

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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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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	Fahmideh Ave
Public title	City
Effect of midwifery counseling with Gamble approach versus control group on post-traumatic stress disorder in women undergoing emergency caesarean section	Hamadan
Purpose	Province
Treatment	Hamadan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	6517838695
Age 18 to 35 years Term and single birth Healthy baby	Approval date
Exclusion criteria:	2022-12-03, 1401/09/12
History of mental illness History of infertility The need for admission to the intensive care unit	Ethics committee reference number
Age	IR.UMSHA.REC.1401.733
From 18 years old to 35 years old	Health conditions studied
Gender	1
Female	Description of health condition studied
Phase	Post-traumatic stress disorder
N/A	ICD-10 code
Groups that have been masked	F43.1
No information	ICD-10 code description
Sample size	Post-traumatic stress disorder (PTSD)
Target sample size: 70	Primary outcomes
Randomization (investigator's opinion)	1
Randomized	Description
Randomization description	Incidence of post-traumatic stress disorder
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.	Timepoint
Blinding (investigator's opinion)	12 hours and 4 weeks after the caesarean section
Not blinded	Method of measurement
Blinding description	Using standard post-traumatic stress disorder questionnaire
Placebo	Secondary outcomes
Not used	empty
Assignment	Intervention groups
Parallel	1
Other design features	Description
Secondary Ids	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)
Ethics committees	Category
1	Other
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	

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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

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

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6517838695

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+98 81 3828 3939

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sol356432@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Full name of responsible person

Maryam Soleimani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Email

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