Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Effect of nurse-led multicomponent intervention on delirium, sleep quality and performance metrics in orthopedic surgery patients

Protocol summary

Study aim
Determine the effect of nurse-led multicomponent intervention on delirium, sleep quality and performance metrics in orthopedic surgery patients

Design
Double-blind clinical trial, 96 patients were randomized into intervention and control groups. STATA software will be used for block randomization.

Settings and conduct
This research will be a randomized controlled clinical trial in patients requiring orthopedic surgery referred to male and female surgery departments of Imam Jafar Sadiq (AS) hospital in Aligudarz city. The four components of this intervention will start with the priority of patient pain management, and then continue with music therapy, cardio-respiratory support, and improving sleep hygiene for the intervention group from 24 hours before surgery to 48 hours after surgery. The data analyst, the nurse assessor (data collector) and the study participants do not know about the random assignment of the groups. Blinding of the interventionist is not possible due to the nature of the study.

Participants/Inclusion and exclusion criteria
Orthopedic traumas including upper, lower limbs, pelvis and single fractures of the spine; age range of 55 years and older; no confusion based on the CAM test; no Suffering from dementia and no history of Traumatic brain injury, brain surgery and stroke in the last 6 months.

Intervention groups
The intervention group will receive a four-component intervention from 24 hours before to 48 hours after surgery, including pain control, music therapy, cardio-respiratory support of the patient using the Threshold device, and improving sleep hygiene. The control group will receive routine care.

Main outcome variables
Delirium; sleep quality; performance metrics

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150919024080N22**
Registration date: **2022-11-27, 1401/09/06**
Registration timing: **prospective**

Last update: **2022-11-27, 1401/09/06**
Update count: **0**

Registration date
2022-11-27, 1401/09/06

Registrant information

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Name of organization / entity
Lorestan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-10, 1402/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of nurse-led multicomponent intervention on delirium, sleep quality and performance metrics in orthopedic surgery patients

Public title
Effect of multicomponent intervention on delirium and sleep quality in orthopedic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with orthopedic traumas including upper, lower limbs, pelvis and single fractures of the spine, who need at least 3 days of hospitalization after surgery in the surgery department and are on the surgery list Having consent to cooperate Not having a hearing problem (based on the whisper test) Age range of 55 years and above The duration of the patient's anesthesia for surgery is between 30 minutes and 3 hours Absence of confusion based on CAM test Mini–mental state examination (MMSE) score in the range of 18 to 30 Non-diagnosis of mental patients and history of taking haloperidol, risperidone, quetiapine, hypnotic herbal supplements and hypnotic drugs before hospitalization (self-report)

Exclusion criteria:
Transfer to another center and not providing treatment due to the death of the patient or medical reasons Concurrent participation in similar research Patients with dementia (MMSE less than 18) Patients with head, face, chest and spinal cord injuries Patients who undergo orthopedic surgery more than once during hospitalization Patients with history of traumatic brain injury, brain surgery and stroke in the last 6 months Occurrence of delirium or severe sleep disorder that makes the patient need drug treatment

Age
From **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the entry and exit criteria, samples from patients with orthopedic trauma requiring surgery referred to the male and female surgery departments of Imam Jafar Sadiq (AS) hospital in Aligudarz city are included in the study non-probably consecutively. In order to equalize the distribution of the two important confounders of age and sex, classes are created based on these two variables as "under 65 years/over 65 years" and "men's class/women's class" and then by block randomization in two The treatment and control groups are balanced. The size of each block is 4 items. The way to choose blocks randomly will be simple and with placement. STATA16 software will be used for block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Coding of groups as group A (intervention) and group B (control) is done by a nurse who has no role in the study, and this coding remains with this independent nurse until the end of data analysis. The data analyst, the nurse assessor (data collector) and the study participants do not know about the random assignment of the groups. Blinding of the interventionist is not possible due to the nature of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Lorestan University of Medical Sciences, Campus Kamalvavd, Vice Chancellor for Research and Technology

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Khorramabad

Province
Lorestan

Postal code
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Approval date
2022-10-19, 1401/07/27

Ethics committee reference number
IR.LUMS.REC.1401.175

Health conditions studied

1

Description of health condition studied
Orthopedic surgery patients

ICD-10 code
M84.9

ICD-10 code description
Disorder of continuity of bone, unspecified

Primary outcomes

1

Description
Delirium
Timepoint
Before the intervention and 48 and 72 hours after surgery
Method of measurement
Confusion Assessment Method (CAM)

