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

Zanjan

Postal code

45156131910

Phone

+98 24 1433 8300

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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

Street address

Zanjan University of Medical Sciences, Azadi Blvd., Zanjan

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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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Zanjan University of Medical Sciences, Gavazang Road

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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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Midwifery

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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