

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 56 3244 0350

Email address

nkafi@bums.ac.ir

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		Not used
Public title	The Effectiveness of Emotional Disclosure on Depression, Anxiety and Stress and Quality of Life in Women after Abortion	Assignment Parallel
Purpose	Supportive	Other design features
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.	Secondary Ids empty
Age	From 18 years old to 45 years old	Ethics committees
Gender	Female	<u>1</u> 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 Mashhad Province Razavi Khorasan Postal code 9138813944 Approval date 2021-02-09, 1399/11/21 Ethics committee reference number IR.MUMS.NURSE.REC.1399.093
Phase	N/A	Health conditions studied
Groups that have been masked	No information	<u>1</u> Description of health condition studied depression ICD-10 code F32.0 ICD-10 code description Major depressive disorder, single episode, mild
Sample size	Target sample size: 70	<u>2</u> Description of health condition studied anxiety ICD-10 code F41.1 ICD-10 code description Generalized anxiety disorder
Randomization (investigator's opinion)	Randomized	<u>3</u> Description of health condition studied stress ICD-10 code F43.0 ICD-10 code description Acute stress reaction
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		

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

Street address

Valiasr Hospital, Ghaffari Ave., Birjand

City

Birjand

Province

South Khorasan

Postal code

971796151

Phone

+98 56 3244 0350

Email

nkafi@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences , Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944
Phone
+98 51 3841 1538
Email
vcresraech@mums.ac.ir
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
Street address
Mashhad Faculty of Nursing and Midwifery, Ibn-e Sina St., Chaharah Doktora Crossing, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
0098 51 3859 1511-3
Fax
+98 51 3859 7313
Email
nkafi@bums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Kobra Mirzakhani

Position
Tutor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Mashhad Faculty of Nursing and Midwifery, Ibn-e Sina St., Chaharah Doktora Crossing
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
0098 51 38591511-3
Email
Mirzakhanik@mums.ac.ir

Person responsible for updating data

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
Street address
School Nursing & Midwifery, Birjand University of Medical Sciences , Ghafari Street
City
Birjand
Province
South Khorasan
Postal code
9۷۱۷۸۵۳۵۷۷
Phone
+98 56 3244 0350
Email
nkafi@bums.ac.ir

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