

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; Aged 18-35 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 7528

Email address

hajarianz951@mums.ac.ir

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

Ayatollah Bahjat street

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Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Fatemeh Zahra Karimi
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Assistant Professor
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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