

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of problem-solving based treatment on women's mental health after spontaneous abortion

Protocol summary

Study aim

Determine the effectiveness of PST on the mental health of women after spontaneous abortion.

Design

Clinical trial with control group, randomized with quadruple blocks, The sample size was considered as 46.

Settings and conduct

The sampling sites are the gynecology and obstetrics departments of Razi and Imam Khomeini hospitals and Ahvaz health centers. By referring to existing medical records, the address and telephone number of women who have spontaneous abortion in the past 1 to 6 months are listed and invited by phone call, a briefing is to be held and After obtaining written consent and ensuring confidentiality of information, The mental health questionnaire is completed by people who have the criteria for entering the study. Meetings are held in the classroom located in the Department of Women's Surgery, Razi Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.minimum 4 weeks and Maximum 6 months have passed since their abortion. 2.In the first pregnancy, abortion occurred. 3.Having at least elementary education 4. Informed consent to participate in the study 5- Earning a score above 65 from the mental health questionnaire Exit criteria: 1.Missing pregnancy is unwanted 2.Drug and psychedelic consumption 3.A history of chronic medical and psychological illnesses, and 4. Mother's disability or having a disabled child 5.The use of psychoactive drugs 6.The experience of an unfortunate incident, such as the death of a first-degree relative, in the past six months 7.Cognitive-behavioral therapy and any psychological intervention within the last 12 weeks 8.Current pregnancy and lactation

Intervention groups

For the intervention group, 1 individual counseling session and 8 group sessions will be held using the problem-solving treatment method. after the research, the control group will receive 2 intensive counseling

sessions.

Main outcome variables

mental health

General information

Reason for update

Acronym

سه حرف درمان حل مسئله PST

IRCT registration information

IRCT registration number: **IRCT20181129041792N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Roghayeh nazaralivand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3653 2786

Email address

nazaralivand.r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-08, 1397/09/17

Expected recruitment end date

2019-03-15, 1397/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of problem-solving based treatment on women's mental health after spontaneous abortion

Public title

Investigating the problem-solving treatment on the mental health of women after spontaneous abortion.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 4 weeks and at most 6 months have passed since their abortion. In the first pregnancy, abortion occurred. Having at least elementary education
Consent to Participate in the Study

Exclusion criteria:

Unwanted missing pregnancy. Drug and psychedelic substances consumption A history of chronic medical and psychological illnesses, Mother's disability or having a disabled child The use of psychoactive drugs such as antidepressants, anti-psychosis and ... The experience of bad events such as the death of a first-degree relative, in the past six months Cognitive-behavioral therapy and any psychological intervention within the last 12 weeks
Current pregnancy and lactation

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning people to the control and test groups is randomized and quadruple blocks (using the table for random permutations). After determining the block size in this study, the block list is provided and the number assigned to them, then random numbers will be chosen between 1 and 6. AABB(1), ABAB(2), ABBA(3), BBAA(4), BABA(5), BAAB(6)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Golestan Highway, Ahwaz University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.AJUMS.REC.1397.616

Health conditions studied**1****Description of health condition studied**

Spontaneous Abortion

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

Primary outcomes**1****Description**

mental health

Timepoint

Before the intervention begins and then one month after the end of the intervention

Method of measurement

Mental Health Questionnaire The symptoms checklist-25

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention group, an individual meeting and 8 group sessions of 23 persons are conducted on a weekly 90-minute basis by consulting a problem-solving methodology researcher and supervised by an advisor in the classroom located in the Department of Women's Surgery, Razi Hospital.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Sasan Mogahie

Street address

Shahid Ahwazian Street, 24 meters to the black bridge

City

Ahvaz

Province

Khouzestan

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6845157971

Phone

+98 61 3222 2818

Email

nazaralivand@gmail.com

2

Recruitment center

Name of recruitment center

Ahvaz Razi Hospital

Full name of responsible person

Farhang Kore Bandi

Street address

Ahvaz, Amanyeh, Palestine Street

City

Ahvaz

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Khouzestan

Postal code

6196514941

Phone

+98 61 3333 5935

Fax**Email**

nazaralivand@gmail.com

3

Recruitment center

Name of recruitment center

Ahvaz West Health Center

Full name of responsible person

Mehrdad Sharifi

Street address

Takhty Alley, Bahman Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mitra Tadayon Najaf Abadi

Street address

Ahvaz, Ahvaz, Golestan, Jundishapur University

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nazaralivand@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mitra Tadayon Najaf Abadi

Position

Faculty of Nursing and Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mitra Tadayn Najaf Abadi

Position

Faculty of Nursing and Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Roghayeh Nazaralivand

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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nazaralivand.r@ajums.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

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

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

Analytic Code

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

Data Dictionary

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