

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of application of "Roy's adaptation model" on blood pressure and quality of life of hypertensive patients

Protocol summary

Study aim

Determination of application of "Roy's adaptation model" on blood pressure and quality of life of hypertensive patients

Design

This is a quasi-experimental study which includes two groups: intervention and control. Participants were chosen randomly but allocation to the groups was not randomized. Also the study was not blinded. Study included 3 phase: pre-intervention, intervention and post-intervention.

Settings and conduct

The study took place in emergency department of Yazd Heart Center. After sampling blood pressure and quality of life were measured. Roy's adaptation model was applied to the intervention group according to nursing process; whereas there was no intervention in the control group. First participants were assessed by Roy's assessment form. Next nursing diagnoses were determined according to incompatible behavior and stimuli. After that a goal was set for every diagnoses. Then the strategies for reaching the goals were planned. Then the strategies (education, referral, advice, follow up) were implemented. Evaluation was done by the amount of reaching the goals.

Participants/Inclusion and exclusion criteria

Hypertensive patients who were 40 to 60 years old and could read and write. Also physician diagnosed them as hypertensive for at least 2 years.

Intervention groups

The study included two groups: intervention and control. Roy's adaptation model was applied in the intervention group whereas there was no intervention in the control group.

Main outcome variables

Reduction of systolic and diastolic blood pressure, Improvement of quality of life score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041971N1**

Registration date: **2019-01-20, 1397/10/30**

Registration timing: **retrospective**

Last update: **2019-01-20, 1397/10/30**

Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Mahboobeh Khani sanij

Name of organization / entity

Tarbiat modares university

Country

Iran (Islamic Republic of)

Phone

+98 35 3821 9013

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-05, 1396/03/15

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

2017-06-05, 1396/03/15

Actual recruitment end date

2017-08-16, 1396/05/25

Trial completion date

2018-02-09, 1396/11/20

Scientific title

The effect of application of "Roy's adaptation model" on blood pressure and quality of life of hypertensive patients

Public title

The effect of application of "Roy's adaptation model" on blood pressure and quality of life of hypertensive patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40-60 years Being diagnosed as hypertensive patient for at least 2 years Being able to read and write Being diagnosed as hypertensive patient by physician

Exclusion criteria:

Admission to hospital during the study Being absent in more than 2 planned sessions

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Tarbiat Modares University

Street address

Nasr, Jalal AleAhmad st.

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2017-01-18, 1395/10/29

Ethics committee reference number

IR.TMU.RES.1395.495

Health conditions studied

1

Description of health condition studied

Hypertnsion

ICD-10 code

I15

ICD-10 code description

Secondary hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Omron Blood pressure monitor, Model M10-IT

2

Description

Quality of life

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Quality of life questionnaire S-F36

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Application of Roy's adaptation model. First of all the participants were assessed by Roy's assessment tool. Maladaptive behavior and stimuli were determined. Then nursing diagnoses and goals were set. Then nursing care plan was set. After that strategies like education, referral, consultation and follow up were implemented. After all the amount of reaching the goals was evaluated.

Category

Lifestyle

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Heart Center

Full name of responsible person

Mahboobe Khani Sanij

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Jomhoori Blvd, Yazd heart center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr Yaghoub Fathollahi

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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

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Dr Zohre Vanaki

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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