Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Investigating the effect of progressive muscle relaxation on the level of anxiety and vital signs of hospitalized elderly

Protocol summary

Study aim

The use of progressive muscle relaxation as a supportive and non-pharmacological treatment method suitable for teaching elderly hospitalized patients to reduce anxiety and stabilize vital signs.

Design

This study is conducted on elderly patients admitted to the hospital as a single blind clinical trial in two random groups. In this study, the research assistant does not know the type of patient group and the data will be provided to him in a coded form.

Settings and conduct

Randomized clinical trial of two groups of intervention and one-blind control (data collector) of the elderly hospitalized in Hazrat Rasool Akram Hospital, Kalaleh city.

Participants/Inclusion and exclusion criteria

Patients who are 60 years old and above and have at least mild anxiety at the beginning of the study are included in the study, and those who take anti-anxiety drugs during hospitalization and undergo other complementary and surgical treatments during the study and do not complete the duration of the intervention for three days are among the exclusion criteria in this study. It will be a study.

Intervention groups

The progressive muscle relaxation technique is performed by the researcher for 20 minutes on hospitalized elderly for 3 consecutive days in the morning and evening. Vital signs (blood pressure, heart rate, breathing) will be measured and recorded by the researcher's assistant before performing the technique and 20 minutes after performing it. The control group, which did not use any technique, will be recorded before and after the same conditions as the intervention group. And at the end, the anxiety questionnaire will be completed by the participants. The obtained information will be analyzed.

Main outcome variables

Anxiety score, blood pressure, heart rate and breathing rate in hospitalized elderly people after progressive muscle relaxation between the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220813055677N1**
Registration date: **2022-09-08, 1401/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-08, 1401/06/17**
Update count: **0**

Registration date

2022-09-08, 1401/06/17

Registrant information

Name

ali Soheyli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3274 8144

Email address

alisoheily70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of progressive muscle relaxation on the level of anxiety and vital signs of hospitalized elderly

Public title
The method of progressive muscle relaxation on the level of anxiety and vital signs of the elderly
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 years and above Having at least mild anxiety upon entering the study Consent of the individual to participate in the study Absence of unstable chronic diseases Absence of neurological defects such as (stroke, Parkinson's disease and paralysis) Not taking anti-anxiety drugs Absence of limiting musculoskeletal disorders Absence of severe congenital defects (vision, hearing and mental disorders, etc.) People who have not participated in similar research. Doctor's approval to participate in the study and no other medical restrictions Absence of previously known mental disorder
Exclusion criteria:
Unstable chronic diseases Neurological defects such as (stroke, Parkinson's disease and paralysis) Taking anti-anxiety drugs Existence of restrictive musculoskeletal disorders Existence of severe congenital defects (vision, hearing and mental disorders, etc.) Participation in similar research Users of anti-anxiety drugs before hospitalization Hospitalization due to complementary treatments and surgery Disinterested in participating in the study
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Block Randomization method with blocks of 4 to 6 will be used. We will use Excel software and function (rand) to prepare random sequences. A specific numerical code will be assigned to each of the randomly generated sequences. When each individual enters the study, the group to which the individual belongs will be announced by contacting the epidemiologist of the study. The names and surnames of the patients along with the code created for them and the type of intervention received are registered and kept by the epidemiologist of the study who has the random chain.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is one-sided blind in that the research assistant who is responsible for completing the questionnaires and measuring vital signs is unaware of the group to which the patient belongs. This research is a one-way blinded randomized clinical trial study on the elderly hospitalized in Rasoul Akram Hospital, in such a way that after receiving the code of ethics and registration on the IRCT website and receiving the registration code at the clinical trial center, we will start recruiting patients. did Individuals after obtaining written informed consent from the patients which is in Appendix 5 (it should be noted that patients must sign two consent forms, one of which must be given to the researcher and the other to the patients) and after meeting the entry and non-entry criteria. , will enter the study and after receiving the initial information by the researcher's assistant, the people will be randomly and completely hidden and blinded as described above, placed in one or two intervention and control groups. The information of these people will be collected in CRF (Clinical Report Forms) which is in Appendix 6. The participants were divided into two intervention and control groups, the control group at 10-11 in the morning and 17-18 in the evening on two occasions for 3 consecutive days with an interval of 20 minutes, the vital signs (blood pressure, heart rate, respiration) are controlled and recorded in 24 4 shifts (three days in total 12 times) will be controlled and recorded by the researcher's assistant and at first the study vans will complete the existing questionnaire. It should be noted that the questionnaires are completed by the participants themselves in the study with them, but if they are unable to complete them with the help of the researcher, it will be completed in the form of an interview.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of North Khorasan University of Medical Sciences
Street address
Faculty of Nursing building, south side of Imam Ali Hospital, Shahriar St
City
Bojnurd

Province
North Khorasan
Postal code
94176-96786
Approval date
2022-07-06, 1401/04/15
Ethics committee reference number
IR.NKUMS.REC.1401.022

Health conditions studied

1

Description of health condition studied
Investigating the effect of progressive muscle relaxation on the level of anxiety and vital signs of hospitalized elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score
Timepoint
At the beginning and end of the study
Method of measurement
Beck's anxiety questionnaire

