

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The Effect of Supportive Care Counseling on Anxiety and Quality of Life of Pregnant Women with a History of Abortion

#### Protocol summary

##### Study aim

Determining the Effect of Supportive Care Counseling on Anxiety and Quality of Life in Pregnant Women with a History of Abortion

##### Design

The present study is a clinical trial study in which first the selection of samples by stratified method and after the selection of samples by four block method are assigned to two groups of intervention and control.

##### Settings and conduct

This Counseling is Performed in Selected Comprehensive Health Centers of Isfahan on Pregnant Women with a History of abortion who Suffer from Anxiety and Reduced Quality of life, according to Swanson Theory, in 5 Stages and in three Sessions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a Current Gestational Age of 8 Weeks or More with Ultrasound Confirmation ; Wanting a Current Pregnancy ; Having a Miscarriage under 20 Weeks in a Previous Pregnancy During the Past Year ; No History of Specific Mental Illness ; Minimum Literacy ; Not Having a Living Child in the Family Exclusion criteria: Reluctance to Continue Participating in the Study ; Loss of Pregnancy ; Occurrence of Accidents and Major Stresses during the Intervention such as the Loss of Loved Ones ; Migrating a pregnant woman

##### Intervention groups

The Intervention Group of Pregnant Women with a History of Abortion who have Experienced Anxiety and reduced quality of Life and the Effect of Supportive Care Counseling on their Anxiety and Quality of Life are Measured and the Control Group for whom no Action is Taken and Compared with the Intervention Group.

##### Main outcome variables

Anxiety Disorder Increase the Quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210827052302N1**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

##### Registration date

2021-11-12, 1400/08/21

##### Registrant information

##### Name

ZOhre Kiani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3442 1622

##### Email address

zohre.kiani81@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-11, 1400/08/20

##### Expected recruitment end date

2021-12-11, 1400/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Supportive Care Counseling on Anxiety and Quality of Life of Pregnant Women with a History of Abortion

## Public title

The effect of midwifery counseling on anxiety and lifestyle in pregnant women who have experienced abortion.

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a Current Gestational Age of 8 Weeks and more with Ultrasound Approval Wanted Current Pregnancy Having a Miscarriage under 20 Weeks in a Previous Pregnancy in the Past Year No History of Specific Mental Illness Minimum Literacy Not Having a Living Child in the Family

### Exclusion criteria:

Reluctance to Continue Participating in the Study Loss Of Pregnancy Occurrence of Unfortunate Events and Great Stress During the Intervention such as the Loss of Loved Ones Immigration of the Pregnant Mother

## Age

No age limit

## 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

In the first stage, which is the stage of selecting samples, the class is done in such a way that first a list of comprehensive health centers in different areas of Isfahan is prepared and then two centers are randomly selected in each area. Then, the number of clients in each center Determine the eligibility of the study and then the estimated sample size in relation to the number of clients in each center is determined, then in each center by blocks with size 4 with the help of <https://www.sealedenvelope.com>. And control allocation It should be noted that to hide the random allocation stage will be done by someone other than the researcher.

## 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

5th Floor, Headquarters, Iran University of Medical Sciences, Between Chamran and Sheikh Fazlolah streets, Hemat Hwy

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Approval date

2020-12-07, 1399/09/17

#### Ethics committee reference number

IR.IUMS.REC.1399.974

## Health conditions studied

## 1

### Description of health condition studied

Spontaneous Abortion

### ICD-10 code

003

### ICD-10 code description

Spontaneous abortion

## Primary outcomes

## 1

### Description

Anxiety

### Timepoint

The beginning of the study and 4 and 8 week after end of study

### Method of measurement

Pregnancy Related Anxiety Questionnaire Vanden Berg 1989

## Secondary outcomes

## 1

### Description

Quality of Life

### Timepoint

The beginning of the study and 4 and 8 week after end of intervention

### Method of measurement

Ware and Sherbourne questionnaire ( SF-36 )

## Intervention groups

## 1

### Description

Intervention Group: Pregnant Mothers who have been Confirmed by their Pregnancy Ultrasound and have Registered their Pregnancy History in a Comprehensive Health Center and have Inclusion Criteria and have been randomly Placed in the Intervention Group, Details of the Plan will be Contacted. They are Invited to Participate in this Project. In the first Session of their Presence in the Center after Obtaining Satisfaction and Completing the Demography questionnaire and Wendenberg pregnancy Anxiety Questionnaire and the Wire and Sherbon Quality of Life Questionnaire, the first Counseling Session based on 5 Stages of Swanson Theory is held with the Presence of the Center Psychologist. a week later, second session and The third Week, the third Session is held and 4 Weeks and 8 Weeks after the Intervention, the Questionnaires are Completed again by the Intervention Group.

### Category

Lifestyle

## 2

### Description

Control Group: Pregnant Mothers who have been Confirmed by their Pregnancy Ultrasound and have filed a Pregnancy Record at the Comprehensive Health Center and have inclusion criteria and have been randomly placed in the control group will be contacted and the details of the plan will be explained. They are invited to participate in the project. In the first session of their presence in the center after obtaining consent, they complete the Demographic and Wendenberg Pregnancy Anxiety Questionnaire and the Wire and Sherbon Quality of Life Questionnaire. This group does not receive any intervention and 4 and 8 weeks after the end of the intervention, the Wendenberg Pregnancy Anxiety Questionnaire and the quality of life of Wire and Sherbon are completed by this group.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Esfahan Health Center

##### Full name of responsible person

dr Masoomeh kheirkhah

##### Street address

School of Nursing and Midwifery, Rashid Yasemi St,  
Above of Vanak Sq, Valiasr St

##### City

Tehran

##### Province

Tehran

##### Postal code

1996713883

##### Phone

+98 21 4365 1000

##### Fax

+98 21 8820 1978

##### Email

shivakheirkhah1345@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Masoomeh Kheirkhah

##### Street address

School of Nursing and Midwifery, Rashid Yasemi St,  
Above of Vanak Sq, Valiasr St

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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

dr Masoomeh kheirkhah

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Education

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**Email**

shivakheirkhah1345@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

dr Masoomeh kheirkhah

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

dr Masoomeh kheirkhah

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

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+98 21 8820 1978

**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**

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**

All researchers, midwives and 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 responsible for studying Masoomeh Kheirkhah  
Email shivakheirkhah1345@gmail.com

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

After confirmation of the research assistant by email to the supervisor email shivakheirkhah1345@gmail.com

**Comments**