Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effect of Benson relaxation and music therapy on fear of movement and postoperative pain in patients undergoing lumbar disc herniation surgery

Protocol summary

Study aim
General purpose: Determining and comparing the effect of Benson relaxation and music therapy on fear of movement and postoperative pain in patients undergoing lumbar disc herniation surgery.

Design
Clinical trial with two intervention groups and one control group, parallel, single-blind, randomized, on 90 patients.

Settings and conduct
This single-score study will be conducted in Imam Hossein (AS) Shahrood Hospital. The researcher, being present at the patient's bedside on the day after the operation, after checking the entry criteria, randomly assigns the patients. Then according to the group in which the patient is placed (Benson's relaxation group, music therapy and control group), the relevant intervention will be done. For the control group, only routine care will be done. Then the pain and fear of moving the patients in 3 stages It will be measured by the standard instrument designed.

Participants/Inclusion and exclusion criteria
Entry criteria include: 1. Perform discectomy 2. Being 18 years old or older 3. Having spontaneous breathing 4. Ability to read and write in Persian language 5. Ability to learn or perform the Benson technique correctly 6. Desire to listen to music

Intervention groups
Benson's relaxation: The technique of this method will be taught to the patient. Music therapy: listening to music without words for 20 minutes Control: will receive only routine care.

Main outcome variables
Fear of movement, postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230911059401N1**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information
Name
majid bagheri
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 23 3251 2173
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-02, 1402/07/10

Expected recruitment end date
2024-04-29, 1403/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of Benson relaxation

and music therapy on fear of movement and postoperative pain in patients undergoing lumbar disc herniation surgery

Public title
A comparative study of the effect of Benson relaxation and music therapy on fear of movement and postoperative pain in patients undergoing lumbar disc herniation surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Perform discectomy surgery Being 18 years of age or older Having spontaneous breathing Ability to read and write in Persian Ability to learn or perform the Benson technique correctly Desire to listen to music Consent to participate in the research verbally and in writing Discectomy by open surgery Having a score of at least 37 in the Tempa questionnaire before the operation Having a pain score of at least 3 before surgery
Exclusion criteria:
Addiction to sedatives lack of consciousness causing any side effects in terms of infection, bleeding, severe pain, etc. until the end of evaluation and interventions Having language, hearing or vision disorders Having experience using relaxation methods in the past Having a history of previous discectomy surgery Having a history of taking sedatives, painkillers for a period of more than one month according to the patient's self-report Having a history of mental disorders and diseases
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
To allocate the samples, the block randomization method will be used with the size of 6 blocks, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the three groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is single blind. Due to the nature of the study, it is not possible to blind the study participants. However, measures have been taken in collecting information. The person collecting information will not be aware of the type of group of people after the intervention. . Also, in the statistical file and questionnaires, the groups are identified as codes, and the analyst does not know about the assignment of codes to the groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences, Haft Tir Square, Shahroud
City
Shahroud
Province
Semnan
Postal code
36147-73943
Approval date
2023-09-11, 1402/06/20
Ethics committee reference number
IR.SHMU.REC.1402.088

Health conditions studied

1

Description of health condition studied
Fear of movement, Low back pain, lumbar disc herniation
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
fear of movement
Timepoint
Once in the morning after the operation, and once in the morning two days after the operation
Method of measurement
Tampa Scale for Kinesiophobia

2

Description
postoperative pain
Timepoint

Once in the morning after the operation, and once in the morning two days after the operation

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (Benson Relaxation Group): In order to perform the correct Benson relaxation technique, this technique will be performed with the following sequence. The patient is asked to lie down in a comfortable position and close his eyes, to remove disturbing thoughts from his mind as much as possible. They are asked to choose a word that always reminds them of peace. Then slowly relax your muscles from the bottom of the body to the top and at the same time slowly start breathing deeply (in such a way that inhale through the nose and exhale through the mouth). Do not think and continue this exercise for at least 20 minutes. Finally, the patient is asked to open his eyes slowly, so that the body is motionless for a few minutes. The first day after the operation, when the pain and fear of movement are the most intense, therefore, the interventions are performed in two times with an interval of twelve hours at 9 am and 9 pm in the surgical department for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group 2 (Music therapy group): Second group (music therapy group): Participants in the other group listen to wordless music for 20 minutes through an audio player. In the music therapy group, the song Weightless by Macaroni Union will be chosen as the wordless music. The melodies of this song have no repetitive pattern and its rhythm varies continuously between 50 and 60 bits per minute. The first day after the operation, when the pain and fear of movement are the most intense, therefore, the interventions are performed in two times with an interval of twelve hours at 9 am and 9 pm in the surgical department for 20 minutes.

Category

Rehabilitation

3

Description

Control group: In the control group, participants will receive only routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein (AS) Shahroud Hospital

Full name of responsible person

Mobin Mottahedi

Street address

Imam Hossein (AS) Shahrood Hospital, Imam St., at the end of 28 meters of Ayat A... Tawhidi, Shahrood

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Ali Abbasi

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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

Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
majid bagheri

Position
Non-faculty instructor

Latest degree
Master

Other areas of specialty/work
Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available