Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison the effect of self-care based on the Orem’s model with the Pender's health promotion model on medication adherence and quality of life of the elderly with hypertension.

Protocol summary

Study aim

Comparison the effect of self-care based on the Orem’s model with the Pender's health promotion model on medication adherence and quality of life of the elderly with hypertension

Design

93 eligible elderly people will be divided into three groups by simple random division method using a table of random numbers, and the type of intervention will be assigned to each group again by random division

Settings and conduct

In the elderly with hypertension referring to the health centers of Rafsanjan city, in the self-care intervention group based on the Orem model and the intervention group based on the Pender model, group training is conducted by the researcher

Participants/Inclusion and exclusion criteria

Entry conditions: 1.over 60 years old, 2. history of hypertension for at least 6 months, 3. poor and moderate medication adherence 4. Basic reading and writing skills 5. Not having a hearing or speech defect 6. Absence of serious physical disability and accompanying chronic debilitating diseases 7. Having a mobile phone 8. Ability to participate in sessions 9. Not suffering from known mental illnesses 10. Willingness to participate in the study Exit conditions: 1. Non-cooperation 2. Hospitalization during the course 3. Consecutive absence in two sessions or absence in one third of all sessions

Intervention groups

At first, all the groups will complete medication adherence and quality of life questionnaires, in the intervention groups, after determining the needs based on the model, content according to Orem models and Pender's health promotion in the two intervention groups for one month. And it will be presented face to face and in groups in 6 sessions of 45 to 60 minutes. At the end of each session, each of the two intervention groups will be given a related educational pamphlet. No intervention is performed in the control group.

Main outcome variables

medication adherence; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N30**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **prospective**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**

Registration date

2023-07-21, 1402/04/30

Registrant information

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Tayebeh Mirzaei
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Rafsanjan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-23, 1402/08/01

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

Scientific title
Comparison the effect of self-care based on the Orem's model with the Pender's health promotion model on medication adherence and quality of life of the elderly with hypertension.

Public title
Comparison the effect of self-care based on the Orem's model with the Pender's health promotion model on medication adherence and quality of life of the elderly with hypertension.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being over 60 years old History of high blood pressure for at least 6 months Elderly people who have poor and moderate medication compliance (getting a score of less than 6 and a score of 6 to less than 8) based on Moriski's eight-question medication adherence questionnaire Basic reading and writing skills Not having a hearing or speech defect Absence of serious physical disability and associated chronic debilitating diseases (such as chronic lung cancer, heart failure disease, rheumatoid arthritis, and lupus erythematosus), which would interfere with self-care Having a mobile phone in order to coordinate meetings and communicate with clients Ability to participate in training sessions Not suffering from known mental illnesses Willingness to participate in the study
Exclusion criteria:
Non-cooperation based on the training programs Hospitalization during the course Consecutive absence in two sessions or absence in one third of all sessions
Age
From **60 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying the elderly who meet the study entry criteria and listing them, they will be divided into 3 groups of 31 people A, B and C by simple random division using a table of random numbers, and then again the groups will be divided by simple random division type Intervention on each group (two 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
2023-07-19, 1402/04/28
Ethics committee reference number
IR.RUMS.REC.1402.050

Health conditions studied

1

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

Primary outcomes

1

Description
medication adherence in elderly with hypertension
Timepoint
All participants will complete Moriski's medication adherence questionnaire at the beginning and then at the end of the interventions
Method of measurement
Moriski's Medication Adherence Questionnaire

2

Description

Quality of life of the elderly with hypertension

Timepoint

All participants will complete the Bowling's quality of life of the elderly questionnaire at the beginning and then at the end of the interventions

Method of measurement

Bowling's Quality of Life of The Elderly Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the self-care intervention group of the Orem model, after stating the goals and obtaining the patients' satisfaction, the self-care needs of the patients will be determined based on the Orem assessment and recognition forms designed by the researcher with an emphasis on medication adherence and quality of life. These needs will be identified in three dimensions: general self-care needs, developmental self-care needs, and health deviation self-care needs. After determining the needs of the patients, self-care program for one month (first session in the first week, second and third session in the second week, fourth and fifth session in the third week and sixth session in the fourth week) and in 6 sessions in the way of face to face and in groups. It will be implemented. The participants will be divided into 3 groups of 8 and one group of 7 people and will be trained in 6 sessions of 45 to 60 minutes. The meetings will be held in the form of discussions, questions and answers, presentation of booklets and pamphlets by the researcher, at the Rafsanjan College of Nursing and Midwifery, the content of the meetings will be prepared based on reliable sources. And during this period, communication will be established with patients through mobile phones. And at the end of each session, an educational pamphlet will be given to the patients according to the recommendations and training given, and during the week the patient will be monitored by phone calls in terms of carrying out the given training. At the end of the study, the standard questionnaire of the quality of life of the elderly and the Moriski medication adherence questionnaire will be completed by the patients.

Category

Lifestyle

2

Description

Intervention group: In the intervention group of the Pender health promotion model, a survey and assessment form for the individual needs of the participants will be designed with an emphasis on medication adherence items and quality of life components. These needs are identified according to the constructs of the model, including evaluation in terms of perceived benefits, perceived barriers, family and social relationships, perceived self-efficacy, knowing the benefits of having a commitment to performing the behavior. After determining the needs of the patients, the content of the intervention was prepared based on reliable sources and the necessary information regarding behavior change for one month (the first session in the first week, the second and third sessions in the second week, the fourth and fifth sessions in the third week and the sixth session in the fourth week) and will be provided to the participants in 6 sessions in the way of face to face and in groups. The participants will be divided into 3 groups of 8 and one group of 7 and will be trained in 6 sessions of 45 to 60 minutes. The sessions will be held in the form of discussions, questions and answers, presentation of booklets and pamphlets by the researcher, at the Rafsanjan College of Nursing and Midwifery. And during this period, communication will be established with patients through mobile phones. And at the end of each session, an educational pamphlet will be given to the patients according to the recommendations and training given, and during the week the patient will be monitored by phone calls in terms of carrying out the given training. At the end of the study, the standard questionnaire of the quality of life of the elderly and the Moriski medication adherence questionnaire will be completed by the patients.

Category

Behavior

3

Description

Control group: During the study period, there will be no intervention in the control group and the questionnaires will be completed by the participants.

Category

N/A

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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Sponsors / Funding sources

1

Sponsor

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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
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 Ravari
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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