Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the effect of intervention based on 5 A's self-management model on the promotion of behaviors related to women's reproductive health after legal abortion

Protocol summary

Study aim

Determining the effect of intervention based on 5 A's self-management model on the promotion of behaviors related to women's reproductive health after legal abortion

Design

Clinical trial with control group, 72 samples are randomly divided into intervention and control groups using random number table.

Settings and conduct

The study is a clinical trial. Study setting is 18 hospitals in Isfahan (educational-therapeutic, academic, private, charitable and affiliated) in which abortion is performed. All pregnant women who have been licensed for medical abortion by Isfahan forensic medicine organization and for whom induced abortion has been performed, are first selected using convenient sampling and then randomly divided into two groups of intervention and control using random number table. The intervention is performed based on the 5 A`s self-management model, in five stages. Data are collected by completing researcher-made questionnaire of measuring behaviors related to women's reproductive health before and two months after the start of intervention in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Women of reproductive age who have had a medical abortion/ having any known psychological problems such as anxiety and depression

Intervention groups

The intervention group will undergo an intervention based on the 5 A`s self-management model, which will be implemented in five stages. Intervention is two-hour training sessions (one session per week) in groups of 6 about sexual health and prevention of sexually transmitted infections, normal and satisfactory sexual function, and family planning. There will be no intervention for the control group and they will receive routine care.

Main outcome variables

Behaviors related to women's reproductive health after legal abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210315050716N1**
Registration date: **2021-05-28, 1400/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-28, 1400/03/07**
Update count: **0**

Registration date

2021-05-28, 1400/03/07

Registrant information

Name

Zahra Mirian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-11, 1400/04/20

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

Scientific title
Evaluation of the effect of intervention based on 5 A's self-management model on the promotion of behaviors related to women's reproductive health after legal abortion

Public title
The effect of intervention based on 5 A's self-management model on the promotion of behaviors related to women's reproductive health after legal abortion
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women of reproductive age who have had a medical abortion based on a legal abortion permit issued by the Isfahan Forensic Medicine Center. Women of reproductive age who are interested to participate in this research project and have consent to participate in the study Have a minimum literacy Not participating in another clinical trial study similar to the present study
Exclusion criteria:
having any known psychological problems such as anxiety and depression that are questioned by the self-reported method of the research units
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly divided into two groups based on a simple randomization method using a random number table. To use a table of random numbers, the researcher must first preset the direction in which to read the numbers (for example, up, down, left or right), the researcher then touches one of the numbers and moves in one of the predetermined directions (in this study, the right direction is selected) and records the numbers. In this way, numbers between 01 and 72 are obtained, the first 36 numbers are divided into the intervention group and the next 36 numbers into the control group. Individuals are placed in the intervention or control group according to their number matching, respectively, when they enter the study.
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 Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology - Isfahan University of Medical Sciences
City
isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-03-15, 1399/12/25
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.819

Health conditions studied

1

Description of health condition studied
Legal abortion, Promote reproductive health
ICD-10 code
Z30.0
ICD-10 code description
Encounter for general counseling and advice on contraception

Primary outcomes

1

Description
Score of behaviors related to women's reproductive health
Timepoint
Before and two months after start of the intervention
Method of measurement
researcher-made questionnaire of measuring behaviors related to women's reproductive health

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will undergo an intervention based on the 5 A`s self-management model, which will be implemented in five stages. 1. Assess phase: This phase will be performed in the hospital after therapeutic abortion and before discharge from the hospital and includes assess and recognition of problems, knowledge, behaviors and beliefs related to sexual and reproductive health after abortion. At this stage, the patient at the time of admission examined for history and cause of medical abortion (maternal disease or fetal disease), the patient's ability and desire to adopt the necessary behaviors immediately after abortion in terms of complications and problems after abortion, including bleeding, infection and pain, genital hygiene and prevention of sexually transmitted infections, sexual function and family planning, and self-management of reproductive health-related behaviors through face-to-face interviews and completing a researcher-made reproductive health-related behavioral questionnaire. 2. Advise stage: This stage is also done in the hospital. At this stage, according to the results of the previous stage, health risks and required training in the field of reproductive health are identified and counseling is provided by providing specific information in a way that is understandable to the patient and individually, so that make relevant skills and behaviors relate self-management to sexual and reproductive health status and at this stage the benefits of changing behavior are emphasized.3. Agree stage: The stage of setting goals with the patient's consent. According to the identified problems, appropriate behavioral goals and agreement with the patient about his performance in the field of reproductive health are planned and an agreement on goals is determined according to the existing obstacles and problems as well as the interests and priorities of samples and their desire and ability to changing behavior in the field of reproductive and sexual health and a practical plan is designed for each of the goals. Three stages (Assess, Advise, Agree) will be performed in the hospital after abortion and after stabilization of the patient's condition. 4. Assist stage: This stage is done one week after the third stage. Samples will be given the necessary training in two-hour training sessions, that each session lasts two hours (one session per week) in groups of 6 on sexual health and prevention of sexually transmitted infections, normal and satisfactory sexual function, and family planning. And the educational booklet containing the above information will be provided to the research units. It should be noted that due to the corona epidemic conditions, if it is not possible to participate in groups of 6 people, training is done individually and face to face. The researcher then establishes continuous communication with the research units by telephone and based on the behavioral goals agreed with the research units, personal barriers to achieving the goals are re-examined and the necessary advice is given. And if there is a need for expert advice, a referral will be made based on it. It should be noted that the researcher will be responsible for the transportation costs of the research units. 5. Arrange stage: In this stage, patients' performance is followed, in fact, to ensure the implementation of practical programs by patients, follow-up for 2 weeks daily and then twice a week by phone call at the end of the period to check the implementation of the practical plan and the agreed behavioral goals. In addition, the patient's progress and success in performing behaviors related to reproductive health and his need for referral should be evaluated so that if there is a need to change the goals or practical plan, the necessary changes will be made by re-agreement and, if necessary, The patient needs to be given the necessary advice during the follow-up phase. The researcher will provide the intervention group with a telephone number for a 24-hour response to resolve possible problems of research units.

Category

Behavior

2

Description

The control group will receive routine post-abortion care (Includes bleeding checks and vital signs and medication if prescribed by a doctor) at the hospital. After the post-test, the educational content will be provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

18 hospitals in Isfahan (educational-therapeutic, academic, private, charitable and affiliated) in w

Full name of responsible person

Mahshid Abdi Shahshahani

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Sponsors / Funding sources

1

Sponsor

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
mahshid Abdi Shahshahani
Position
Faculty member of the Department of Midwifery and Reproductive Health
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Protocol of study and reporting of study in the form of articles and theses

When the data will become available and for how long
since it released forever

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
I have not decided yet

From where data/document is obtainable
Library or magazine site where the article is published

What processes are involved for a request to access data/document
No special process required

Comments
To date, no intervention studies have been performed for those who have had a legal abortion.