Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of midwifery counseling based on gamble approach on depression, anxiety, posttraumatic stress disorder after traumatic childbirth in nulliparous women

Protocol summary

Summary

This Study is a randomized clinical trial. In the first stage, stratified sampling will be done from all health centers of the Zanjan University of Medical Sciences. At first, two centers will be selected randomly from each socio-economic areas, then 520 mothers who are in the third trimester of pregnancy and affiliated to these centers will be selected based on stratified sampling. The maternal depression will be screened based on the Edinburgh scale. Then those without depression, the age range between 18 to 35 years old, with a single pregnancy, willing to participate in the study and can read, write and understand the Persian language will enter to the second stage. In the second stage, during the first 72 hours after birth, women will be screened for traumatic childbirth using a DSM-5 scale. Then, 90 subjects who have experienced traumatic childbirth will be selected by convenience sampling and will be allocated into two groups of intervention (n = 45) and control (n = 45) on the random blocked allocation. The intervention group will receive counseling and the control group will receive usual care after childbirth. After the last session, the questionnaire will be completed in both the intervention and control groups by a trained interviewer who is unaware of the group assignment of the women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608285417N2**
Registration date: **2017-02-21, 1395/12/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

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Elham Jafari
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-11-06, 1395/08/16

Expected recruitment end date

2017-02-04, 1395/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of midwifery counseling based on gamble approach on depression, anxiety, posttraumatic stress disorder after traumatic childbirth in nulliparous women

Public title

The effect of midwifery counseling based on gamble approach on depression, anxiety, posttraumatic stress disorder after traumatic childbirth in nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 35 years old; Single pregnancy; nulliparous; willingness to participate in the study; the ability to complete the questionnaire; the ability to speak to Persian language; no history of miscarriage; stillbirth and infertility; no history of depression during pregnancy; the lack of a history of postpartum depression in first-degree relatives; not using drugs that can cause symptoms of depression (such as anti-epileptic; antihypertensive; steroids; anti-Parkinson's and sedative drugs); no history of mental illness; lack of psychological and medical treatment. No Chronic illnesses and diseases that are caused depression (epilepsy, multiple sclerosis, migraine); non-occurrence of a traumatic event in recent year (such as relative or husband’s death; the occurrence of sudden financial problems; marital problems and divorce, drug abuse). Exclusion criteria included: changing living area so that she not available; newborn congenital anomalies, mothers or their infants who will need special care; Having no tendency to continue the study.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

random blocked allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard,

Street address

Zanjan

City

Zanjan

Postal code

Approval date

2016-11-02, 1395/08/12

Ethics committee reference number

Zums.rec.1395.197

Health conditions studied

1

Description of health condition studied

traumatic childbirth

ICD-10 code

F43.1

ICD-10 code description

Arises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone

Primary outcomes

1

Description

Post-traumatic stress disorder

Timepoint

4-6 weeks after intervention and 3 months after delivery.

Method of measurement

Post-traumatic stress disorder scale

Secondary outcomes

1

Description

depression

Timepoint

4-6 weeks after intervention and 3 months after delivery.

Method of measurement

Edinburgh Depression scale

2

Description

anxiety

Timepoint

4-6 weeks after intervention and 3 months after delivery.

Method of measurement

Hamilton Anxiety scale scale

Intervention groups

1

Description

the control group will receive usual care after childbirth.

Category

Prevention

2

Description
In the intervention group, face to face and telephone consultations will be conducted in two sessions.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Leila Asadzadeh
Street address
Ayatollah Mousavi Hospital, Road Gavazang, Zanjan
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2

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Leila Asadzadeh
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Imam Hossein Hospital, Farhang Street, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North
Full name of responsible person
Dr Alireza Shoghli
Street address
North Side Azadi Boulevard Zanjan
City
Zanjan
Grant name
پایان نامه
Grant code / Reference number
A-11-326-3
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty