Assessment of 10 weeks of home- versus gym-based combined exercise training effect on the plasma levels of TXNIP, Insulin Sensitivity and Lipid profiles in men with primary hypertension

Protocol summary

Study aim
Assessment of 10 weeks of home- versus gym-based combined exercise training effect on the plasma levels of TXNIP, Insulin Sensitivity and Lipid profiles in men with primary hypertension

Design
A clinical trial, with a control group and two experimental groups (Gym-based combined training group, Home-based combined training group), 60 patients, randomized

Settings and conduct
Blood variables and the blood pressure will be measured before and after the training program (intervention). The correct way to perform the combined training program at the gym and home is given to the patients in a short video format after instructing by coach. This study will be conducted in Birjand town.

Participants/Inclusion and exclusion criteria
Inclusion criteria: men with primary hypertension (140-159/90-99 millimeter of mercury), non-athlete
Exclusion criteria: having joint problems, smoking and drug addiction, using of calcium channel blockers such as verapamil, amlodipine, diltiazem

Intervention groups
Intervention groups: Experimental group 1 (gym-based combined training): combined training (aerobic, resistance using pin-loaded resistance equipment and stretching exercise) for 70 to 85 minutes per session, four sessions per week, with 60 to 80 percentage of 1-repetition maximum intensity will be performed at gym for 10 weeks. Experimental group 2 (home-based combined training): combined training (aerobic, resistance using an elastic exercise band and stretching exercise) for 70 to 85 minutes per session, four sessions per week, with 12 to 15 rating of perceived exertion of Borg scales intensity will be performed at home for 10 weeks. Control group: This group will not receive intervention.

Main outcome variables
TXNIP, Insulin Sensitivity, Lipid profiles, hypertension

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20160317027092N2
Registration date: 2020-02-08, 1398/11/19
Registration timing: retrospective

Last update: 2020-02-08, 1398/11/19
Update count: 0
Registration date
2020-02-08, 1398/11/19

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-21, 1398/02/01
Expected recruitment end date
2019-05-21, 1398/02/31
Actual recruitment start date
empty
Assessment of 10 weeks of home- versus gym-based combined exercise training effect on the plasma levels of TXNIP, Insulin Sensitivity and Lipid profiles in men with primary hypertension

Inclusion criteria:
- Age range between 30-70 years is allowed. According to a specialist doctor's diagnosis, they have primary hypertension and at least one year has passed since their illness. Doctors' permission to participate in an exercise program and no need for a specific drug (calcium channel blockers such as verapamil that significantly decrease TXNIP in Langerhans beta cells) (Poudel & Kafle, 2017), at least until Completion of the research period (10 weeks) is required. Do not take more than one type of antihypertensive pill daily. Their minimum systolic blood pressure was 140 mmHg and diastolic blood pressure was 90 mmHg. They do not have a history of regular exercise in the six months leading up to the time of the study. People should not participate in specific weight loss programs. Do not have diabetes, fatty liver, Hypothyroidism or hyperthyroidism, anemia (Hb <10 g / dl) and kidney disease (> 1.5 mg / dl creatinine) and Do not have a history of Myocardial infarction, heart attack, cardiac arrhythmia. Also do not have ischemic heart disease or unstable angina (Farinatti et al., 2016). This information will be obtained through the medical records of individuals. They have no history of any heart surgery.

Exclusion criteria:
- Having bone, muscles, and joints problems that prevent exercise. Have a blood pressure higher than 180 mmHg. Take calcium channel blocker drugs such as verapamil, amlodipine, diltiazem. Smoking or addiction to any drug or alcohol (Moraes et al., 2012). Participate in any other exercise program (recreational or professional) while conducting research. Have no interest in participating in a sports activity program.

