Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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. Exclusion 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
Tehran university of medical sciences, school of midwifery and nursing

Full name of responsible person
Fereshteh Jahdi

Position
Master of Science, Faculty of nursing and midwifery

Other areas of specialty/work

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Other areas of specialty/work

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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