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
Name
Maryam Masoudi
Name of organization / entity
Birjand University
Country
Iran (Islamic Republic of)
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Email address
masoudimaryam290@yahoo.com
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
**Scientific title**
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

**Public title**
Assessment of combined exercise training effect in men with primary hypertension

**Inclusion/Exclusion criteria**

**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. They 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.

**Age**
From 30 years old to 70 years old

**Gender**
Male

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: 60

**Randomization (investigator's opinion)**
Randomized

**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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TXNIP Plasma Level</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Enzyme – Linked ImmunoSorbent Assay (ELISA kit for TXNIP)</td>
</tr>
<tr>
<td>2</td>
<td>Plasma insulin levels</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Enzyme – Linked ImmunoSorbent Assay (ELISA kit for insulin)</td>
</tr>
<tr>
<td>3</td>
<td>Fasting glucose</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Enzymatic method of glucose oxidase</td>
</tr>
<tr>
<td>4</td>
<td>Plasma triglyceride levels</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Spectrophotometry (enzymatic colorimetry) using Pars Test kits</td>
</tr>
<tr>
<td>5</td>
<td>Plasma total cholesterol levels</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Spectrophotometry (enzymatic colorimetry) using Pars Test kits</td>
</tr>
<tr>
<td>6</td>
<td>HDL plasma level</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Spectrophotometry (enzymatic colorimetry) using Pars Test kits</td>
</tr>
</tbody>
</table>

### Secondary outcomes
empty

### Intervention groups

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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.</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Spectrophotometry (enzymatic colorimetry) using Pars Test kits</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
<td>At the beginning of the study (before the intervention), at the end of the study (after the intervention)</td>
<td>Spectrophotometry (enzymatic colorimetry) using Pars Test kits</td>
</tr>
</tbody>
</table>

### Category
Lifestyle
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.

Category
Lifestyle

3

Description
Control group: This group will not receive any intervention

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Rezvan Medical Complex
Full name of responsible person
Tuba Kazemi
Street address
No. 12, Taleghani 3/3 (Shohada 2), Taleghani Ave
City
Birjand
Province
South Khorasan
Postal code
9714833446
Phone
+98 56 3222 2974
Email
drtooba.kazemi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University
Full name of responsible person
Hamidreza Najafi (Deputy of Research and Technology)
Street address
Central Organization, University of Birjand, University Blvd
City
Birjand
Province
South Khorasan
Postal code
9717434765
Phone
+98 56 3220 2516
Email
h.r.najafi@birjand.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
The University of Birjand
Full name of responsible person
Maryam Masoudi
Position
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Latest degree
Master
Other areas of specialty/work
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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