Purpose
Supportive

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Ethics committees
1

Ethics committee
Name of ethics committee
National Ethics Committee on Biomedical Research
Street address
No. 3, Fifth Alley, Mirmad St, 5th Alley, Motahhari St
City
Tehran
Province
Tehran
Postal code
1587958711
Approval date
2019-12-14, 1398/09/23
Ethics committee reference number
IR.SSRC.REC.1398.108

Health conditions studied
1
Description of health condition studied
Primary hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1
Description
TXNIP Plasma Level
Timepoint
At the beginning of the study (before the intervention),
at the end of the study (after the intervention)
Method of measurement
Enzyme – Linked ImmunoSorbent Assay (ELISA kit for
TXNIP)

2
Description
Plasma insulin levels
Timepoint
At the beginning of the study (before the intervention),
at the end of the study (after the intervention)
Method of measurement
Enzyme – Linked ImmunoSorbent Assay (ELISA kit for
insulin)

3
Description
Fasting glucose
Timepoint
At the beginning of the study (before the intervention),
at the end of the study (after the intervention)
Method of measurement
Enzymatic method of glucose oxidase

4
Description
Plasma triglyceride levels
Timepoint
At the beginning of the study (before the intervention),
at the end of the study (after the intervention)
Method of measurement
Spectrophotometry (enzymatic colorimetry) using Pars
Test kits

5
Description
Plasma total cholesterol levels
Timepoint
At the beginning of the study (before the intervention),
at the end of the study (after the intervention)
Method of measurement
Spectrophotometry (enzymatic colorimetry) using Pars
Test kits

6
Description
HDL plasma level

Secondary outcomes

Intervention groups

1
Description
First intervention group: Gym-based exercise program;
combined exercise (aerobic, resistance and stretching) for
70 to 85 minutes per session, four sessions per week,
for 10 weeks will be performed as follows; Resistance
training: The resistance component involved 40 to 50
minutes of eight resistance training exercises for the
trunk, upper and lower body (eg, squat, calf raise, leg
press, bicep curl, triceps push-down, lateral pull-down,
chest press or scapula retraction) using pin-loaded
resistance equipment, with 8 to 12 repetition, at 60 to 80
percentage of their 1-repetition maximum intensity for 2
to 3 set. Aerobic Exercise: The aerobic component of the
exercise involved up to 15 minutes of stationary bike,
treadmill or cross trainer. The rating of perceived
exertion scale and 40 to 60 percentage of heart rate
reserve was used to monitor a safe moderate intensity.
The stretching component involved 5 minutes of upper
and lower limb stretching (eg, pectoral, shoulder, calf,
hamstring and quadriceps) with two repetitions of each
static stretch prescribed for 30 seconds.

2
Description
Second intervention group: Home-based program with
telephone support: combined exercise (aerobic,
resistance and stretching) for 70 to 85 minutes per
session, four sessions per week, for 10 weeks will be
performed at home as follows; Resistance training: The
resistance component involved 40 to 50 minutes of eight
resistance training exercises for the trunk, upper and
lower body (eg, sit to stand, calf raise, leg press, bicep
curl, triceps push-down, lateral pull-down, chest press or
scapula retraction) using body weight or an elastic
exercise band to provide resistance, with 8 to 12
repetition, at 12 to 15 percentage of their rating of perceived exertion scale (approximately 60 to 80 percentage of their 1-repetition maximum intensity) for 2 to 3 set. Aerobic Exercise: The aerobic component of the exercise involved up to 15 minutes of stationary bike, treadmill, walking or cross trainer. The rating of perceived exertion scale and 40 to 60 percentage of heart rate reserve was used to monitor a safe moderate intensity. The stretching component involved 5 minutes of upper and lower limb stretching (eg, pectoral, shoulder, calf, hamstring and quadriceps) with two repetitions of each static stretch prescribed for 30 seconds.

### Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Rezvan Medical Complex

**Full name of responsible person**

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### Sponsors / Funding sources

1

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**Position**

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Birjand University
Full name of responsible person
Maryam Masoudi
Position
Student

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