Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Age
From **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
Zanjan

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