

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Self-help Groups on Self-care Behaviors of Women Aged 30-35

Protocol summary

Summary

Overall Objectives: Determining the effect of self-help groups on self-care behaviors of women aged 30-60 years old. This study is done in two stages. Cross-sectional study to assess the reliability and validity of the questionnaire - An educational interventional study on 100 hypertensive patients (in each group of 50 people). This study is carried out through the following steps: - Selection of samples - Blood pressure measurement and index Body mass of the subjects - pre-test by distributing the questionnaire and studying the motivation, self-efficacy and self-care behavior of hypertensive patients before intervention. Self-care curriculum package based on pre-defined needs assessment - Provide self care curriculum to two intervention and control groups - Formation of self-help groups based on the instructions for forming self-help groups in groups of 10 and steering groups in Organizing self-care sessions once a week - Organizing training sessions for group leaders - Involving researchers in self-help group sessions as facilitators for four sessions and then indirectly through leaders - Performing a post-test and redistributing a three month questionnaire. Next, the criteria for entering the study are: - proven blood pressure disease - having records in the health database Exclusion criteria: side effects of blood pressure ; pregnancy blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062634769N1**
Registration date: **2017-08-20, 1396/05/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Fateme Safari

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-07-16, 1396/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Self-help Groups on Self-care Behaviors of Women Aged 30-35

Public title

High Blood Pressure Self-care

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:(Proven blood pressure disease; Having a case at the health center) Exclusion criteria: (side effects of blood pressure ; pregnancy blood pressure)

Age
From **30 years** old to **59 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Governmental

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square,
Sardasht, Arak

City

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Postal code

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.ARAKMU.1395.447

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Self-care is blood pressure

Timepoint

3 Month

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Increase self-care

Timepoint

3 month

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: only booklet

Category

Behavior

2

Description

Intervention group:Booklet and self-help group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shazand Health Center

Full name of responsible person

Fateme Safari

Street address

Health Center, Shahied Motahari Hospita Street,
Shazand

City

Shazand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Arak University of
Medical Sciences

Full name of responsible person

Fateme Safari

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Arak University of Medical Sciences, Basij Square,
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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
Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty