding, The Effect Of Faith In God, Trust, Forgiveness, Repentance And Meditation In Reducing

Stress And Breastfeeding Stress. Control Group: They Will Receive Regular Prenatal Care.

Main outcome variables

Breastfeeding Self-efficacy; Perceived Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N14**

Registration date: **2020-05-22, 1399/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-22, 1399/03/02**

Update count: **0**

Registration date

2020-05-22, 1399/03/02

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

2020-05-19, 1399/02/30

Expected recruitment end date

2020-08-07, 1399/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Counseling With Spiritual Therapy Approach in Improving Breastfeeding Self-efficacy And Perceived Stress in Primipara Women

Public title

The Effect of Counseling With Spiritual Approach In Improving Breastfeeding Self-efficacy And Decreasing Perceived Stress in Primipara Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having The Score Of Breastfeeding Self-efficacy Lower Than Median Having The Score of Perceived Stress 18-36 Based On Cohen Questionnaire First Time Pregnancy Wanted Pregnancy

Exclusion criteria:

Twin Pregnancy Breastfeeding Contraindication Having Psychological Disease

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

3

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

Randomized

Randomization description

Sixty Eligible Women Will be Selected Based on Convenience Sampling . Given a Block Size of Four, The Participants Will be Assigned Into Two Groups (Intervention And Control) in A Random Manner.

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

Zanjan, Azadi Blvd., Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.ZUMS.REC.1398.244

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

Breastfeeding Self-efficacy

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Perceived Stress

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

Breastfeeding Self-efficacy

Timepoint

Before, After the Intervention, One Month After Childbirth

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

2**Description**

Perceived Stress

Timepoint

Before, After the Intervention, One Month After Childbirth

Method of measurement

Cohen's Perceived Stress Questionnaire

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

Breastfeeding Self-efficacy

Timepoint

Before, After The Intervention, One Month After Childbirth

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

2

Description

Perceived Stress

Timepoint

Before, After The Intervention, One Month After
Childbirth

Method of measurement

Cohen's Perceived Stress Questionnaire

Intervention groups

1

Description

The Intervention Group Will Be Receive Counseling With A Spiritual Approach At 32 To 36 Weeks Of Gestation. Spiritual Group Counseling Will Be Held In 8 Sessions, Twice Per A Week, Each Session For 45 To 60 Minutes. The Content Of The Sessions Includes Breastfeeding Self-Efficacy, Factors Affecting Self-Efficacy, Emotion Management In Dealing With Stressors Related To Breastfeeding, The Effect Of Faith In God, Trust, Forgiveness, Repentance And Meditation In Reducing Stress And Breastfeeding Stress.

Category

Prevention

2

Description

Control group:They Will Receive Regular Prenatal Care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Childbirth Preparation Classes of Ardabil City

Full name of responsible person

Munes Yousefi

Street address

Hafez Town - Ardabil Health Center

City

Ardabil

Province

Ardabil

Postal code

5614844753

Phone

+98 45 3371 4664

Email

munesyousefi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Zanjan, Azadi Blvd., Zanjan University of Medical
Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3524 2075

Email

munesyousefi@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Lack of funding

Proportion provided by this source

1

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

Munes Yousefi

Position

Master Of Sciences Student In Midwifery Counseling

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Gavazang Road, Zanjan University Of Medical
Sciences, Zanjan

City

Zanjan

Province

Zanjan

Postal code

5614844753

Phone

+98 45 3345 1618

Email

munesyousefi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Azam.Maleki

Position

PhD in Maternal & Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Gavazang Road, Zanjan University Of Medical Sciences, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24334206519

Email

Makekia@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Azam.Maleki

Position

PhD In Maternal & Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Gavazang Road, Zanjan University Of Medical Sciences, Zanjan

City

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Province

Zanjan

Postal code

4515613191

Phone

+98 24334206519

Email

Malekia@zums.ac.ir

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

There is no further information

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