# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

IIndividually 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)

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**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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**3**

**Recruitment center**
**Name of recruitment center**
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## Sponsors / Funding sources

**1**

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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

## Person responsible for general inquiries

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Msc in Midwifery Counseling
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## Person responsible for updating data

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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