

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 Fazlollah 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

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Fax

+98 21 8820 1978

Email

shivakheirkhah1345@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

dr Masoomeh kheirkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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

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

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

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

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

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