Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of aromatherapy with music therapy on the patients anxiety level before inguinal herniorrhaphy

Protocol summary

Study aim

Overall purpose: Determining and comparing the effect of aromatherapy with music therapy on anxiety level of patients before inguinal herniorrhaphy

Design

The total number of specimens determined with the sample drop would be 141. After selecting the sample and obtaining patient satisfaction and ensuring the confidentiality of the information and introducing the questionnaires, the researcher will first assess the level of anxiety using the Spielberger Anxiety Inventory. After completing the questionnaires, the samples will be randomly assigned to three groups of aromatherapy with geranium extract and music therapy and control. Random allocation to three groups will be performed by patients by removing cards (a), (b) and (c).

Settings and conduct

This study will be a clinical trial. The research environment is Imam Khomeini Hospital in Mahabad. Participants who qualify for the study will complete a written consent form. This study will be single-blind, the researcher analyzing the statistical data will be unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Satisfaction to participate in the study No chronic anxiety Ages over 18 and under 60 years

Intervention groups

The aromatherapy group for 30 minutes smells the extract of 50% aromatic geranium extract on a cotton ball that is attached to the patient's collar within 20 cm of the nose. The music therapy group will provide patients with a set of relaxing music that will be played by the headphones for 30 minutes. In the control group, there will be no intervention and they will rest in bed for half an hour.

Main outcome variables

Level of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131112015390N2**
Registration date: **2020-02-27, 1398/12/08**
Registration timing: **retrospective**

Last update: **2020-02-27, 1398/12/08**
Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name
Naser Parizad
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2019-08-07, 1398/05/16

Actual recruitment end date

2019-12-10, 1398/09/19

Trial completion date

2019-12-19, 1398/09/28

Scientific title
Comparing the effect of aromatherapy with music therapy on the patients anxiety level before inguinal herniorrhaphy

Public title
Comparing the effect of aromatherapy with music therapy on the patients anxiety level before inguinal herniorrhaphy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction to participate in the study Ability to read and write No history of hearing, olfactory or visual impairments No mood disorders and lack of systemic diseases such as diabetes and cardiovascular disease No pain relief, analgesic or anxiety medication such as inderal for more than a month, no pain No history of thyroid disease and effective medications No drug addiction No history of inguinal hernia repair No chronic anxiety (Spiel Berger questionnaire scores above 76 in open anxiety and 73 on hidden anxiety) Not having allergies to geranium extract Ages above 18 and under 60 years

Exclusion criteria:
Unwillingness to continue in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **141**
Actual sample size reached: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation to three groups will be performed by patients by removing cards (a), (b) and (c) and the researcher will be divided into three groups: music therapy, aromatherapy and control using cards (a), (b) and (c). Patients who were included in the study would then be admitted to the music therapy group, card (b) to the aromatherapy group, and card (c) to the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study will be single-blind, so that, the researcher analyzing statistical data unaware of the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Resalet Boulevard, Emergency Cui

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2019-08-07, 1398/05/16

Ethics committee reference number
IR.UMSU.REC.1398.172

Health conditions studied

1

Description of health condition studied
Inguinal Hernia

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Anxiety Scale in Spielberger's Hidden and Obvious Anxiety Scale Questionnaire: In this study, the effects of music therapy and aromatherapy on anxiety of patients before inguinal hernia surgery were evaluated. The researcher will first measure the level of anxiety by using the Spiel Berger Anxiety Inventory and latent anxiety questionnaire. After completing the questionnaires, the samples will be randomly assigned to three groups of aromatherapy with geranium extract and music therapy and control group.

Timepoint
Anxiety was measured before the intervention and then half an hour after the intervention

Method of measurement
Spielberger's Invisible and Hidden Anxiety Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Music therapy Group; In the music therapy group, a collection of relaxing music previously produced by the researcher will be provided to patients, which will be played by the headphones for as long as 30 minutes. During this period, there will be no treatment other than music therapy for these patients.

Category
Behavior

2

Description
Intervention group: Aromatherapy Group with geranium aroma; In the aromatherapy group, ten drops of geranium extract of 50% aromatic geranium extract is dripped onto a cotton ball (2 to 2.5 cm in radius) and positioned by a collar to the patient's collar at a distance of 20 cm from the nose. The patient is asked to breathe normally for 30 minutes.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital in Mahabad

Full name of responsible person
Naser Parizad

Street address
Sarbaz Street, Shahid Abdullah Pour Boulevard

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Mahabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
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Grant name
School of Nursing and Midwifery, Urmia University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Naser Parizad

Position
Assistant Professor

Latest degree
Ph.D.

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be 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
Data related to the main outcome of the study will be shared.
When the data will become available and for how long
Data access will begin three months after the results are published.
To whom data/document is available
All researchers and practitioners in the field can access the results.
Under which criteria data/document could be used
Anyone can access the results by pointing to the source used.
From where data/document is obtainable
People can access data from reputable databases that publish results.
What processes are involved for a request to access data/document
Searching for the main outcome of the research or the researchers conducting the research after publishing the results in valid databases
Comments