

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of inhalation aromatherapy and music on anxiety and vital signs of patients under extracorporeal shock wave lithotripsy

Protocol summary

Study aim

Comparison of the effect of aromatherapy and music on the level of anxiety and vital signs of patients undergoing ESWL

Design

Eligible patients participating in the study are readily available and randomly assigned to one of the intervention groups (music, aromatherapy, music composition and aromatherapy) and control. The sample size is 176 people.

Settings and conduct

Eligible patients participating in the study are readily available and randomly assigned to one of the intervention groups (music, aromatherapy, music composition and aromatherapy) and control.

Participants/Inclusion and exclusion criteria

The participants in this study are all patients with kidney stones and urinary tract patients who refer to the ESWL unit. Criteria for entering the study include: willingness to participate in the study, having a minimum age of 18 and a maximum age of 65, literate and able to communicate and communicate effectively, no allergies or respiratory diseases, having a healthy sense of smell and hearing, not using hearing aids, no previous history of ESWL, no high blood pressure, no treatment with antihypertensive drugs, no diseases associated with high blood pressure. Criteria for withdrawal from the study include receiving drugs and anti-anxiety drugs during the study and the impossibility of continuing the patient's participation in the study for any reason.

Intervention groups

Aromatherapy - Music Therapy - Combination - Control

Main outcome variables

Anxiety and vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100913004736N23**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

Email address

akhatony@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of inhalation aromatherapy and music on anxiety and vital signs of patients under extracorporeal shock wave lithotripsy

Public title

The effect of aromatherapy and music on the anxiety and vital signs of patients undergoing lithotripsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age 18 to 65 years
Literate Stability of vital signs Healthy sense of smell
Healthy sense of hearing

Exclusion criteria:

Previous history of lithotripsy drug addiction
consumption of psychoactive drugs Any kind of allergy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a random block of 8 will be created using the website <https://www.sealedenvelope.com>. Regarding the implementation of the random allocation process, the following are considered: A) Blocks of 8 are considered. B) One letter is assigned to each group: A to the band, B to the aromatherapy, C to the combination of music and aromatherapy, and D to none of the interventions (control group) C) A sequence of letters will be created for a sample size of 200. D) For the random allocation concealment process, 25 opaque envelopes and 200 cards will be created. Inside each envelope, eight cards are placed in sequence. The number of blocks is written on each envelope. On each card, the name of the desired group will be written in sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person collecting sample information and controlling their vital signs, as well as the data analyst, are unaware of assigning samples to study groups.

Placebo

Used

Assignment

Factorial

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

Shahid Behesht BLVD.,

City

Kermanshah

Province

Kermanshah

Postal code

6714634698

Approval date

2020-08-18, 1399/05/28

Ethics committee reference number

IR.KUMS.REC.1399.651

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the lithotripsy

Method of measurement

Spielberger Anxiety Questionnaire

2

Description

Blood pressure

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the lithotripsy

Method of measurement

Mercury sphygmomanometer

3

Description

Temperature

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the lithotripsy

Method of measurement

Tympanic thermometer

4

Description

Heart Rate

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the lithotripsy

Method of measurement

Counting the number of radial pulse in one minute

5

Description

Respiratory rate

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the lithotripsy

Method of measurement

Counting the number of breaths in one minute

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (music group): In this group, during the lithotripsy, traditional Iranian music is played through headphones.

Category

Prevention

2

Description

The second intervention group (aromatherapy group): In this group, during the lithotripsy, aromatherapy is performed with three drops of 25% Rose Damascena essential oil.

Category

Prevention

3

Description

Third intervention group (music and aromatherapy group): In this group, a combination of traditional Iranian

music and aromatherapy with three drops of 25% Rose Damascena essential oil is used.

Category

Prevention

4

Description

Control group: There is no intervention in this group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Alireza Khatony

Street address

Nurse Blvd., Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

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farid_n32@yahoo.com

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
Alireza Khatony
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

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