Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of midwife-led postpartum counseling on psychological distress in women with traumatic childbirth

Protocol summary

Study aim
To define effect of midwife-led postpartum counseling on psychological distress in women with traumatic childbirth

Design
A clinical trial with a control group, with parallel, unblinded, randomized groups, and random blocked allocation

Settings and conduct
At first, pregnant women referred to prenatal care clinic Imam Ali Hospital who have inclusion criteria will be selected. Then, during the first 72 hours after birth, women will be screened for traumatic childbirth using a DSM-IV scale. 96 subjects with traumatic experienced childbirth will be selected by convenience sampling and allocated into two groups of intervention and control. At 12 weeks after delivery, the questionnaires will be completed again in both groups by a trained interviewer who is unaware of the group assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged18-35 years; mother's willingness and consent to participate in the study; singleton pregnancy; ability to complete questionnaires; traumatic childbirth; Exclusion criteria: history of infertility; history of abortion; history of stillbirth; history of postpartum depression in first-degree relatives; depression during pregnancy; mental illness; medical disorder; occurrence of an unfortunate accident during the last 6 months

Intervention groups
In the intervention group, counseling by the midwife is performed on the basis of "the Gamble's strategy" individually for 3 sessions, one sessions of face-to-face contact consultation during the first 72 hours after child birth and two session of telephone consultations in the fourth week and the eighth week after delivery, ranging 40 - 60 minutes. For the control group, usual care after childbirth is provided.

Main outcome variables
psychological distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221024056280N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date
2023-05-15, 1402/02/25

Registrant information

Name
Mouloud Aghajani Delavar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3227 4881

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectiveness of midwife-led postpartum counseling on psychological distress in women with traumatic childbirth

Public title
Effectiveness of midwife-led postpartum counseling on psychological distress
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
age range 18-35 years mother's willingness and consent to participate in the study singleton pregnancy ability to complete questionnaires
Exclusion criteria:
history of infertility history of abortion history of stillbirth history of postpartum depression in first-degree relatives depression during pregnancy mental illness medical disorder occurrence of an unfortunate accident during the last 6 months
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: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
The sequence of random allocation and the list of blocks will be obtained with the help of software (https://www.sealedenvelope.com) in blocks of 4. Blocking and allocation sequence for concealment will be done by a person not involved in the research. The allocation ratio of the samples will be 1.1 and will be placed in two groups receiving counseling and control. Then, based on the obtained blocks and the sequence of allocation, counseling will be given to the patients who reported a traumatic childbirth. This is an open-label study and blinding will not happen.
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 Babol University of Medical Sciences
Street address
Babol University of Medical Sciencesol, Ganj Afrooz Ave, Daneshga Blvd, Babol
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Postal code
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Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.MUBABOL.REC.1401.176

Health conditions studied

1

Description of health condition studied
postpartum psychological distress
ICD-10 code
O90.6
ICD-10 code description
Postpartum mood disturbance

Primary outcomes

1

Description
postpartum psychological distress
Timepoint
Measurement at the beginning of the study (before the start of the intervention) and 12 weeks after birth
Method of measurement
Using Stanford Acute Stress Reaction Questionnaire, Impact of Event Scale - Revised, and post-traumatic stress checklist inventory

Secondary outcomes

1

Description
State-trait anxiety inventory
Timepoint
Before the intervention and 12 weeks after child birth
Method of measurement
Spielberger State-Trait Anxiety Inventory (STAI-20)

Intervention groups

1

Description
In the intervention group, counseling is performed on the basis of "the Gamble's strategy" individually for 3 sessions, one sessions of face-to-face contact consultation during the first 72 hours after child birth and

two session of telephone consultations in the fourth week and the eighth week after delivery, ranging 40 - 60 minutes by the researcher midwife. The counseling intervention is consistent with trauma theory and draws on cognitive behavioral therapy principles (C B T). Counseling strategies provided women with opportunities to talk about their birth experience, express feelings about what happened. The counseling intervention including fostering social support, reinforcing positive approaches to coping and exploring solutions to restoring self-confidence and reducing anxiety.

Category

Prevention

2

Description

Control group: The control group will be received usual care after childbirth.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Mouloud Aghajani Delavar

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Imam Ali Hospital, Chamestan Ave, Shaykh Faslolah Nori Ave, Amol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mouloud Aghajani Delavar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available