

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effect Of Stress Management Counseling on Breastfeeding Self-Efficacy and Duration Of Exclusive Breastfeeding In Primiparous Women

Protocol summary

Study aim

The Effectiveness of Stress Management Counseling on Self-efficacy and The Duration of Exclusive Breastfeeding in Primiparous Women

Design

In this Clinical Trial, 96 Eligible Pregnant Women will be selected Using Convenience Sampling Methode and will be randomly allocated into Two Groups of Intervention and Control using 4- Bolcked. The Outcomes of Study are Breastfeeding Self-efficacy and Duration of Exclusive Breastfeeding. Self-efficacy will be checked by Denise's Breastfeeding Self-efficacy Questionnaire in before Intervention, The First Month after delivery and then 4 Months after Delivery. The Duration of Exclusive Breastfeeding and The Level of Lactation will be done using Telephonic Follow-up after Delivery per monthly up to 4 Months after Delivery.

Settings and conduct

Individually Stress Management Counseling will be done for The Intervention Group. Totally 4 Sessions will be done 2 times per Week at 35 and 36th Week of Pregnancy. Consultation Sessions will be held at The Maternity Hospital Preparation at Ayatullah Mousavi Hospital, Imam Hossein Hospital, Health Center No. 3 Zanjan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous, The Absence of Known Systemic and Psychosomatic Diseases in Recent Pregnancy (major depression), Cohen Perceived Stress Scale score higher than 18. Exclusion criteria: Preterm Delivery, Complications of Pregnancy (Pre-eclampsia and Diabetes), Neonatal Abnormalities, Neonatal Death, The Breastfeeding Contraindication, Not Participating in Counseling Sessions more than Two Sessions

Intervention groups

Individually Stress Management Counseling will be done for The Intervention Group. Totally 4 Sessions will be

done 2 times per Week at 35 and 36th Week of Pregnancy. Control Group will be got Rotine Care.

Main outcome variables

Breastfeeding Self-Efficacy; Duration Of Exclusive Breastfeeding; Level of lactation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N10**

Registration date: **2018-05-23, 1397/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

Registration date

2018-05-23, 1397/03/02

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

Deputy of Research and Technology of Zanjan University of Medical Sciences

Expected recruitment start date

2017-12-01, 1396/09/10
Expected recruitment end date
2018-08-01, 1397/05/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect Of Stress Management Counseling on Breastfeeding Self-Efficacy and Duration Of Exclusive Breastfeeding In Primiparous Women

Public title
The Effect Of Stress Management Counseling On Breastfeeding Self-Efficacy And Duration Of Exclusive Breastfeeding In Primiparous Women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to Participate in The Study Having Reading and Writing Skills Primiparous Women Wanted Pregnancy The Gestational Age is 35-36 Weeks The Absence of Known Systemic and Psychosomatic Diseases in Recent Pregnancy (major depression) Higher than 18 Based on Cohen Perceived Stress Scale score

Exclusion criteria:

Preterm Delivery Birth Weight Less than 2500 gr Complications of Pregnancy (pre-eclampsia and diabetes) Discontinue Participate to The Study Fetus with Known Abnormalities Neonatal Death Breastfeeding Contraindication Unexpected Events During Pregnancy Period or After Childbirth Ex. The Death of Relatives Not Participating in Counseling Sessions more Than Two Sessions,

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible Women will be Selected Using The Convenience Sampling Method and Allocating of The Intervention and The Control Groups will be Randomized Using 4-Block.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used

Assignment
Other

Other design features

The Intervention Group will be Considered Counseling Sessions and The Control Group will be Received Routine Care.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

•Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Boulevard

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2017-10-17, 1396/07/25

Ethics committee reference number

ZUMS.REC.1396.165

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

Breastfeeding Self-Efficacy

Timepoint

Before Intervention, One Month after Delivery, Four Months after Delivery

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

2

Description

Duration Of Exclusive Breastfeeding

Timepoint

One Month after Delivery, Two Months after Delivery, Three Months after Delivery, Four Months after Delivery

Method of measurement

Determination of Breastfeeding (at Three Levels: Exclusive Breastfeeding, Breastfeeding, and other

Liquids or Formula, Feeding Bottles and Without Breast Milk) followed by the Phone

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: four sessions of stress management counseling individually and face-to-face, 2 sessions per week, each session 2 hours, at 35 and 36 weeks of pregnancy will receive.

Category

Behavior

2

Description

Control group: will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Ayatollah Mousavi Hospital childbirth preparation class

Full name of responsible person

Azizi Elmira, Master of Science in Midwifery Counseling

Street address

Ayatollah Mousavi Hospital, Gavazang Road,Zanjan

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2

Recruitment center

Name of recruitment center

Zanjan Imam Hussein hospital childbirth preparation class

Full name of responsible person

Azizi Elmira, Msc in Midwifery Counseling

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3

Recruitment center

Name of recruitment center

Comprehensive Health Center (3) Childbirth Preparation Class

Full name of responsible person

Azizi Elmira, Msc in Midwifery Counseling

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University Of Medical Sciences

Full name of responsible person

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Grant name

پایان نامه

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

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Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for scientific inquiries

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Person responsible for updating data

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Malekia@zums.ac.ir
Web page address

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