

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The Effect of couples counseling on improving of breastfeeding among women with unwanted pregnancy

#### Protocol summary

##### Study aim

The Effect of couples counseling on improving breastfeeding in women with unwanted pregnancies

##### Design

Phase 3 of a randomized clinical trial, has a control group with parallel groups. That will be performed on 60 couples(30 Interventions and 30 Control). 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

Sampling will be done from four health centers In Zanjan city. Sixty eligible couples will be selected using the convenience method then they will be allocated into the intervention and control groups based on the four block design. The number of blocks will be selected from the random number table.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Obtaining less than 3 scores based on the London unplanned pregnancies questionnaire; gestational age 36-34 weeks ; obtaining a score of 18-36 based on the Cohen perceived stress questionnaire.  
Exclusion Criteria: Breastfeeding contraindication; absence of more than two sessions in counseling sessions;not desire to continue participation; simultaneous participation in similar training classes, history of known mental disorder, history of chronic debilitating illness

##### Intervention groups

The Intervention Group Six sessions of breastfeeding counseling will beheld using Bandura self-efficacy approach with the participation of couples. It will be Individually, Twice a week and each session for 45 to 60 minutes. The control group will only receive routine care.

##### Main outcome variables

Breastfeeding Self-efficacy In Unwanted Pregnancy

#### General information

##### Reason for update

Change the sampling date

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150731023423N18**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **1**

##### Registration date

2020-11-09, 1399/08/19

##### 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

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of couples counseling on improving of breastfeeding among women with unwanted pregnancy

## Public title

The Effect of couples counseling on improving of breastfeeding among women with unwanted pregnancy

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

A score of less than 3 based on the London unplanned pregnancy scale Gestational age 36-34 weeks Score 18-36 based on the Cohen perceived stress questionnaire

### Exclusion criteria:

Breastfeeding contraindication Absence in counseling sessions more than two sessions Not desire to continue the participation Simultaneous participation in similar training classes History of known mental disorder History of chronic debilitating disease

## Age

No age limit

## Gender

Female

## Phase

3

## 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. According to the sample size, they will be randomly allocated to the intervention and control groups using randomized 4-Block by table of random number. The sequence of blocks will be placed on a separate sheet inside the matte envelope. In the present study, we do not have blinding.

## 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

2020-07-16, 1399/04/26

## Ethics committee reference number

IR.ZUMS.REC.1399.137

## Health conditions studied

### 1

#### Description of health condition studied

Unplanned Pregnancy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Breastfeeding Self-efficacy

#### Timepoint

Before ; Immediately After The Consultation Sessions; Six Weeks After Delivery

#### Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

## Secondary outcomes

### 1

#### Description

Stress is perceived

#### Timepoint

Before immediately after the consultation sessions and six weeks after delivery

#### Method of measurement

Cohen Perceived Stress Questionnaire

## Intervention groups

### 1

#### Description

Intervention group will be received 6 sessions of couples counseling according to the Bandura' Self-efficacy Protocol, twice a week and each session for 45 to 60 Minutes. The Content of the sessions includes: breastfeeding self-efficacy, factors Affecting of breastfeeding self-Breastfeeding education, discussion about couples' attitudes toward pregnancy, accepting unwanted pregnancies, the role of spouse participation in controlling women's emotions and stress, self-efficacy

and its role in breastfeeding, anti-self-efficacy drug, emotion management, improving attitudes toward pregnancy, the role of spouse participation Breastfeeding.efficacy, emotion management in dealing with breastfeeding and pregnancy related stressors, attitudes toward pregnancy, increasing spouse participation in stress management and breastfeeding.

**Category**

Prevention

**2****Description**

Pregnancy routine care control group that will receive 8 routine sessions during pregnancy, including nutrition, breastfeeding, personal hygiene, etc.

**Category**

Prevention

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

Zanjan Health Centers

**Full name of responsible person**

Mahnaz Abozari

**Street address**

Four centers in different areas

**City**

Zanjan

**Province**

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45156131910

**Phone**

+98 24 1433 8300

**Email**

mahnaz.abozari123@gmail.com

**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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Zanjan University of Medical Sciences, Azadi Blvd.,  
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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**

Mahnaz Abozari

**Position**

Master Student of Counseling in Midwifery

**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**

Azam Maleki

**Position**

PhD in Maternal and Child Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

### Contact

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Zanjan University of Medical Sciences  
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**Position**  
PHD of Maternal and Child Health  
**Latest degree**  
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**Other areas of specialty/work**  
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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

Possibility of dissatisfaction of 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