Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effects of two resistance and concurrent training programs with high protein diets on physical performance, biochemical markers, and body composition in resistance trained males

Protocol summary

Study aim

To study the effects of a 16-week different resistance and concurrent training programs with two types of high-protein diets on muscle strength, power, endurance, biochemical markers in adipose tissue, liver and kidney, maximum oxygen consumption, and body composition in resistance trained males

Design

Measurements will be collected at baseline, week 8, and after 16 weeks. Participants first will complete four preliminary testing days: on the first visit, questionnaires will be assessed; on the second visit, blood draw and body composition will be performed; on the third visit, maximal aerobic capacity (Vo2max) and performance tests will be performed.; on the fourth visit, participants will complete chest press and leg press 1RM, muscular endurance tests (75% 1RM), and muscular power.

Settings and conduct

After randomization and pre-testing, training protocols will be performed in the gym.

Participants/Inclusion and exclusion criteria

In terms of health status; Healthy and having no specific problems or diseases. Have an age range between 18 and 35 years. Male participants. Have a history of resistance training for at least 1 year on a regular basis (at least three training sessions per week). Have not used anabolic steroids and peptides in the past year. Being free from musculoskeletal disorders. Exclusion criteria: Musculoskeletal injuries Not following the prescribed diet Anabolic steroid injection Contributing in exercises out of prescribed ones Lack of inner desire to carry on exercise or diet intervention

Intervention groups

Resistance training + 1.6 g/kg/day Resistance training + 3.2 g/kg/day Concurrent training + 1.6 g/kg/day Concurrent training + 3.2 g/kg/day

Main outcome variables

Muscle strength, strength, endurance, biochemical markers in adipose tissue, liver and kidney, maximum oxygen consumption, and body composition (body fat percentage , lean mass, BMC, BMD, etc.)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045612N2**
Registration date: **2022-01-31, 1400/11/11**
Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**
Update count: **0**

Registration date

2022-01-31, 1400/11/11

Registrant information

Name

Sajjad Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3824 2314

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-09, 1400/11/20

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of two resistance and concurrent training programs with high protein diets on physical performance, biochemical markers, and body composition in resistance trained males

Public title

Comparison of two high protein diets and physical activity on physical performance, biochemical markers and body composition in resistance-trained males

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Have a history of resistance training for at least 1 year on a regular basis (at least three training sessions per week). All the participants will be males. Having a normal sleep state. In terms of health status; Healthy and have no specific problems or diseases. Between the age of 18 to 35 years.

Exclusion criteria:

Musculoskeletal injuries Not following the prescribed diet Anabolic steroid injection Contributing in exercises out of prescribed ones Lack of inner desire to carry on exercise or diet intervention

Age

From **18 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method using random number table is used. This method first uses a random number table, which is a set of numbers that have no pattern or order and which is completely generated. The researcher divides these numbers randomly between the intervention groups (both resistance training groups are the controls of concurrent training groups). With the presence of clients, the researcher begins to read the numbers in the specified order. Each participant receives its own number and is randomly assigned to either resistance training groups (2 groups: resistance training with 1.6 g/kg/day of protein and resistance training with 3.2 g/kg/day of protein) or concurrent training groups (2 groups: concurrent training + 1.6 g/kg/day of protein and concurrent training + 3.2 g/kg/day of protein).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study. Since the researcher and the participants should not be aware of the group and the amount of protein consumed, a third person who is not aware of the objectives of the study will do the group assignment and protein recommendation. Also, the third person will codify them randomly and then provide the researcher with the code. It should be noted that all participants will be informed about the research and objectives, but will not be given information about which group they belong to. Data analysis will also be performed by an out-of-group biostatics specialist who is not aware of the participants and group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Two resistance training groups will be the control groups for concurrent training groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of university of Isfahan

Street address

Isfahan, Azadi Square, University of Isfahan

City

Isfahan

Province

Isfehan

Postal code

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Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.UI.REC.1400.098

Health conditions studied

1

Description of health condition studied

Body composition, muscular and cardiovascular adaptation in resistance-trained males

ICD-10 code

Y93.B

ICD-10 code description

Activities involving other muscle strengthening exercises

Primary outcomes

1

Description
Muscle strength
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
1RM tests for chest and leg press

2

Description
Power
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
Wingate test for upper and lower body

3

Description
Biochemical markers for adipose tissue, liver and kidney.
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
Measurements with laboratory kits

4

Description
Vo2max
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
Through Bruce test

5

Description
Muscular endurance
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
Through 75% of 1RM for chest and leg press

6

Description
Body composition
Timepoint
Pre-test, week 8 and week 17 (after 16 weeks of training)
Method of measurement
Through DXA, 3D scan, and BIA

Secondary outcomes

1

Description
The relationship between lean mass and muscular adaptation
Timepoint
At the end of the study
Method of measurement
With statistical analysis methods

2

Description
Comparison between DXA, BIA, and 3D scan
Timepoint
Pre-test, week 8 and week 17
Method of measurement
Hologic Discovery, Inbody device, and 3d scan

Intervention groups

1

Description
Intervention group 1: Resistance training + high protein diet (1.6 g/kg/day). In this group, participants will train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of resistance training will be the same and there will be only a difference in the dose of protein consumed. Regarding testing sessions for all intervention groups, on the first visit, questionnaires will be assessed; on the second visit, blood draw (after 48 hours of rest and 8 overnight sleep), and body composition will be performed; on the third visit, maximal aerobic capacity (Vo2max) and performance tests will be performed; on the fourth visit, participants will complete chest press and leg press 1RM, muscular endurance tests (75% of 1RM), and muscular power. After completing the pre-test process, the participants will be visited by a nutritionist and will be informed about the nutritional conditions of the study.
Category
N/A

2

Description
Intervention group 2: Resistance training + high protein diet (3.2 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of resistance training will be the same and there will be only a difference in the dose of protein consumed.
Category
N/A

3

Description
Intervention group 3: Concurrent training + high protein diet (1.6 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of concurrent training will be the same and there will be only a difference in the dose of protein consumed. In this group, participants will perform resistance training at the beginning of the session and then will perform endurance training.

Category
N/A

4

Description
Intervention group 3: Concurrent training + high protein diet (3.2 g/kg/day). In this group, participants will also train for 4 sessions per week for 16 weeks. It should be noted that resistance training in the two groups of concurrent training will be the same and there will be only a difference in the dose of protein consumed. In this group, participants will perform resistance training at the beginning of the session and then will perform endurance training.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Nuclear research center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
University of Isfahan

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
University of Isfahan

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Position
PhD student

Latest degree
Master

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable