Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Progressive Relaxation Technique on Blood Pressure and Worry among Aged People With Blood Pressure : A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of progressive relaxation technique on elderly blood pressure Determining the impact of progressive relaxation technique on elderly concerns Determining the mediating role of concern about the relationship between relaxation and elderly blood pressure

Design

The research is a parallel clinical trial with a test and control group in which data is collected twice before and after. Sampling is a sequence of random block allocation. (Data collector and data analyst will not be notified of how individuals are assigned to groups)

Settings and conduct

Progressive relaxation technique is performed for people who refer to the blood pressure clinic of Imam Hossein Hospital's specialized clinic, who have high blood pressure and anxiety. Individuals in the test group are divided into four groups of ten, each of which is given a lecture and PowerPoint presentation during a training session on the steps to be taken and how to perform the technique.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age 60 and older - Understanding and speaking Persian - Being at elevated levels and levels 1 and 2 blood pressure - Cognitive ability based on MMSE test results - Gaining individual independence score in ADL test Output criteria: - Take sedatives over the past 1 week - Using previous relaxation techniques in the last 6 months - Having a depressive background based on the GDS-15 test

Intervention groups

The advanced relaxation technique will be performed by members of the test group for 4 weeks. Initially, the researcher will hold a meeting with the test group members to teach and explain the steps, and this technique will be performed twice a day in the morning and afternoon by people at home. Will run. During these 4 weeks, there will be no intervention on the control group and they will continue their routine care.

Main outcome variables

1- Worry 2- Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045524N1**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **prospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Amirheidar Bakhshiarab

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-19, 1399/03/30

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Progressive Relaxation Technique on Blood Pressure and Worry among Aged People With Blood Pressure : A Parallel Randomized Clinical Trial

Public title
Effectiveness Progressive Relaxation on Blood Pressure and Worry In The Elderly
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
60 years and older Understanding and speaking Persian language Being at elevated levels and levels 1 and 2 blood pressure Cognitive ability is shortened based on cognitive status testing Mini-Mental State Examination (MMSE) test results Earn individual independence scores on daily life activities Activity of Daily Livivng (ADL) test
Exclusion criteria:
Use sedatives over the past 1 week Using previous relaxation techniques in the last 6 months Having a depressive background based on a test of 15 questions of depression in the elderly Geriatric Depression Scale-15 (GDS-15) test
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation sequence and block list will be obtained by the software consultant with the help of the software. The https://www.sealedenvelope.com website is a useful site for generating random sequences for block randomization. This site is designed so that there is no limit to the number of groups to be assigned randomly. The four-volume block method is used with spss software to generate random allocation sequences. Patients will be selected according to the researcher's criteria and will be randomly divided into two groups (intervention) and group B (control group). Randomization will be done in secret. This means that there are 100 envelopes packed in A and B code each. After obtaining informed consent and determining that the individual is participating in the study, the researcher picks up the envelope in the specified order and proceeds according to the envelope group recorded.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research of Shahroud University of Medical Sciences
Street address
7th Square, Research and Technology, Shahroud University of Medical Science, Shahroud Town
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2020-05-09, 1399/02/20
Ethics committee reference number
IR.SHMU.REC.1399.033

Health conditions studied

1

Description of health condition studied
Blood Pressure And Worry
ICD-10 code
Z01.3
ICD-10 code description
Encounter for examination of blood pressure

Primary outcomes

1

Description
Examine the blood pressure level of people with a blood pressure monitor (ALPK2) that is calibrated before starting the procedure and also calibrated on a specific day each week. In this study, people with high blood pressure and blood pressure levels 1 and 2 entered the study according to the American Heart Association.
Timepoint
At the beginning of the study (before the start of the intervention) and 4 weeks after the intervention
Method of measurement
By the ALPK2 hand blood pressure monitor, which is calibrated before starting the procedure, and also

calibrated on a specific day each week.

2

Description

worry studies in people with high blood pressure are assessed through the Pennsylvania Concern Questionnaire. The range of scores for the questionnaire ranges from 16 to 80. The score is between 16 and 32: The severity of worry is low. Between 32 and 48: The severity of worry is moderate.