Secondary outcomes

1

Description
blood pressure
Timepoint
Four times a day for three days before and 20 minutes after the intervention
Method of measurement
KD 595 digital easy life blood pressure monitor

2

Description
Breathing rate
Timepoint
Four times a day for three days before and 20 minutes after the intervention
Method of measurement
It is counted by the research assistant in one minute

3

Description
Number of heartbeats
Timepoint
Four times a day for three days before and 20 minutes after the intervention
Method of measurement
Measurement with pulse oximeter

Intervention groups

1

Description
Intervention group: The control group will be monitored and recorded vital signs (blood pressure, heart rate, breathing) at 10-11 am and 17-18 pm on two occasions for 3 consecutive days at 20 minutes intervals. In 24 hours, 4 times (three days in total 12 times) are controlled and recorded by the assistant of the researcher and he completed the existing questionnaire at the beginning and end of the study. It should be noted that the questionnaires are completed by the study participants themselves or with them, but if they are unable to complete it with the help of the researcher, it is completed in the form of an interview. Blood, caffeinated drinks, feeling of elimination, consumption of heavy meals) and with a digital sphygmomanometer in a semi-sitting position, blood pressure of the patients from the right hand, heart rate by a pulse oximeter device (Beaver model) by the help of the researcher who has been trained by the researcher. And the correctness of the work of the researcher's assistant and the devices used and the method of measurement by him have been ensured and controlled and tested, and no intervention was done in these people. In the intervention group, the technique was performed on the patient's bed for 3 consecutive days in such a way that step by step along with the researcher, he was first taught step by step relaxation by progressive muscle relaxation method and he was asked to relax each of his muscles. Contract for 5 seconds. then release it for 10 seconds, in this way, first for the right hand and right forearm, right arm, left hand and forearm, left arm, forehead, eyes and cheeks, mouth and chin, neck, shoulders, shoulder girdle and the back of the neck, chest and abdomen, hips, right leg thigh, right leg leg, left thigh leg, left leg leg, then be completely relaxed and do deep tennis for 2 minutes in relaxation and relaxation and repeat this process twice a day. And from the second day of hospitalization (according to the approval of the attending physician), they were allowed to do relaxation exercises. Before performing the technique, all the additional equipment of the patient, such as watches, bracelets, rings, and fittings, and all equipment that could be separated, were separated from the patient and placed next to the patient. The patient is in a semi-sitting position with an angle of 30 degrees, according to the conditions of the inpatient department, this case is available for all subjects of the study. This technique is performed for the patient at 10-11 in the morning and 17-18 in the evening for 3 consecutive days for 20 minutes each time. After performing the technique, the vital signs (blood pressure, heart rate, breathing) are controlled and recorded by the assistant of the researcher after 20 minutes. In 24 hours, 4 times (three days in total 12 times) before and after the implementation of the technique, the patients' vital signs are monitored and recorded.
Category
Rehabilitation

2

Description
Control group: Individual characteristics questionnaire at the beginning of the study, anxiety questionnaire at the beginning of the study vans will be completed. Vital signs will be measured every day between 10-11 in the morning and 17-18 in the evening on two occasions with an interval of 20 minutes for 3 consecutive days by the researcher's assistant and recorded in the relevant checklist.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool Akram hospital in Kalaleh city

Full name of responsible person
Fateme Khorashadizadeh

Street address
Hazrat Rasool Akram Hospital, Al-Ghadir Blvd, Kalala City

City
Kalaleh

Province
Golestan

Postal code
49918 57311

Phone
+98 17 3544 7991

Email
alisoheily70@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Fateme Khorashadizadeh

Street address
Faculty of Nursing building, south side of Imam Ali Hospital, Shahriar St

City
Bojnurd

Province
North Khorasan

Postal code
9417696786

Phone
+98 58 3229 7096

Email
nurse.info@nkums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences

Full name of responsible person
Fateme Khorashadizadeh

Position
Assistant Professor of Bojnurd University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing building, south side of Imam Ali Hospital, Shahriar St.

City
Bojnurd

Province
North Khorasan

Postal code
94176-96786

Phone
009858332297096

Email
khorashadizadehf891@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Fateme Khorashadizadeh

Position
Assistant Professor of Bojnurd University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing building, south side of Imam Ali Hospital, Shahriar St.

City
Bojnurd
Province
North Khorasan
Postal code
94176-96786
Phone
009858332297296
Email
khorashadizadehf891@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Fateme Khorashadizadeh
Position
Assistant Professor of Bojnurd University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing building, south side of Imam Ali Hospital, Shahriar St.
City
Bojnurd
Province
North Khorasan
Postal code
94176-96786
Phone
009858332297296
Email
khorashadizadehf891@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, all clinical and demographic information is coded in SPSS software for sharing.
When the data will become available and for how long
The access period starts 6 months after the publication of the results
To whom data/document is available
Doctors and nurses working in academic institutions related to medical sciences
Under which criteria data/document could be used
Use of this research data will be permitted in meta-analysis studies
From where data/document is obtainable
Contact: alisoheily70@gmail.com to receive the data
What processes are involved for a request to access data/document
The applicant will be contacted within 48 hours, and if the academic and employment records of the research environment are properly submitted, research data will be provided to the applicant upon confirmation of the identity of the originator.
Comments