Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of spiritual care based on GALB SALIM model on quality of life and psychological well – being of elderly with hypertension

Protocol summary

Study aim

Determining the effect of spiritual care based on the healthy heart model on the quality of life and psychological well-being of elderly people with high blood pressure

Design

This study is a phase 4 clinical trial. The sample size is 70 elderly patients with high blood pressure and eligible volunteers are divided into groups using a block-based permutation randomization method. Using random numbers generated by the rand function in Excel software, 12 blocks are selected and individuals are placed in groups based on the block codes. Based on the selected software, the samples are divided into two intervention and control groups, with 35 people in each group.

Settings and conduct

After receiving the research agreement from the university research council and receiving the code of ethics, the researcher will visit Valiasr Hospital and comprehensive health centers in Fasa city and provide them with the project questionnaires. The questionnaire includes a demographic questionnaire, a blood pressure patients' quality of life questionnaire, and a psychological well-being questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people over 60 years old, suffering from high blood pressure, not suffering from a serious illness such as cancer, unable to read and write, not deaf or blind Exclusion criteria: participation in a similar study

Intervention groups

For the spiritual care intervention group based on the Healthy Heart Model, which emphasizes four aspects of connection with God, connection with self, connection with others, and connection with nature, 9 training sessions will be conducted in a combined format (in-person and virtual). An educational booklet will also be prepared and made available to the group.

Main outcome variables

Quality of life and psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250611066184N2**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date

2025-10-07, 1404/07/15

Registrant information

Name

Azam Zare Banadkoki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-31, 1404/08/09

Expected recruitment end date

2026-02-18, 1404/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
the effect of spiritual care based on GALB SALIM model on quality of life and psychological well – being of elderly with hypertension

Public title
the effect of spiritual care based on GALB SALIM model on quality of life and psychological well – being of elderly with hypertension

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
People over 60 years old Suffering from high blood pressure Not having a serious illness such as cancer Not having a mental illness No drug use Ability to read and write Willingness to participate in the study Not being deaf or blind Self-awareness of current illness

Exclusion criteria:
Participating in a similar study Absence from more than one training session Reluctance to cooperate

Age
From **60 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be divided into study groups using a randomization method based on random block permutation. First, a four-word block is generated, from which 12 blocks are selected using Excel software, and individuals are placed into two intervention and control groups based on the block codes.

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 of fasa University of medical sciences

Street address
Abn Sina Squre

City
Fasa

Province
Fars

Postal code
74616-86688

Approval date
2025-09-22, 1404/06/31

Ethics committee reference number
IR.FUMS.REC.1404.133

Health conditions studied

1

Description of health condition studied
Elderly with High blood pressure

ICD-10 code
I10_115

ICD-10 code description
Hypertensive diseases

Primary outcomes

1

Description
Quality of life

Timepoint
Before, After, 1Month Later

Method of measurement
To assess the quality of life of elderly people with high blood pressure, a specific questionnaire for the quality of life in people with high blood pressure was designed by Shamsi and Dehghan Nayiri in 2022. This questionnaire is in accordance with the culture and customs of Iranian society.

Secondary outcomes

1

Description
Psychological well-being

Timepoint
Before, After,1 Month Later

Method of measurement
The Psychological Well-Being Questionnaire was designed by Riff in 1989. The components of this questionnaire include: self-acceptance, positive relationships with others, autonomy, purposeful living, personal growth, and mastery of the environment, which has 18 questions. Latifi et al. standardized this questionnaire in Iran.

Intervention groups

1

Description

Intervention group: Before the intervention, the demographic checklist, Quality of Life Questionnaire, and Psychological Well-being Questionnaire are completed by the intervention group. For the intervention group, an educational spiritual care intervention based on the 'Sound Heart Model' will be conducted, consisting of 9 mixed educational sessions (in-person and virtual). At the beginning of the study, all participants will join a WhatsApp group where supplementary materials will be shared and their questions answered. Additionally, an educational booklet will be prepared and distributed to the intervention group during the study. The first session focuses on familiarization and building rapport with the participants, discussing the study's objective, the timing and number of educational classes, the study process, and the necessity of strengthening moral virtues. The second session addresses the positive aspects of challenges and educates participants on the concept of spiritual health, characteristics of individuals with a 'Sound Heart,' the impact of spiritual health on various dimensions of well-being, and methods to achieve spiritual health. The third session teaches problem-solving skills and essential skills for lifestyle modification. The fourth session emphasizes self-connection, providing education on hypertension (disease symptoms, complications, risk factors, appropriate diet and activity, etc.), and also discusses human dignity and the story of human creation with divine love, starting with Adam. The fifth session focuses on connection with God, playing audio files of prayers and the Quran. Recommendations are also made for prayer and supplication, performing daily prayers (Salat), reciting the Quran, and narrating Quranic stories. The sixth session (connection with others) teaches about visiting relatives, paying attention to one's spouse and children, laughter and cheerfulness, charity (infaq), forgiveness, and showing love to others. In the seventh session (connection with nature), patients are advised to observe flowing water, trees, and flowers, to smell them, cultivate flowers, and show compassion to animals, etc. Additionally, pleasant sounds such as rain, flowing water, and bird songs are played. In the eighth session, the patient's values and motivations are identified, and assistance is sought from the patient's closest individual to foster motivation. In the ninth and final session, illustrative anecdotes are used to give meaning to life events, self-control skills are taught, and finally, patients' opinions on the classes and their impact on their lives are evaluated. Immediately and one month after the educational classes, the Quality of Life and Psychological Well-being questionnaires are re-completed by the individuals.

Category

Lifestyle

2

Description

Control group: Initially, individuals in this group complete the demographic checklist, Quality of Life Questionnaire, and Psychological Well-being Questionnaire. The control group does not receive any training. Immediately and one month after the educational sessions (of the intervention group), this group will re-complete the Quality of Life and Psychological Well-being questionnaires.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Waliasr Hospital Fasa

Full name of responsible person
Azam Zare

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Recruitment center

Name of recruitment center
Fasa Comprehensive health centers

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Office of Research , fasa University of medical sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Fasa 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

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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

All data can be shared after the individuals participating in the study are de-identified.

When the data will become available and for how long

Access begins four months after results are published.

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

To write meta-analysis studies

From where data/document is obtainable

Dr. Azam Zare, Fasa University of Medical Sciences

What processes are involved for a request to access data/document

Send a written request

Comments