

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison of effect of pre-operative educational approach by nurses and peers on anxiety of the women undergoing ovarian puncture

#### Protocol summary

##### Study aim

Comparing the Effects of nurse and peer-Based Education Methods on the pre-operative anxiety of Surgery candidate infertile women

##### Design

Clinical trial with three groups of nurse education, peer education and control, Permutation on 198 patients randomized blocks. Random Allocation software was used for randomization.

##### Settings and conduct

This study was performed in the period of February 2017 to August 2017 at the Infertility Research Center in Yazd, Iran. In this clinical trial, 210 eligible people were selected from 240 members of the available population. The samples were selected by availability and assigned randomly to the three groups of nurse training, peer training and control by permutation block method. The number of samples in each group was 70 people.

##### Participants/Inclusion and exclusion criteria

Our inclusion criteria were as follows: age between 18 and 45 yr, knowledge persian language, and literate. Women with mental illness, addiction, egg donor, cancer and those taking anti-anxiety medications were excluded.

##### Intervention groups

Training group by nurse Training group by peer Control group The two intervention groups were trained by the nurse and peers after collecting data on the day of admission. However, the control group samples were trained according to the routine section only at the time of discharge.

##### Main outcome variables

Anxiety

#### General information

##### Reason for update

Description of randomization

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2017010331753N1**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-12, 1400/04/21**

Update count: **1**

#### Registration date

2017-06-30, 1396/04/09

#### Registrant information

##### Name

Atharah Kalantari

##### Name of organization / entity

Yazd University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 259 0449

##### Email address

a.kalantari@ssu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Yazd University of Medical Sciences.

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2017-08-21, 1396/05/30

#### Actual recruitment start date

2017-02-13, 1395/11/25

#### Actual recruitment end date

2017-08-01, 1396/05/10

#### Trial completion date

2017-08-01, 1396/05/10

#### Scientific title

Comparison of effect of pre-operative educational

approach by nurses and peers on anxiety of the women undergoing ovarian puncture

#### Public title

Comparison of two method of preoperative training on anxiety

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Candidate patients undergo ovarian puncture Willingness to participate in the study Age between 18 and 45 years knowledge persian language Literacy for reading and writing

##### Exclusion criteria:

Mental illness, addiction, cancer Taking anti-anxiety drugs Donor

#### Age

From **18 years** old to **45 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **210**

Actual sample size reached: **198**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Sampling was performed using special randomized software with permutation block method with a volume of 6 people and eligible samples were placed in one of the three groups of nurse training, peer training and control.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

In this study, individuals were assigned to three groups using permutation block method.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

##### Street address

Yazd University of Medical Sciences, Bahonar Square

##### City

Yazd

#### Province

Yazd

#### Postal code

8916978477

#### Approval date

2017-01-01, 1395/10/12

#### Ethics committee reference number

IR.SSU.REC.1395.202

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committee Research and Clinical Center for Infertility, Yazd, Iran

##### Street address

Safaieh , Bouali Street

##### City

yazd

##### Province

Yazd

##### Postal code

8916877391

#### Approval date

2017-02-12, 1395/11/24

#### Ethics committee reference number

IR.SSU.RSI.REC.1395.30

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

generalized anxiety disorder

### 2

#### Description of health condition studied

infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Baseline, preoperative

#### Method of measurement

Spielberger questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Preoperative training by a nurse: The nurse-educated group was on 30-60 min group education program after the completion of the primary questionnaire. The educational package contained the type and duration of surgery, postoperative cares, including diet, medicine consumption, the quality and amount of rest after surgery, and postoperative activity. During this education, the nurse was allowed to express positive experiences. The questionnaire was filled out in a self-report manner in the researcher's presence at the time of admission (two days before the operation) and immediately after the intervention (prior to surgery).

#### Category

Prevention

### 2

#### Description

Preoperative training by a peer: The peer-educated group was on 30-60 min group education program after the completion of the primary questionnaire. The educational package contained the type and duration of surgery, postoperative cares, including diet, medicine consumption, the quality and amount of rest after surgery, and postoperative activity. During this education, the peer was allowed to express positive experiences. To educate the peer group, three qualified peers were selected according to the following criteria: history of successful ovarian puncture, high school diploma or higher, and having low levels of anxiety based on the STAI. These selected peers were educated before sampling by the nurse educator or another group about their roles in the study, the importance of instructing patients, and the educational content in two sessions. Then, through an experimental instruction, one of the peers was selected as the educator for the peer-educated group. She was a 24-yr-old housewife and a resident of Yazd who had a high school diploma and a child from IVF. The questionnaire was filled out in a self-report manner in the researcher's presence at the time of admission (two days before the operation) and immediately after the intervention (prior to surgery).

#### Category

Prevention

### 3

#### Description

the control group was only educated at the time of their discharge, which is part of the section's routines.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Reproduction Sciences Institute

##### Full name of responsible person

Atharah Kalantari

##### Street address

Bouali avenue, timsar falahi street, Yazd.

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877391

##### Phone

+98 35 3824 7085

##### Fax

+98 35 3824 7087

##### Email

yazd-rsi@ssu.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

.

##### Street address

Yazd University of Medical Sciences, Bahonar Square

##### City

yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Email

info@ssu.ac.ir

##### Grant name

-

##### Grant code / Reference number

-

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Atharah Kalantari

**Position**

Master in Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Bouali Ave, Safaeyeh, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3525 2291

**Fax**

**Email**

a.kalantari@ssu.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Farahnaz Farnia

**Position**

Ph.D in Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Bouali Ave, Timsar Falahi street

**City**

Yazd

**Province**

Yazd

**Postal code**

916777443

**Phone**

+98 35 3824 5777

**Fax**

**Email**

farnia@ssu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Atharah Kalantari

**Position**

Master student in nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Bouali Ave, Timsar falahi street

**City**

Yazd

**Province**

Yazd

**Postal code**

8917735513

**Phone**

+98 35 3525 2291

**Fax**

**Email**

kalantariathara@gmail.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

The data from the study were published as an article.

**When the data will become available and for how long**

Since 1401

**To whom data/document is available**

All people in the field of medicine and nursing

**Under which criteria data/document could be used**

To reduce preoperative anxiety in surgical candidates

**From where data/document is obtainable**

Email to the person performing the project

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

Email to the moderator - Request from the Vice

Chancellor for Research- If yes, provide information to

the applicant  
**Comments**