Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counselling on anxiety,acute stress reactions and posttraumatic stress reactions of women with miscarriage

Protocol summary

Summary

Main objective of the study is The impact of counselling on anxiety,acute stress reactions and posttraumatic stress reactions of women suffer from miscarriage. This study is a randomized control trial. Inclusion criteria include nulligravides with definite symptoms of miscarriage, literate, no addiction, no history of using antidepressant and relaxant agents, no stressful events since 6 month ago, no known mental disease and refractory chronic diseases, no history of infertility. Exclution criterias are: taking antidepressant and relaxant agents during 2 first weeks of intervention;accurance of stressful events during study.100 patients using randomized form are divided into intervention and control groups. Intervention includes 3 counselling sessions in 3 weeks. Every session lasts 40-60 minutes. control group will receive routines care. Just after third session, 1,2 and 3 months later,questionnaires will filled again by patients. In this study we use 4 questionnaires: demographic, Hospital anxiety and depression scale,Stanford acute stress reaction and Impact of events scale.At the end, anxiety, acute stress reactions and posttraumatic stress reactions will compared between control group and intensive group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401042248N13**
Registration date: **2014-03-04, 1392/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-04, 1392/12/13

Registrant information

Name
Fereshteh Jahdi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counselling on anxiety,acute stress reactions and posttraumatic stress reactions of women with miscarriage

Public title

The effect of counselling on anxiety,acute stress reactions and posttraumatic stress reactions of women with miscarriage

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterias: nulligravides with definite symptoms of miscarriage; literate; no addiction; no history of using

antidepressant and relaxant agents; no stressful events since 6 month ago; no known mental disease and refractory chronic diseases; no history of infertility. Exclution criterias:taking antidepressant and relaxant agents during 2 first weeks of intervention;accurance of stressful events during study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran university of medical sciences

Street address

Sixth floor,Central building of university, Next to Ghods street,Keshavarz bulivard,Tehran,Iran

City

Tehran

Postal code

Approval date

2013-11-23, 1392/09/02

Ethics committee reference number

130/1909/92/د

Health conditions studied

1

Description of health condition studied

Miscarriage

ICD-10 code

o03

ICD-10 code description

Pregnancy with abortive outcome(o00-o08)

Primary outcomes

1

Description

Post traumatic stress reactions

Timepoint

Before intervention,after intervention,1 month,2 months and 3 months after

Method of measurement

Impact of events scale

2

Description

Anxiety

Timepoint

Before intervention,after intervention,1 month,2 months and 3 months after

Method of measurement

Hospital anxiety and depression scale

3

Description

Acute stress reactions

Timepoint

Before intervention,after intervention,1 month and 2 months after

Method of measurement

Stanford acute stress reactions questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Interventional group: three individual counseling session for 40-60 min during first 24 hours after miscarriage,1 and 2 weeks later

Category

Behavior

2

Description

Control group: Post abortion routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbar Abadi Hospital

Full name of responsible person

Mahnaz Mosayeb Moradi
Street address
Tehran, Molavi crossroads, Bagh Ferdos station
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Fereshteh Jahdi
Street address
School of nursing and midwifery, Nosrat east avenue , Tohid square ,Tehran,Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Web page address
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty