Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of educational intervention based on the Pender model on perceived stress and sleep quality of elderly people with hypertension

Protocol summary

Study aim
Determining the effect of training intervention based on the Pender model on perceived stress and sleep quality of elderly people with hypertension

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 66 patients. Block randomization method will be used for randomization in this study

Settings and conduct
Eligible elderly people who visit Nik-e-Iqbal and Imam Reza clinics in Jahrom during the study period will be included in the study after obtaining informed consent. Participants will be randomly assigned to two intervention and control groups using a randomized block design. This study will be conducted without blinding, but the data analyst will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 60 years, ability to read and write in Persian, having grade 1 or 2 hypertension, and willingness to participate in the study. Exclusion criteria: Participation in educational programs during the past six months, immobility, and consumption of alcohol or caffeine.

Intervention groups
Participants in the intervention group will attend one 45-minute training session each week for six weeks. The training is designed based on the Pender Health Promotion Model and will be delivered in groups of eight in the clinic classroom. The content includes stress management, improving sleep quality, strengthening self-efficacy, and promoting health behaviors. The training will be delivered by the researcher using slides and direct presentation.Participants in the control group will receive only routine clinic care during the study period, including regular doctor visits, vital signs checks, and general health monitoring. No additional educational interventions will be provided to this group.

Main outcome variables
Perceived stress, sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250518065790N1**
Registration date: **2025-07-19, 1404/04/28**
Registration timing: **prospective**

Last update: **2025-07-19, 1404/04/28**
Update count: **0**

Registration date
2025-07-19, 1404/04/28

Registrant information

Name
Reihaneh Sepehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5447 5601

Email address
reresep5@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2025-08-06, 1404/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of educational intervention based on the Pender model on perceived stress and sleep quality of elderly people with hypertension

Public title

Training based on the Pender model on perceived stress and sleep quality in elderly people with hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals over 60 years old. The ability to speak, read, and write in Persian. diagnosed with grade 1 or 2 hypertension by a cardiologist. Stage 1 hypertension includes systolic blood pressure of 140-159 or diastolic blood pressure of 90-99, and stage 2 hypertension involves systolic blood pressure equal to or greater than 160 or diastolic blood pressure equal to or greater than 100. participants must have a willingness to take part in the study.

Exclusion criteria:

Participation in educational programs in the past six months Individuals who use hydrotherapy and massage therapy. Individuals who are immobile "Individuals who consume alcohol and caffeine

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method will be used using a random number table. Block randomization with a block size of 4 with equal probability for eligible elderly people to the intervention (group B) and control (group A) groups will be used. Given the block size of 4, there will be 6 possible combinations of group assignments including: ABAB, AABB, BBAA, BABA, BAAB, ABBA. First, one of the arrangements will be randomly selected and four eligible elderly people will be assigned to each block in order. This process will be repeated many times until eligible elderly people are included.

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

Research Ethics Committees of Jahrom University of Medical Sciences

Street address

Pardis Site, Jahrom University of Medical Sciences, Ostad Motahari Street, Jahrom, Fars Province, Iran

City

Jahrom

Province

Fars

Postal code

74148-46199

Approval date

2025-05-17, 1404/02/27

Ethics committee reference number

IR.JUMS.REC.1404.021

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

R03

ICD-10 code description

Abnormal blood-pressure reading, without diagnosis

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

Pitsburgh Sleep Quality Questionnaire

2

Description

Perceived stress

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

Cohen's Perceived Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Participants in the intervention group will attend one 45-minute educational session per week for six consecutive weeks (a total of six sessions). These sessions will be designed based on the Pender Health Promotion Model and will be delivered in groups of eight in the clinic’s classroom.The content of the sessions will include:Stress management using relaxation techniques (e.g., deep breathing and progressive muscle relaxation),Improving sleep quality through sleep hygiene education,Strengthening self-efficacy in performing healthy behaviors,Promoting daily health-related behaviors.The training will be delivered by the researcher through direct instruction and PowerPoint slides. Interactive methods such as group discussion, Q&A, and practical exercises will be used in each session. At the end of each session, an educational brochure related to the topic will be provided to participants. Sessions will be held in the clinic’s education room equipped with audiovisual facilities, comfortable seating, appropriate lighting, and controlled temperature. No medication or chemical substances will be used.

Category
Lifestyle

2

Description
Control group: Participants in the control group will receive only routine clinic care during the study period, including regular doctor visits, vital signs checks, and general health monitoring. No additional educational interventions will be provided to this group. At the end of the study, in order to comply with ethical principles, a summary of the educational content will also be provided to this group.

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik Iqbal Clinic, Jahrom City
Full name of responsible person
Reihaneh sepehr
Street address
Imam Reza Street, Adib Street, Farhangshahr, Jahrom
City
Jahrom
Province
Fars
Postal code
7413653335
Phone
+98 71 5447 5608
Email
Rersep5@gmail.com

2

Recruitment center
Name of recruitment center
Imam Reza (AS) Clinic, Jahrom City
Full name of responsible person
Reihaneh sepehr
Street address
Imam Reza Clinic, Monouchehri Street, Kolvan (Farhang) District, Jahrom, Fars Province
City
Jahrom
Province
Fars
Postal code
7413653335
Phone
+98 71 5423 0010
Email
Rersep5@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Amir Abdoli
Street address
Vice-Chancellor for Research, Jahrom University of Medical Sciences, Motahari Blvd., Jahrom, Fars Province
City
Jahrom
Province
Fars
Postal code
74148-46199
Phone
+98 71 5434 1501
Email
research@jums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Reihaneh Sepehr

Position

Master's Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Pardis Campus, Jahrom University of Medical Sciences, After Nursing School, Ostad Motahari Street, Jahrom, Fars Province, Iran

City

Jahrom

Province

Fars

Postal code

7414846199

Phone

+98 71 5447 5608

Email

Reresep5@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Ali Dehghani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Pardis Campus, Jahrom University of Medical Sciences, After Nursing School, Ostad Motahari Street, Jahrom, Fars Province, Iran

City

Jahrom

Province

Fars

Postal code

7414846199

Phone

+98 71 5447 5608

Email

Ali.Dehghani2000@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Reihaneh Sepehr

Position

Master's Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Pardis Campus, Jahrom University of Medical Sciences, After Nursing School, Ostad Motahari Street, Jahrom, Fars Province, Iran

City

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Province

Fars

Postal code

7414846199

Phone

+98 71 5447 5608

Email

Reresep5@gmail.com

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