Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of self-care education based on Orem model with acceptance and commitment therapy on lifestyle of patients with hypertension.

Protocol summary

Study aim
Comparison of the effect of self-care education based on Orem model with acceptance and commitment therapy on lifestyle of patients with hypertension .

Design
120 eligible seniors will be divided into 3 groups (two intervention groups and one control group) using a simple random division method using a random number table, and the type of intervention will be determined again by random division on each group.

Settings and conduct
In patients with uncontrolled hypertension referred to health centers in Rafsanjan, intervention in the self-care group is done as a group training by the researcher and in the treatment group based on acceptance and commitment of group training by a clinical psychologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: high blood pressure, being 40 years old or older, having a phone, ability to attend training sessions, minimum primary education, no known mental illness and willingness to participate. Exclusion criteria include: non-cooperation, hospitalization during the study period and illnesses that force the patient to take antihypertensive drugs during the study, and consecutive absence in two sessions or absence in a quarter of all sessions

Intervention groups
At first, all groups will complete a health-promoting lifestyle questionnaire, and then in the self-care intervention intervention group, according to the Orem model, 8 90-minute sessions will be held for individuals for one month. At the end of each session, educational pamphlets related to individuals will be given. In the acceptance and commitment-based treatment intervention group, 8 90-minute sessions will be held by the clinical psychologist for one month, and at the end of the sessions, educational pamphlets will be given to the individuals. Routine care is performed in the control group.

Main outcome variables
life style

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N27**
Registration date: **2023-02-06, 1401/11/17**
Registration timing: **retrospective**

Last update: **2023-02-06, 1401/11/17**
Update count: **0**

Registration date
2023-02-06, 1401/11/17

Registrant information

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Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-04-21, 1401/02/01

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

Scientific title
Comparison of the effect of self-care education based on Orem model with acceptance and commitment therapy on lifestyle of patients with hypertension.

Public title
Comparison of the effect of self-care education based on Orem model with acceptance and commitment therapy on lifestyle of patients with hypertension.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The certainty of having uncontrolled blood pressure through the control of blood pressure recorded in the previous three periods Having an age range of 40 years and above Having a phone and knowing how to use it Ability to participate in training sessions Minimum primary education No known mental illness Willingness to participate in the project
Exclusion criteria:
Non-cooperation based on training programs Hospitalization during the research period Consecutive absence in two sessions or absence in a quarter of all sessions Suffering from diseases that force the patient to take blood pressure medications during research
Age
From **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying the depressed elderly according to the inclusion criteria and its listing, they will be divided into 3 groups of 40 people A, B and C by simple random division using a table of random numbers and then the groups will be divided again by simple random division. On each group (2 intervention groups and one control group) it will be determined what intervention will be done on each group
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 Committee of Rafsanjan University of Medical Sciences
Street address
School of Nursing and Midwifery, Nurse Avenue, Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Approval date
2021-11-22, 1400/09/01
Ethics committee reference number
IR.RUMS.REC.1400.188

Health conditions studied

1

Description of health condition studied
hypertention
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Lifestyle of patients with hypertension
Timepoint
All individuals will complete a health-promoting lifestyle questionnaire at the beginning and then at the end of the intervention, and eight weeks after the intervention.
Method of measurement
HPLP Health Promoting Lifestyle Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the education group according to the Orem model, after random allocation, expression of goals and gaining patients 'satisfaction, first the patients'

self-care needs based on the forms of examination and recognition of Orem including self-care needs based on the Orom model (including 44 cases in three dimensions: general self-care needs, needs Self-care and self-care needs have been deviated from health). After determining the needs of patients, a self-care program will be developed which will be held in groups in 8 sessions of 90 minutes through discussion for patients in the experimental group. Attention to the stage of reviewing and recognizing the needs of self-care based on the Orem model will be designed and developed in the form of educational-supportive nursing care program, and after creating the needs, appropriate educational materials will be evaluated. And then will be approved by a cardiologist. The training content will be taught in eight 90-minute sessions for one month. Training will be done in groups. During this time, patients will be contacted regularly via mobile phone. At the end of each session, a training pamphlet in accordance with the training given to patients will be given and during the week the patient will be monitored by phone for the training given and the researcher number will be given to the patient. At the end of these four weeks, patients will complete a lifestyle questionnaire.

Category

Lifestyle

2

Description

Intervention group: Intervention group: Interventions in the acceptance and commitment group training group will be held in 8 sessions of 90 minutes, twice a week for a month by a group psychologist based on the model of Hayes, Stroessel and Wilson and at the end of each A session of an educational pamphlet will be given to the individual in accordance with the training given. During the week, the researcher will communicate with patients by telephone. And the researcher number will be given to individuals. At the end of the sessions, patients will complete a lifestyle questionnaire. The questionnaires will be completed again eight weeks after the interventions.

Category

Lifestyle

3

Description

Control group: Control group: There will be no intervention in the control group during the study period. Only routine care will be provided and questionnaires will be completed by individuals.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Rafsanjan

Full name of responsible person

Dr. Ali Ravari

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Faculty of Nursing, Nurse blvd., Jomhury street, Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan 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?

No

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person
Dr. Ali Ravary
Position
Associate Professor
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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