2

Description
Sleep quality
Timepoint
Before the intervention and 48 hours after surgery
Method of measurement
Richards Campbell Sleep Questionnaire

Secondary outcomes

1

Description
Length of stay of orthopedic surgery patients after surgery in the surgery department
Timepoint
The length of the patient's stay in the ward after surgery until discharge
Method of measurement
Based on the patient's electronic file

2

Description
Mortality rate during the first month after surgery
Timepoint
30 days after surgery
Method of measurement
Telephone interview

Intervention groups

1

Description
Intervention group: First, in order to check the patient's medical history, allergy history, drug history and to ensure the absence of allergies and specific drug reactions, the electronic medical record of the patient is studied and he is also interviewed. In the intervention group, they will receive a 4-component intervention from 24 hours before to 48 hours after surgery - in the order explained below. In developing the schedule for the implementation of the intervention, it has been noted that the hours of implementation of the intervention components do not interfere with the hours of routine care in the ward and the distribution of meals to the patients. It should be noted that the resumption of interventions after the patient's surgery will be after the patient's clinical condition returns to a stable state. The entire intervention process will be carried out by the main researcher (student), and if there are two patients in the intervention group at the same time, the help of a trained and experienced researcher will be taken. Necessary arrangements will be made with the officials of the surgery departments to place the patients of the intervention group in a separate room. The four components of this intervention will start with the priority of patient pain management, and then continue with music therapy, cardio-respiratory support, and improving sleep hygiene for the intervention group. To control the pain, first, with the aim of checking the pain - after coordination with the patient's doctor - using the numerical pain rating scale (NRS) every 6 hours (6-12-18-24), the patient's pain score from one day before to two days It will be determined after surgery. Then, in order to treat the pain, analgesics will be prescribed by the nurse according to the developed protocol of literature review and expert panel. Medications mainly include nonsteroidal anti-inflammatory drugs such as ketorolac and paracetamol, and this protocol allows the nurse to independently administer analgesics to the patient. 30 to 60 minutes after the administration of the drugs, based on the method of administration and pain intensity, we will re-evaluate the patient's pain and if the pain is not controlled (i.e. pain score greater than 4) or there are side effects and adverse reactions to pain relievers, the appropriate decision will be made. Regarding the re-use of the analgesic or its discontinuation, it will be taken through consultation with the patient's physician. For patients with a known allergy to analgesics, the patient's physician will be consulted about an alternative medication. Oral analgesics will be prescribed with the expectation that the patient will not vomit and tolerate the oral route. For music therapy intervention, the type and style of music is based on the patient's preference and for 3 days (one day before and two days after the surgery), 2 times a day and each time for 30 minutes, between 15:00 and 21:00 based on The patient's preference for the patients of the intervention group will be implemented inside the department for the patient using the mp3 player and Sony brand headphones made in China. The volume of the music will be adjusted according to the patient's comfort and the intervention can be stopped at the request of the patient. Inspiratory muscle training will be done using the Threshold device (POWER breathe Classic, IMT Technologies Ltd, Birmingham, UK). Before starting the intervention, patients will be introduced to this device and will receive practical instructions on efficient diaphragmatic breathing. This intervention will be performed daily for 3 days and every day for 30 minutes from one day before to two days after surgery at 15:00. Each 30-minute session per day will consist of 3-minute training sets followed by short 1-minute rest intervals between sets, and will begin with the minimum pressure adjustable by the Threshold device and gradually increase and be performed in a comfortable position. The sleep hygiene intervention will also be carried out for 3 nights (one night before and two nights after the surgery) as follows:

First, a sleep hygiene package to ensure the patient's comfort and convenience (taking into account the patient's preferences), including blindfolds, Earplugs, lavender-scented bags, and caffeine-free drinks to patients in the intervention group. Patients in the intervention group will be placed in a standard room (in terms of temperature and light, away from noise, TV, computer, etc.) Or wear glasses.

Category
Treatment - Other

2

Description
Control group: The control group will receive routine care including receiving narcotics if needed according to the physician's order, receiving haloperidol in hyperactive delirium attacks according to the physician's order and other prescribed treatment measures.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Jafar Sadiq (AS) Hospital

Full name of responsible person
Goodarz Goodarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Ebrahim Falahi

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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
Khoram-Abad University of Medical Sciences

Proportion provided by this source
10

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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Mansureh Sohrabi

Position
University student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Associate professor

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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