

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Evaluation of the effect of midwifery counseling based on Gamble approach on coping strategies and self-efficacy of women with the first abortion

#### Protocol summary

##### Study aim

Evaluating the effects of midwifery counseling in Gamble's method on the women's self-efficacy and ability to cope with the first abortion

##### Design

The present study is randomized controlled trial with a control group, in which the samples are 100 women with the first abortion who meet the inclusion criteria according to the inclusion criteria. The type of sampling is random and parallel using block randomization method and table of random numbers which samples are non-blind with two groups of intervention (50 people) and control (50 people) are divided.

##### Settings and conduct

The researcher continuously visits Kamali Educational and Medical Center in Karaj every morning and invites primiparous women who have recently experienced abortion to participate in the study and the table will be assigned to two groups of 50 intervention and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with spontaneous abortion and therapeutic abortion, no use of antidepressants and psychotropic drugs before and after abortion, no history of attending counseling classes according to the mother, no occurrence of a tragic accident in the last 6 months according to the mother, no Attend a counseling session : Exclusion criteria: history of infertility, history of recurrent miscarriage, having a physical and mental illness affecting abortion.

##### Intervention groups

The two groups of 50 people are intervention and control. In addition to routine services, the routine care control group and the intervention group will receive face-to-face counseling based on the Gamble counseling model. The intervention group will receive counseling in 2 sessions of 45-75 minutes, the first session during the first 72 hours and the second session one month after

abortion.

##### Main outcome variables

Coping strategies; Self efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210221050437N1**

Registration date: **2021-09-28, 1400/07/06**

Registration timing: **retrospective**

Last update: **2021-09-28, 1400/07/06**

Update count: **0**

##### Registration date

2021-09-28, 1400/07/06

##### Registrant information

##### Name

Farzane Hasanzade Tahraband

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3330 8904

##### Email address

hasanzadefarzaneh1990@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-03-27, 1400/01/07

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of midwifery counseling based on Gamble approach on coping strategies and self-efficacy of women with the first abortion

**Public title**

"The effect of midwifery counseling in Gamble's method on the women's self-efficacy and their coping with first abortion"

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with spontaneous abortion and therapeutic abortion Taking no antidepressants or psychotropic drugs before and after abortion No history of attending counseling classes, based on the patient's testimony No experience of tragic event in the last 6 months, based on the patient's testimony Having a smartphone and messenger software and the ability to work with it Living with spouse Ability to read and write in Farsi Iranian Nationality

**Exclusion criteria:**

Attend any previous counseling sessions History of infertility History of repeated abortion Suffering from any physical or mental illnesses predisposing to abortion

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method was done using the website <https://www.sealedenvelope.com>, so that the samples are identified by block randomization method with 4 blocks and using random numbers table of under the web (online randomization). The control group was randomly assigned with the letter A and the intervention group with the letter B.

**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 Iran University of Medical Sciences

**Street address**

No. 1, 2 Hades Alley, East 4th St, Eram Boul, Mehrshahr

**City**

Karaj

**Province**

Tehran

**Postal code**

3186754384

**Approval date**

2020-11-08, 1399/08/18

**Ethics committee reference number**

IR.IUMS.REC.1399.742

**Health conditions studied****1****Description of health condition studied**

Abortion

**ICD-10 code**

O03

**ICD-10 code description**

Spontaneous abortion

**Primary outcomes****1****Description**

Coping strategies

**Timepoint**

During 72 hours after abortion up to 3 months after abortion

**Method of measurement**

Coping Inventory questionnaire

**2****Description**

Self-efficacy

**Timepoint**

During 72 hours after abortion up to 3 months after abortion

**Method of measurement**

Schwartz General Self-efficacy Questionnaire

**Secondary outcomes**

empty

## Intervention groups

Hasanzadefarzaneh1990@gmail.com

### 1

#### Description

Intervention group: Self-efficacy and coping strategies questionnaires will be administered to patients within 72 hours after first abortion and then they will undergo midwifery counseling by Gamble's method. Gamble counseling strategy includes: Therapeutic connection between midwife and woman, accept and work with women's perceptions, support the expression of feelings, filling in the missing pieces, connect the event with emotions and behaviors, review the abortion management, enhance social support, Reinforce positive approaches to coping and explore solutions. Intervention group undergo counseling in two 45-75 minutes sessions. The first session is done in person during the first 72 hours and the second session is done by phone 4-6 weeks after the abortion. After one month, patients will undergo counseling by telephone and will fill the self-efficacy and coping strategies questionnaires through online platforms. These questionnaires will be filled again two months after the second counseling session for the third time, through online platforms. Patients in intervention group will receive educations upon breast examination and necessity of pap smear test within 72 hours, one month and three months after the first abortion.

#### Category

Other

### 2

#### Description

Control group: Patients in control group will receive educations upon breast examination and necessity of pap smear test within 72 hours, one month and three months after the first abortion.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali Hospital

##### Full name of responsible person

Masoume Kheirkhah

##### Street address

Kheyabane Shahid Yasmi

##### City

Tehran

##### Province

Tehran

##### Postal code

3186754384

##### Phone

+98 26 3330 8904

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Masoume Kheirkhah

##### Street address

Mehrshahr

##### City

Karaj

##### Province

Alborz

##### Postal code

3186754384

##### Phone

+98 26 3330 8904

##### Email

Hasanzadefarzaneh1990@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Masoume Kheirkhah

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Education

##### Street address

Nursing and Midwifery Faculty, Rashid Yasmi St, Vanak Square, Valiasr St, Teheran

##### City

Tehran

##### Province

Tehran

**Postal code**  
3186754384  
**Phone**  
+98 26 3330 8904  
**Email**  
Hasanzadefarzaneh1990@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Masoumeh Kheirkhah  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Education  
**Street address**  
Nursing and Midwifery Faculty, Rashid Yasmi St,  
Vanak Square, Valiasr St, Teheran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
3186754384  
**Phone**  
+98 912 478 7691  
**Email**  
shivakheirkhah1345@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Masoumeh Kheirkhah  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Education  
**Street address**

Nursing and Midwifery Faculty, Rashid Yasmi St,  
Vanak Square, Valiasr St, Teheran

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
3186754384  
**Phone**  
+98 912 478 7691  
**Email**  
shivakheirkhah1345@gmail.com

## 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

No - There is not 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

No - There is not a plan to make this available

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

Information about the main outcome is shared

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

Access period starts 6 months after the results are published

### To whom data/document is available

Researchers, midwives, doctors

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

Documentary researchers can be used for scientific advancement. It is possible to access the data by sending an email to the supervisor. Email: Shivakheirkhah1345@gmail.com

### From where data/document is obtainable

Scientific party of the study Masoumeh Kheirkhah  
Email:Shivakheirkhah1345@gmail.com  
Mobile:09124787691

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

After approval by the research assistant by email to the supervisor Email:Shivakheirkhah1345@gmail.com

### Comments