

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

Country

Iran (Islamic Republic of)

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+98 44 1348 7649

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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

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Sarbaz Street, Shahid Abdullah Pour Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

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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