

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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

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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

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

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Person responsible for scientific inquiries

Contact

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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

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