

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of Midwifery Counseling on postpartum Quality of Life of Primiparous Women With Body image Concerns

#### Protocol summary

##### Study aim

Determining The Effect of Consultation on Postpartum Quality of Life in Primiparous Women with Body image Concern

##### Design

Clinical trial is a randomized, with Control group and parallel groups, not blinded,

##### Settings and conduct

After obtaining informed consent of participants samples based on quarterly block randomization will be divided into two intervention and control groups. In This study blinding is impossible

##### Participants/Inclusion and exclusion criteria

Having a score lower than 138 from a body image questionnaire, be Iranian, First pregnancy. Exit criteria: Non-participation in 1 Full Sessions of Weekly Counseling,

##### Intervention groups

Intervention group: Primiparous Women with Body image concerns with entry criteria; who will receive weekly counseling in 3 sessions (60-90 minutes). And the control group will not receive any advice

##### Main outcome variables

Quality of life; Body image Concern;

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150119020719N8**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

##### Registration date

2018-05-14, 1397/02/24

#### Registrant information

##### Name

Sara Esmaelzadeh Saeieh

##### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3433 6007

##### Email address

s-esmaelzadeh@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-02-19, 1396/11/30

##### Expected recruitment end date

2018-04-19, 1397/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Effect of Midwifery Counseling on postpartum Quality of Life of Primiparous Women With Body image Concerns

#### Public title

The Effect of Consultation on Postpartum Quality of Life in Primiparous Women with Body image Concern

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having a score lower than 138 from the body image questionnaire Iranian nationality The interval between 6-12 months after Delivery, At least the reading and writing skills no addiction, or smoking Non-exclusive

nutrition with powder milk, fluent in Persian, First pregnancy, Full Term pregnancy, Baby without anomaly, single pregnancy and live birth fetus, without pregnancy complications, (Diabetes, preeclampsia, etc.), without known medical illness and mental problems according to one's own words

**Exclusion criteria:**

Non-participation in 1 Full Sessions of Weekly Counseling  
Having hormonal problems  
Use of drugs  
Psychological problems  
Having burning scar or lesion on the body  
Body mass index more than 30

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Use the quadruple random block

**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 Alborz University of Medical Sciences

**Street address**

Alborz University of Medical Sciences, Azimieh, Alborz, Iran

**City**

Alborz

**Province**

Alborz

**Postal code**

3186947535

**Approval date**

2018-01-19, 1396/10/29

**Ethics committee reference number**

Abzums.Rec.1396.167

**Health conditions studied**

1

**Description of health condition studied**

Quality of life after childbirth

**ICD-10 code**

**ICD-10 code description**

2

**Description of health condition studied**

Body Image concern after delivery

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Quality of life after childbirth

**Timepoint**

Before intervention, After intervention and two weeks  
After intervention

**Method of measurement**

Quality of Life Questionnaire (SF-36)

2

**Description**

Body Image concern after delivery

**Timepoint**

Before intervention, After intervention and two weeks  
After intervention

**Method of measurement**

Multidimensional Body- Self Relationship Questionnaire (MBSRQ)

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: The intervention group in 3 sessions (60-90) minutes will be advised. Session1: explaining the purpose of the study, Introduction, definition of body image and the problems arising from body dissatisfaction and Quality of Life, group discussion about appearance changes related to pregnancy, delivery, and postpartum; body image self-assessment tests, recommendation for exercise. Session 2: Recognizing negative body image roots; training to write daily diary of body image; training Postpartum exercise; Session 3: Reviewing Past meetings, remembering and practicing the techniques described, question and answer at the end of the session. Quality of Life Questionnaire, and Multidimensional Body- Self Relationship Questionnaire

will be completed before and after the counseling sessions and two weeks later in both intervention and control groups.

**Category**

Behavior

**2**

**Description**

Control group: Receive routine care

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Selected health care centers of Alborz

**Full name of responsible person**

Sedigheh Salehi

**Street address**

Attached to Mehrshahr Health Center, later the crossroads of the Mellat Bank, Phase 4 of Mehrshahr, Karaj, Alborz

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**Email**

sadighehsalehi6@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

The Research choncellor Department Of Alborz University of Medical Sciences

**Full name of responsible person**

Mohammad Noorisepehr

**Street address**

The Research choncellor Department Of Alborz University of Medical Sciences, Azimieh, Alborz, Iran

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**Grant name**

Alborz University of Medical Sciences-vice President of

Research

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The Research choncellor Department Of Alborz 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Sara Esmaelzadeh Saeieh

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery, first Golestan, Alborz

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**Person responsible for scientific inquiries**

**Contact**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Postal code**

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**Phone**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All participant data can be shared after being unidentified

**When the data will become available and for how long**

Start the access period after printing the results

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in studies allowed.

**From where data/document is obtainable**

Sedigheh Salehi, sadighehsalehi6@gmail.com

**What processes are involved for a request to access data/document**

The application will be sent to the project implementer by email and within 24 hours will receive the necessary items.

**Comments**