

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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.

**Age**From **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.

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5138947977

##### **Phone**

+98 41 3479 6770

#### **Email**

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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

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5138947977

##### **Phone**

+98 41 3479 6770

##### **Email**

sehhatief@tbzmed.ac.ir

#### **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

##### **Street address**

South Shariati st.Nursing and Midwifery faculty.

##### **City**

Tabriz

**Province**

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+98 41 3479 6770

**Email**

shasani735@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fahime Sehhati Shafaie

**Position**

Assistant professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fahime Sehhati Shafaie

**Position**

Assistant professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

South Shariati st.Nursing and Midwifery faculty

**City**

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**Province**

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**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

sehhatief@tbzmed.ac.ir

**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**