Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effect of two methods of Benson relaxation and breathing exercises in preoperative anxiety of patients undergoing hysterectomy.

Protocol summary

Study aim

the effect of two methods of Benson relaxation and breathing exercises in preoperative anxiety of patients undergoing hysterectomy.

Design

A randomized, single-blind, 2 parallel-groups, controlled clinical trial was conducted on 93 patients. Randomization was performed using a method based on random permuted blocks.

Settings and conduct

Patients undergoing hysterectomy surgery at a selected hospital affiliated with Kermanshah University of Medical Sciences. Location: Women's inpatient ward. Procedure: First, after obtaining informed consent, the samples will be selected through convenience sampling from among eligible individuals. This pre- and post-intervention study will be conducted across three groups (Benson relaxation technique,Breathing exercises, Routine care) Before the intervention begins, an anxiety questionnaire will initially be distributed among the participants by an individual who is unaware of the group assignments. After collecting the questionnaires, training for Benson relaxation and breathing exercises will be provided by the researcher one day before the surgery and on the day of the surgery in the women's inpatient ward. Then, on the morning of the surgery, the researcher will redistribute the Spielberger State-Trait Anxiety Inventory questionnaire among the patients.

Participants/Inclusion and exclusion criteria

Inclusion : informed consent; Iranian nationality;no respiratory problems; no speech disorders; no history of using Benson relaxation methods; no participation in a similar research project; regular attendance at educational sessions. Exclusion : unwillingness of the individual to participate; absence from educational sessions.

Intervention groups

First: The Benson relaxation Second: Breathing exercises Third: No intervention

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251129068151N1**
Registration date: **2026-01-26, 1404/11/06**
Registration timing: **retrospective**

Last update: **2026-01-26, 1404/11/06**
Update count: **0**

Registration date

2026-01-26, 1404/11/06

Registrant information

Name
Mahtab Nikravesh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 83 3835 8943
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-06, 1404/09/15

Expected recruitment end date

2026-01-10, 1404/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of two methods of Benson relaxation and breathing exercises in preoperative anxiety of patients undergoing hysterectomy.

Public title

Effect of two methods of Benson relaxation and breathing exercises in preoperative anxiety of patients undergoing hysterectomy.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Informed and written consent to participate in the study Patients have Iranian nationality Patients who do not have respiratory problems Patients who do not have speech, hearing, or vision impairments Patients who do not have prior experience with Benson relaxation techniques or mindfulness Patients who do not participate in similar research projects

Exclusion criteria:

Not having willing to participate in study Patients who get psychotherapy treatment

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Since this study involves the comparison of three groups, the randomization method will be based on the use of random permuted blocks. To implement this technique, different permutations designated by the letters A, B, and C will be used, utilizing a random sequence generated by the statistical consultant through the website https://www.sealedenvelope.com/. The selected random blocks, prepared by the statistical consultant, will be provided to the study executor. Each block consists of 6 individuals who will be sequentially assigned to the specified groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blind in nature, meaning that the analyst may not know whether the data belong to the control group or the intervention group. During the implementation phase, to reduce the risk of performance bias, the training for breathing exercises and the Benson relaxation technique will be conducted by the principal researcher. However, data collection (anxiety questionnaire) will be performed by another individual who is unaware of the group assignments. In this way, roles are separated, and the likelihood of bias will be minimized.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2025-11-01, 1404/08/10

Ethics committee reference number

IR.KUMS.REC.1404.437

Health conditions studied

1

Description of health condition studied

hysterectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety levels in all three groups: Benson relaxation, breathing exercises, and routine care.

Timepoint

Anxiety measurement before the intervention and one day after the intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group one: Benson relaxation - The Benson relaxation intervention will be performed completely on the patients by the researcher on the patient's bed. First, the intervention will be fully taught to the patient based on the Benson relaxation text. Patients will practice the intervention in the presence of the researcher until they master it, and all the patient's questions will be answered. This intervention will be performed on the patients in two sessions (the night before the operation and the day of the operation before entering the operating room), each time for 20 minutes.
Category
Behavior

2

Description
Second intervention group: Breathing exercises - Breathing exercises will be taught to patients individually by the researcher the day before surgery in the patients' hospital room using simple and understandable sentences and face to face. The training will continue until learning occurs. Patients will practice the intervention in the presence of the researcher until they master it. This intervention will be performed on patients in two sessions (the night before surgery and the day of surgery before entering the operating room) for 20 minutes each time.
Category
Behavior

3

Description
Control group: No intervention - In this group, no intervention will be performed by the researcher and only routine care will be provided to the patients.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Selected Hospital in Kermanshah
Full name of responsible person
Mahtab Nikravesh
Street address
Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Parisa Rizevandi
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Nasim Hatefi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Master

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
In this study, some of the data can be shared after approval by the main researcher.

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
The data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data can be used by researchers working in academic and scientific institutions upon request from the corresponding author.

From where data/document is obtainable
Data are available upon request from the corresponding author via email.

What processes are involved for a request to access data/document
After the results are published, the requester can request access to the data via email to the corresponding author. The data will be available after approval by the corresponding author.

Comments