Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The effect of counseling based on Gamble's approach on psychological birth trauma in primigravid women

Protocol summary

Study aim
Determining the effect of counseling based on Gamble's approach on psychological birth trauma in primigravid women

Design
Randomized clinical trial with a control group, on 74 pregnant women in parallel groups

Settings and conduct
Pregnant women referred to the maternity care clinic of Umm Al Binin Hospital who have inclusion criteria are randomly assigned into two groups of control and intervention. In the intervention group, counseling by the midwife is performed on the basis of the Gamble's strategy individually for 3 sessions before delivery and one session after delivery.For the control group, routine prenatal care is provided

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mother's willingness and consent to participate in the study; Residence in Mashhad; primigravid; Aged18-35 years; Reading and writing literacy; Gestational age 35 weeks; Single and healthy pregnancy; Wanted pregnancy; Phone Access. Exclusion criteria: En fetal abnormalities in ultrasound; post traumatic stress disorder; high risk pregnancy; medical disorder; history of infertility or abortion.

Intervention groups
In the intervention group, counseling by the midwife is performed on the basis of the Gamble's strategy individually for 3 sessions before delivery and one session after delivery.For the control group, routine prenatal care is provided.

Main outcome variables
psychological birth trauma and its five dimensions include: anxiety and hot birth, mental manifestations, helplessness, collapse and a sense of death, physical manifestations

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180520039747N1**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-31, 1397/08/09**
Update count: **0**

Registration date
2018-10-31, 1397/08/09

Registrant information
Name
Zahra Hajarian Abhari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-05, 1397/05/14

Expected recruitment end date
2019-02-03, 1397/11/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of counseling based on Gamble's approach on psychological birth trauma in primigravid women

Public title
The effect of counseling based on Gamble's approach on psychological birth trauma in primigravid women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mother's willingness and consent to participate in the study Residence in Mashhad primi gravid Aged 18-35 years Reading and writing literacy Gestational age 35 weeks Single and healthy pregnancy Wanted pregnancy Phone Access
Exclusion criteria:
fetal abnormalities in ultrasound post traumatic stress disorder high risk pregnancy medical disorder history of infertility or abortion
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: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sampling into intervention and control groups with simple randomization method using Spss software
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 Mashhad University of Medical Sciences
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2018-06-18, 1397/03/28
Ethics committee reference number
IR.MUMS.NURSE.REC.1397.006

Health conditions studied

1

Description of health condition studied
psychological birth trauma
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
psychological birth trauma
Timepoint
6-12 hours after intervention
Method of measurement
psychological birth trauma Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, counseling by the midwife is performed on the basis of the Gamble's strategy individually for 3 sessions before delivery and one session after delivery.
Category
Prevention

2

Description
Control group: In the control group, routine prenatal care is provided.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
ommol-Banin Specialized Obstetrics and Gynecology Hospital
Full name of responsible person
Dr. Fatemeh Tara
Street address
Ayatolah Bahjat street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohammad Reza Darabi Mahboob
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Hajjarian Abhari
Position
Student
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Person responsible for updating data

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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

Not applicable

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