Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

Effect of midwifery counseling with Gamble approach versus control group on post-traumatic stress disorder in women undergoing emergency caesarean section: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of midwifery counseling with Gamble approach versus control group on post-traumatic stress disorder in women undergoing emergency caesarean section

Design
This is a randomized clinical trial with parallel control group without blinding, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Fatemieh Hospital in Hamadan city on 70 women undergoing emergency caesarean section. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 35 years Term and single birth Healthy baby Exclusion criteria: History of mental illness History of infertility The need for admission to the intensive care unit

Intervention groups
Intervention group: Usual services after caesarean section plus counseling with Gamble's approach individually and face-to-face for 40 to 60 minutes after caesarean section Control group: Usual services after caesarean section

Main outcome variables
Primary outcome: Post-traumatic stress disorder

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N454**
Registration date: **2022-12-28, 1401/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-28, 1401/10/07**
Update count: **0**

Registration date
2022-12-28, 1401/10/07

Registrant information

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Jalal Poorolajal

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
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of midwifery counseling with Gamble approach versus control group on post-traumatic stress disorder in

women undergoing emergency caesarean section: a randomized clinical trial

Public title
Effect of midwifery counseling with Gamble approach versus control group on post-traumatic stress disorder in women undergoing emergency caesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 35 years Term and single birth Healthy baby
Exclusion criteria:
History of mental illness History of infertility The need for admission to the intensive care unit
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: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
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Hamadan
Postal code
6517838695
Approval date
2022-12-03, 1401/09/12
Ethics committee reference number
IR.UMSHA.REC.1401.733

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Incidence of post-traumatic stress disorder
Timepoint
12 hours and 4 weeks after the caesarean section
Method of measurement
Using standard post-traumatic stress disorder questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Usual services after caesarean section plus counseling with Gamble's approach individually and face-to-face for 40 to 60 minutes after caesarean section (including: good therapeutic communication between midwife and mother, acceptance of mother's perceptions about emergency caesarean section, mother's support in expressing her feelings and resolving her doubts about the emergency cesarean section, and strengthening the mother's positive thoughts to adapt to the situation, encouraging her to express her feelings and thoughts about childbirth through open questions, active listening and giving feedback on the mother's concerns, clarifying and removing misunderstandings and strengthening the mother's positive thoughts and providing solutions)
Category
Other

2

Description
Control group: Usual services after caesarean section
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Maryam Soleimani
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Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
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Midwifery Student
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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