

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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: aged 18-35 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)

Phone

+98 11 3227 4881

Email address

moloodaghajani@yahoo.com

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		Ethics committee of Babol University of Medical Sciences	
Public title	Effectiveness of midwife-led postpartum counseling on psychological distress	Street address	Babol University of Medical Sciencesol, Ganj Afrooz Ave, Daneshga Blvd, Babol
Purpose	Supportive	City	Babol
Inclusion/Exclusion criteria		Province	Mazandaran
Inclusion criteria:	age range 18-35 years mother's willingness and consent to participate in the study singleton pregnancy ability to complete questionnaires	Postal code	۴۷۱۷۶-۴۷۷۴۵
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	Approval date	2023-03-06, 1401/12/15
Age	From 18 years old to 35 years old	Ethics committee reference number	IR.MUBABOL.REC.1401.176
Gender	Female	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 96	postpartum psychological distress	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
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.	O90.6	
Blinding (investigator's opinion)	Not blinded	ICD-10 code description	
Blinding description		Postpartum mood disturbance	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids		postpartum psychological distress	
empty		Timepoint	
Ethics committees		Measurement at the beginning of the study (before the start of the intervention) and 12 weeks after birth	
1		Method of measurement	
Ethics committee		Using Stanford Acute Stress Reaction Questionnaire, Impact of Event Scale - Revised, and post-traumatic stress checklist inventory	
Name of ethics committee		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

Street address

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

City

Amol

Province

Mazandaran

Postal code

41497- 46171

Phone

+98 11 4426 4661

Email

info@scanteb.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

Street address

Babol University of Medical Sciences, Ganj Afroz Ave, Daneshga Blvd, Babol

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 7667

Email

research@mubabol.ac.ir

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

Street address

Babol University of Medical Sciences, Ganj Afroz Ave, Daneshga Blvd, Babol

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9592

Email

moloodaghajani@yahoo.com

Person responsible for scientific 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

Street address

Babol University of Medical Sciences, Ganj Afrooz
Ave, Daneshga Blvd, Babol

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9592

Email

moloodaghajani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mouloud Aghajani Delavar

Position

Proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Babol University University of Medical Sciences, Ganj
Afrooz, Daneshga Blv, Babol

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3236 0714

Email

moloodaghajani@yahoo.com

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