

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of education based on Levental's self regulation model on illness perception and lifestyle in patients with hypertension .

Protocol summary

Study aim

Determining the Effect of Intervention Based on the Levental's Self-regulation model on illness perception and Lifestyle of Patients with Hypertension

Design

The study was a clinical trial with control group, with parallel groups, 90 patients with hypertension randomly divided into two groups of control and test.

Settings and conduct

90 patients with primary hypertension type 1 and 2 are assigned randomly into two groups of 45 intervention and control groups. The educational intervention is carried out at the Shahid Dastgheib Health Center in Yasuj, Iran. The data collection tool was a questionnaire for perceived disease and lifestyle that was completed before and 3 months after intervention by the patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: Early diagnosis of high blood pressure
Early diagnosis of hypertension with expert opinion, aged 18 to 65 years, at least six months of hypertension diagnosis, having a willingness to participate in the study, gaining a lifestyle score of 105 or less, no psychological intervention, or counseling about Hypertension, hypertension, hypertension, stage 1 or 2
Exit criteria: Cancellation of the continuation of the study whenever the patient wishes, the occurrence of new illness or critical complications of high blood pressure such as heart and brain attack and dialysis

Intervention groups

Intervention group undergoes 5 sessions of training in a group based on the sub-scales of identity, cause, duration, outcome, control and treatment, coherence of the disease, emotional manifestations of illness and lifestyle education in person. The control group is not subject to any intervention.

Main outcome variables

illness Perception : lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020401N6**

Registration date: **2019-05-08, 1398/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

Nazafarin Hosseini

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 5144

Email address

hosseini.nazafarin@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-08, 1398/01/19

Expected recruitment end date

2019-06-08, 1398/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on Levental's self regulation model on illness perception and lifestyle in patients with hypertension .

Public title

The effect of education based on Levental's self regulation model in patients with hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Early diagnosis of high blood pressure Early diagnosis of hypertension with expert opinion aged 18 to 65 years at least six months of hypertension diagnosis having a willingness to participate in the study gaining a lifestyle score of 105 or less no psychological intervention, or counseling about Hypertension hypertension, stage 1 or 2

Exclusion criteria:

Being afflicted with critical complications of high blood pressure such as heart and brain and doing dialysis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

A random block method is used. with the aim of equalizing the number of people in the intervention and control group, factor 2 is used by factoring law And 24 blocks of 4 persons that differ in their ordering so that in each block two samples of the control and intervention group and in the form of a draw, one of the blocks is selected. Sampling is continued until 45 patients in 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

Ethics committee of yasuj University of Medical Sciences

Street address

Assistance of Research and Technology of the University , Yasouj University of Medical Sciences , Shahid Motahari Blvd., Yasuj , Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2019-03-01, 1397/12/10

Ethics committee reference number

IR.YUMS.REC.1397.147

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

illness perception

Timepoint

Before and 3 months after the intervention

Method of measurement

IPQ-R questionnaire(illness perception questionnaire revised)

2

Description

lifestyle

Timepoint

Before and 3 months after the intervention

Method of measurement

LSQ Life Style Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 45 people undergo a 5-sessions 60-minutes training course on the perception of illness and lifestyle

Category

Prevention

2

Description

Control group: 45 patients in group control do not receive educational

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Yasuj Health Center

Full name of responsible person

Nazafarin Hosseini

Street address

nursing school , Dr. Shahid Jalil street, Yasouj , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Vice-chancellor of Research, Dr. Hossein Mari Oryad

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Nazafarin Hosseini

Position

Ph.D. Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Contact

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Phone**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