

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling based on health promotion awareness on mental health and self-esteem in women with ectopic pregnancy: A randomized controlled clinical trial

Protocol summary

Study aim

Determine the effect of counseling on mental health and self-esteem in women with ectopic pregnancy

Design

The clinical trial with two groups of intervention and control, with parallel groups, without blinding, is randomized, with 34 participants in each group who will be followed up 2 weeks after the end of the intervention.

Settings and conduct

This randomized, controlled clinical trial will be conducted on women with ectopic pregnancy treated at al-Zahra hospital in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with ectopic pregnancy who are admitted in surgical wards, Women who are at the reproductive age, Women who are willing to participate in the study. exclusion criteria: Women who have severe psychological problems, personal disorders and psychiatric disorders according to their own statements. women who use psychoactive drugs. women who have experienced mental and psychological problems like lost and losing their family members during last 3-6 months. women who have taken psychiatric drugs, including anti-anxiety and anti-depressant drugs before being pregnant. women who have had history of ectopic pregnancy and have had lose both of their uterine (Fallopian)tubes.

Intervention groups

A group as intervention group will receive 4-6 sessions of group counseling based on health promotion awareness by a researcher in a face to face way in 45-60 minutes. The control group will also receive routine care after ectopic pregnancy and the context of the consultation will be provided for them if they are inclined to do so at the end of study. The counselling sessions will be held a week after their discharge and will be held weekly for 4-6 weeks in a separate room (which has all facilities for

counseling) at the Alzahra Hospital

Main outcome variables

Determine of mean scores of mental health and self-esteem of women with ectopic pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100109003027N41**

Registration date: **2018-08-04, 1397/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on health promotion awareness on mental health and self-esteem in women with ectopic pregnancy: A randomized controlled clinical trial

Public title

The effect of counseling based on health promotion awareness on mental health and self-esteem in women with ectopic pregnancy: A randomized controlled clinical trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with ectopic pregnancy who admitted in surgical wards Women of reproductive ages Women who are willing to participate in the study.

Exclusion criteria:

Women who, according to themselves expressions, have been severe psychological problems, personality disorder, and psychiatric disorders. Women who use psychoactive drugs. Women who have experienced mental and psychological problems like lacks and problems such as losing their loved ones in the last 3 to 6 months. Women with a history of ectopic pregnancy who have lost both of their uterine (Fallopian) tubes.

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

Individuals who completed the pre-test questionnaires were randomly assigned to www.random.org and through block randomization with four and six blocks (stratification based on the tear of uterus tube and history of live child) and assigned a 1: 1 assignment ratio to two groups (one group receiving counseling and one control group). Block randomization will be done by the person who not involved in sampling and data analysis. To hide the allocation, the type of intervention will be written on the paper and will be placed in a series of consecutively numbered (1-68), sealed, opaque envelopes (Allocation Concealment).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

South Shariate Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2018-06-04, 1397/03/14

Ethics committee reference number

.IR.TBZMED.REC.1397.223

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

ectopic pregnancy

ICD-10 code

O00.9

ICD-10 code description

Ectopic pregnancy, unspecified

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

Determine of mental health score

Timepoint

Measurement of mental health score before intervention

Method of measurement

GHQ-28 questionnaire

2**Description**

Determine of self-esteem score

Timepoint

Measurement of self-esteem score before intervention

Method of measurement

Rosenberg self-esteem questionnaire

3

Description

Determine of self-esteem score

Timepoint

Measurement of mental health score 2 weeks after the end of the intervention

Method of measurement

GHQ-28 questionnaire

4

Description

Determine of self-esteem score

Timepoint

Measurement of self-esteem score 2 weeks after the end of the intervention

Method of measurement

Rosenberg self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention consists of 4 to 6 sessions of health awareness-rising counseling on a weekly basis.

Category

Other

2

Description

Control group: The control group will receive the routine care after ectopic pregnancy and will be given the counseling content at the end.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al Zahra hospital

Full name of responsible person

Fahime Sehhati Shafaie

Street address

South Shariati st.

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Tabriz

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5138947977

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+98 41 3479 6770

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sehhatief@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Tabriz-Azadi St.- Golghast St.- Tabriz University of Medical Sciences- Central Building- No. 2- Jesh Vice Chancellor for Research

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Sonia Hasani

Position

Ms. student of Midwifery education

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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South Shariati st.Nursing and Midwifery faculty.

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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences
Full name of responsible person
Fahime Sehhati Shafaie
Position
Assistant professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the information, such as information on the main outcome and the secondary outcomes after being unidentified, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers working in academic institutions

Under which criteria data/document could be used

In order to conduct research by researchers and under the terms of the law approved by the Declaration of the International Committee of Medical Publishers

From where data/document is obtainable

refer to the supervisor professor, Fahime sehhatie.

What processes are involved for a request to access data/document

After submitting the necessary documentation on the topic of research and approval by the relevant university

Comments