

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

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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

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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

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Bouali avenue, timsar falahi street, Yazd.

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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

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Full name of responsible person

Farahnaz Farnia

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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