Timepoint

At the beginning of the study (before the start of the intervention) and 4 weeks after the intervention

Method of measurement

Pennsylvania Concerns Questionnaire. The scope of the questionnaire scores is from 16 to 80. Score between 16 and 32: The severity of worry is low. The score is between 32 and 48: The severity of worry is moderate.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The research community includes all the elderly who refer to the blood pressure clinic of the specialized clinic of Imam Hossein Hospital in 1399. After selection, individuals will be assigned to both test and control groups based on entry criteria. First, the MMSE (Mini-Mental State Examination) and ADL (Activity of Daily Living) and GD5-15 (Geriatric Depression Scale-15) questionnaires are completed for individuals, and then the concern questionnaire confirming the presence of the problem in individuals and so on. Blood pressure testing, which is performed at elevated levels and levels 1 and 2 as defined by the American Heart AHA (Association), is performed on individuals in the Jacobson Intervention Group. After selecting the test group members based on the criteria for entering and obtaining informed consent, they are trained in the same blood pressure clinic. The subjects of the test group are divided into four groups of 10 people and all groups are taught separately by the researcher in one session in the blood pressure clinic. A 60-minute session will explain the research objectives, blood pressure, and Worry and relaxation techniques. At the end of the session, how to implement the advanced relaxation technique and independent implementation of patients to ensure the correct implementation of the technique will be done. Also, at the end of the training phase, the research units will have a booklet that includes division of blood pressure levels and correct blood pressure measurement. According to the American Heart Association, progressive relaxation techniques are given. After the training, it is done in such a way that the members of the test group perform the technique they have been trained in at home for 20 to 30 minutes a day in the morning (7 to 8) and in the afternoon (4 to 5). Once a week, in order to follow up on the technique and the process of doing the work and the technique of the test group members, they refer to the medical service centers that are covered so that the person trained by the researcher monitors the work process of the test group members. A blood pressure monitor checks all test group members. This is done continuously for up to 4 weeks, and the test group and control group are again asked to be assessed by the Worry and blood pressure measurement questionnaire. The technique is to first close the eyes. And as much as possible, they are in a relaxed state and focus all their attention on their breathing. They take five deep breaths and slowly empty. At the same time, they think of peace, liberation, and weakness in their minds. After this stage, patients should contract and expand the muscle for 14 muscle groups, respectively, including the facial muscles (forehead, eyelids, jaw, lips), neck muscles, fingers, palms, forearms, arms, shoulders, back, waist, chest. , Abdomen, sitting, thighs, legs, feet, soles of the feet, do. It takes 5 seconds for each muscle to contract and 10 seconds for it to expand. Also, when the muscles contract, they should not tighten too much and put pressure on themselves. Finally, relax your whole body and take 5 deep breaths, slowly open your eyes and return to normal. For the group, the routine care control center is provided to control blood pressure and reduce Worry.

Category

Other

2

Description

Control group: People with high blood pressure and worry who go to the blood pressure clinic are the specialized clinic of Imam Hossein Hospital, which receives the center's routine care, and at the end of the study, the educational booklet is provided to patients.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Blood pressure clinic, specialized clinic of Imam Hossein Shahroud Hospital

Full name of responsible person

Amir Heidar Bakhshi Arab

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No 24, Alley 3, Kharghani Street, Shahroud Town

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
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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
AmirHeidar Bakhshi Arab
Position
Master's degree student inMaster's degree student inMaster's degree student in geriatric nursing, Sh
Latest degree
Bachelor
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)
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
Undecided - It is not yet known if there will be 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
Part of the patient's demographic information is shared after people have not been identified. All information related to measuring worry and blood pressure in patients can be shared after people have not been identified.

When the data will become available and for how long
Access started in September 1399

To whom data/document is available
Researchers and students of academic and scientific institutions

Under which criteria data/document could be used
Raw data for correlation studies

From where data/document is obtainable
amirheidar770@yahoo.com

What processes are involved for a request to access data/document
Clear explanation of the reason for the need to access data and provide data after two weeks

Comments