Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Emotional Disclosure on Depression, Anxiety and Stress and Quality of Life in Women after Abortion

Protocol summary

Study aim
Determining the effect of emotional disclosure on depression, anxiety and stress and quality of life in women after abortion

Design
Two arm parallel group randomized trial, on 70 women. A random sequence generated using www.randomization.com was used for randomization.

Settings and conduct
Women who have been admitted to the gynecology wards of Birjand hospitals for a spontaneous abortion within the last 48 hours and are eligible for inclusion in the study will be easily selected.In the intervention group, after teaching the emotional disclosure method, they do it both in writing and orally.

Participants/Inclusion and exclusion criteria
Iranian women aged 18-45 who have been hospitalized in women's wards for the past 48 hours following a spontaneous abortion

Intervention groups
In the intervention group, in addition to the usual hospital training and medical care, during one session, the method of individual emotional disclosure and face-to-face, in the hospital, is fully taught by the researcher in an explanatory manner and they are asked to do 1± 4 sessions for 15 - 20 minutes for 2 consecutive weeks (1± 2 sessions per week) in a secluded and convenient place at home, write their deepest negative feelings and emotions freely and fluently on the reminder sheets. At the end of each week, a verbal exposure session (two sessions in total) will be conducted by the researcher making a telephone call to them and the researcher will listen to them for 15-20 minutes. The control group receives only routine training and care.

Main outcome variables
depression, anxiety and stress and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210528051421N1**
Registration date: **2021-06-29, 1400/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-29, 1400/04/08**
Update count: **0**

Registration date
2021-06-29, 1400/04/08

Registrant information

Name
Maleknaz Ghannadkafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3244 0350

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-10, 1400/03/20

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effectiveness of Emotional Disclosure on Depression, Anxiety and Stress and Quality of Life in Women after Abortion

Public title

The Effectiveness of Emotional Disclosure on Depression, Anxiety and Stress and Quality of Life in Women after Abortion

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1-Women who have had a miscarriage within 48-24 hours. 2- Will be willing to participate in the study and complete the informed consent form. 3- Be a Muslim and an Iranian. 4- To be 18-45 years old. 5- Pregnancy is the desire of the couple. 6- Does not have chronic physical diseases. 7 - Do not have a disability. 8- Has no other psychological disorders. 9- Be literate. 10- Do not have major stressful events in the last 6 months. 11- Has not taken sedatives and psychotropic drugs in the last 6 months. 12- Not addicted to drugs, tobacco and alcohol. 13- Have a spouse and live with his. 14- Has no history of infertility. 15- Depression score between 10-20 (mild and moderate depression) has been obtained from the Depression, Anxiety and Stress Questionnaire 21-DASS. 16- Anxiety score higher than 7 (mild anxiety up) has been obtained from the Depression, Anxiety and Stress Questionnaire 21-DASS. 17- Stress score higher than 14 (mild stress upwards) has obtained from the Depression, Anxiety and Stress Questionnaire 21-DASS.

Exclusion criteria:

Unable to write, speak or listen. Have severe physical complications from abortion. Do not have access to a mobile phone. Be pregnant with assisted reproductive techniques.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is a simple individual randomization that using random sequence generated by www.randomization.com, individuals in the group are divided into two groups of intervention and control. In this way, the generated random sequence is written on small sheets and kept in a closed envelope, and when each person is selected, the envelope door is opened and she enters each group according to the code (A and 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 Mashhad University of Medical Sciences-School of Nursing and Midwifery

Street address

Chaharah Doktora Crossing, Ibn-e Sina St, Mashhad Faculty of Nursing and Midwifery

City

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Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.093

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3

Description of health condition studied

stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description
Depression score in Anxiety, Stress, Depression Questionnaire (DASS -21)
Timepoint
Before the intervention, end of the intervention and one month after the intervention
Method of measurement
Anxiety, stress, depression questionnaire (DASS -21)

2

Description
Anxiety score in Anxiety, Stress, Depression Questionnaire (DASS -21)
Timepoint
Before the intervention, end of the intervention and one month after the intervention
Method of measurement
Anxiety, stress, depression questionnaire (DASS -21)

3

Description
Stress score in Anxiety, Stress, Depression Questionnaire (DASS -21)
Timepoint
Before the intervention, end of the intervention and one month after the intervention
Method of measurement
Anxiety, stress, depression questionnaire (DASS -21)

4

Description
Quality of life score in the World Health Organization quality of life questionnaire
Timepoint
Before the intervention, end of the intervention and one month after the intervention
Method of measurement
World Health Organization Quality of Life Questionnaire - Short Form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: emotional disclosure. In this group, in addition to the usual medical care of the hospital, during an individual session, in an explanatory manner and face to face, emotional disclosure (written and spoken) is taught to women after spontaneous abortion. Then, they are asked to freely express their deepest negative feelings and emotions for 1 ±4 sessions, each time for 15-20 minutes for 2 consecutive weeks (2 ±1 sessions per week) in a secluded and completely quiet and comfortable place at home. And write fluently on reminder sheets. They are told to free their minds and focus entirely on the writing experience. When writing, do not worry about spelling words or structural rules of sentences and the spatial and temporal order of events, and continue writing until the end of time. At the end of each week, an oral disclosure session (two sessions in total) will be conducted by telephone with them for 15-20 minutes.
Category
Rehabilitation

2

Description
Control group: They receive medical education and care, including control of vital signs and vaginal bleeding until they stabilize after an abortion and receive medication.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals of Birjand
Full name of responsible person
Maleknaz Ghannadkafi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Maleknaz Ghannadkafi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable