Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Protocol summary

Study aim

Determining the effect of the educational program designed by midwives on the level of anxiety and perceived pain intensity of performing

Design

Clinical trial with control and intervention group, single groups, single-blind, randomized, phase 2 on 86 patients, random number table was used for randomization.

Settings and conduct

This study is conducted on infertile women who are candidates for HSG, referring to the imaging department of Royan Research Institute. After admission, people are placed in intervention and control groups based on even and odd days. For blinding, none of the subjects were told which group they were in.

Participants/Inclusion and exclusion criteria

Entry requirements: Infertile women volunteer for Hysterosalpingography Age range 20-49 years Iranian nationality Ability to speak Persian Literacy for reading and writing Not suffering from known anxiety disorders or other mental illnesses affecting anxiety under treatment Failure to enter: History of (HSG) Early diagnosis of tubal and uterine lesions that cause severe pain in a person.

Intervention groups

In the intervention group, after accepting and obtaining informed consent, the people of this group are offered a face-to-face training program where people can ask their questions to the trainer. People complete the relevant questionnaires after each stage. In the control group, after accepting and providing an explanation about the research, people complete the questionnaires and tools with informed consent. And no educational intervention is done for them.

Main outcome variables

Reduction of anxiety and pain perceived by women undergoing (HSG). Decrease heart rate and blood pressure of people Increasing people's awareness of (HSG)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150905023897N6**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

Registration date

2023-05-16, 1402/02/26

Registrant information

Name

Dr. Shahideh Jahanian Sadatmahalleh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4826

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Public title
Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Voluntary infertile women Age 20-49 years Iranian nationality Ability to speak Persian Literacy Not suffering from known anxiety disorders or other mental illnesses affecting anxiety under treatment No history of HSG People who are inclined to participate in the study.

Exclusion criteria:
Patient withdrawal from the study Failure to complete the HSG process for any reason Presence of tubal or uterine lesions, such as cervical stenosis, which cause "severe pain" in the HSG process

Age
From **20 years** old to **49 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to perform randomization, the researcher put 4 balls, including 2 white balls: intervention and control, and 2 black balls: even day and odd day, which he named in this way and put them in a container and asked someone to pick up two different colors. This is the way that those balls were selected: even day and intervention, odd day and control. In this way, people who visit on even days are in the intervention group, and people who visit on odd days are in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
After admission, people are randomly assigned to each of the intervention and control groups. None of them were informed about their group and they just trained about the stages what should they do.

Placebo
Not used

Assignment
Single

Other design features
In this research, it should be measured the level of target group's knowledge about hysterosalpingography. To achieve this, a questionnaire should be prepare by researcher whose validity and reliability are also measured.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat Modares University

Street address
Tarbiat Modares University, Nasr bridg, Ale ahmad high way,Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۱۱۷۱۳۱۱۶

Approval date
2022-10-03, 1401/07/11

Ethics committee reference number
IR.MODARES.REC.1401.144

Health conditions studied

1

Description of health condition studied
Female infertility

ICD-10 code
N97.1

ICD-10 code description
Female infertility of tubal origin

Primary outcomes

1

Description
The patient's heart rate

Timepoint
Heart rate measurement at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement
Pulse meter

2

Description
The patient's blood pressure

Timepoint
Blood pressure measurement at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement

Sphygmomanometer

3

Description
Patients' awareness of hysterosalpingography
Timepoint
Measuring the patient's knowledge about hysterosalpingography at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention
Method of measurement
Hysterosalpingography awareness questionnaire (made by a researcher)

4

Description
Patient anxiety
Timepoint
Measuring the patient's anxiety at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention
Method of measurement
State Trait Anxiety Inventory (STAI)

5

Description
Perceived pain from the hysterosalpingography procedure
Timepoint
Measurement of perceived pain in the initial study (before the intervention), half an hour before the intervention, treatment and half an hour after the intervention
Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group: After accepting people according to the entry criteria, and obtaining informed consent, people are randomly assigned to the control and intervention groups. The control group does not receive any educational or counseling intervention and only the center's routine admission is done for them. The other mentioned cases are the same in both groups. including questionnaires and timings necessary to measure the variables.
Category
Behavior

2

Description
Intervention group: After accepting people according to the entry criteria, and obtaining informed consent, people are randomly assigned to control and intervention groups. People in the intervention group receive educational items and counseling (educational intervention) before performing hysterosalpingography.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Ṡhahideh Jahanian Sadatmahalleh
Street address
East Hafez St, North Bani Hashem St, Resalat Highway, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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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
Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
Shahideh Jahanian Sadatmahalleh
Position
دانشیار
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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
No - There is not 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
No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome of the study

When the data will become available and for how long

2023

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Use for additional research in the future

From where data/document is obtainable

Email Addressing Responsible for study

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

Submit a request to study and follow up

Comments