Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Design, Implementation, and Evaluation of the Impact of a Second-Stage Labor Management Program on Pelvic Floor Muscle Health: A Mixed-Methods Evaluation Design

Protocol summary

Study aim

To determine the effect of a structured Second Stage of Labor Management Program on pelvic floor muscle health and related postpartum outcomes.

Design

A two-arm randomized controlled clinical trial. Eligible pregnant women will be consecutively recruited and assigned to the intervention or control group according to the group allocation of their attending midwife. Outcomes will be assessed at 8–12 weeks postpartum by trained assessors.

Settings and conduct

This study will be conducted at Mother Government Hospital in Ramhormoz, Khuzestan Province, Iran. Midwives allocated to the intervention group will implement the Second Stage of Labor Management Program, while those in the control group will provide routine intrapartum care. Outcome assessments will be performed at 8–12 weeks postpartum.

Participants/Inclusion and exclusion criteria

Inclusion criteria included Willingness to participate in the study, Maternal age between 18 and 45 years, Singleton live fetus , Cephalic fetal presentation Low-risk pregnancy, Gestational age between 37 and 41 weeks of pregnancy. Exclusion criteria included Attendance at more than four childbirth preparation classes, Performing perineal massage during pregnancy, Presence of a birth companion (professional labor support midwife/doula or a family member), high-risk pregnancy, contraindications to vaginal birth , maternal medical conditions documented in the medical record .

Intervention groups

Participants in the intervention group will receive a structured Second Stage of Labor Management Program aimed at preserving pelvic floor muscle health. Participants in the control group will receive routine intrapartum care.

Main outcome variables

The primary outcome is pelvic floor muscle strength at 8–12 weeks postpartum. Secondary outcomes include urinary incontinence, bowel dysfunction, pelvic organ prolapse symptoms and sexual dysfunction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260805070545N1**
Registration date: **2026-08-27, 1405/06/05**
Registration timing: **prospective**

Last update: **2026-08-27, 1405/06/05**
Update count: **0**

Registration date

2026-08-27, 1405/06/05

Registrant information

Name

Hadis Bahmaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-06, 1405/06/15

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design, Implementation, and Evaluation of the Impact of a Second-Stage Labor Management Program on Pelvic Floor Muscle Health: A Mixed-Methods Evaluation Design

Public title
Effect of second stage of labor management program on pelvic floor muscle
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Maternal age between 18 and 45 years Singleton live fetus Cephalic fetal presentation Low-risk pregnancy Gestational age between 37 and 41 weeks of pregnancy
Exclusion criteria:
Attendance at more than four childbirth preparation classes Performing perineal massage during pregnancy Presence of a birth companion (professional labor support midwife/doula or a family member) high-risk pregnancy Presence of contraindications to vaginal birth Presence of maternal medical conditions documented in the medical record
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **420**
Randomization (investigator's opinion)
Randomized
Randomization description
Midwives are divided into two intervention and control groups with a 1:1 allocation ratio using stratified randomization based on the variable of work experience (less than 5 years and 5 years or more). The randomization sequence is generated by an independent person from the research team using a random number table. The final allocation is kept in opaque, sealed, and numbered envelopes and is known only to the independent person until the results are announced.
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
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences
Street address
Ground Floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University Campus, Ahvaz, Khuzestan, Iran
City
رامهرمز
Province
Khouzestan
Postal code
61357-15794
Approval date
2026-08-15, 1405/05/24
Ethics committee reference number
IR.AJUMS.REC.1405.203

Health conditions studied

1

Description of health condition studied
Pelvic floor disorders after vaginal delivery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pelvic floor muscle strength
Timepoint
8–12 weeks postpartum
Method of measurement
Pelvic floor muscle strength will be assessed using the Modified Oxford Scale (MOS) through standardized digital vaginal examination performed by trained assessors. The MOS is a validated 6-point grading system ranging from 0 (no palpable contraction) to 5 (strong contraction).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive a Second Stage of Labor Management

Program designed to protect pelvic floor muscle health during childbirth. The program will be implemented by trained midwives and includes evidence-based interventions during the second stage of labor, such as guidance on spontaneous pushing, appropriate maternal birthing positions, controlled breathing techniques, perineal support, controlled delivery of the fetal head, and other standardized practices aimed at reducing pelvic floor muscle strain and birth-related pelvic floor injury.

Category

Treatment - Other

2

Description

Control group: Participants in the control group will receive routine intrapartum care according to the standard clinical protocols of the study setting. Labor and birth management will be conducted by the attending healthcare providers without implementation of the structured Second Stage of Labor Management Program.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother Government Hospital, Ramhormoz, Khuzestan, Iran

Full name of responsible person

Mina Iravani

Street address

Iran, Ahvaz, Golestan Highway, Ahvaz Jundishapur University

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hadis Bahmaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Midwifery

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Name of organization / entity

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Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
The documentation will be published as articles on scientific websites.

When the data will become available and for how long
Access period begins 6 months after the publication of results.

To whom data/document is available
Researchers at academic and scientific institutions, students, and midwives working in public and private centers.

Under which criteria data/document could be used
For the purpose of conducting further research or applying the results in clinical settings or scientific documentation.

From where data/document is obtainable
Articles published on domestic and international scientific and research websites will be accessible.

What processes are involved for a request to access data/document
Scientific articles based on research findings are eligible for publication in journals following rigorous peer review.

Comments