

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The effect of aerobic physical activity alone and in combination with hemp seed powder consumption on biophysical, metabolic and neurological parameters in sedentary young men

#### Protocol summary

##### Study aim

Determining the effect of aerobic physical activity alone with hemp seed powder consumption on biophysical, metabolic and neurological factors in sedentary young men

##### Design

Randomized, double-blind clinical trial with four parallel groups

##### Settings and conduct

The study will be performed in the ergometrics laboratory of the Faculty of Health and Nutrition and in clinics affiliated to Tabriz University of Medical Sciences and the duration of the supplementary course will be 8 weeks. hemp seed powder and placebo capsules will be coded by the person in charge of preparation and the main researchers and patients will be blind to the type of supplement taken in each group.

##### Participants/Inclusion and exclusion criteria

Use any medication or diet and exercise supplement for at least 2 months before the start of the study, respiratory disease, cardiovascular disease and hypertension, diabetes, thyroid disease, neurological disease, musculoskeletal disease, autoimmune disease, skeletal and joint problems

##### Intervention groups

The intervention group will consume 2 capsules of hemp powder daily and will also work out on the treadmill three times a week. The control group will also take a capsule containing cornstarch (placebo) which will be similar to the supplement.

##### Main outcome variables

Biophysical factors (balance, strength, mental function), Brain derived neuronal factor (BDNF), Neuropeptide Y (NPY), Blood insulin and insulin resistance, Fasting blood sugar, Lipid profile, Renal function indicators (total iron-binding capacity, creatinine, urea, uric acid), Serum electrolytes (total iron-binding capacity, magnesium,

iron, calcium, phosphorus), high-sensitivity C-reactive protein, Liver function (ALT, AST, direct bilirubin, ALP, albumin, total bilirubin, total protein), Lactate dehydrogenase activity, Creatine kinase activity, testosterone, SHBG, oxidative stress status (MDA, SOD, GPX, TAC, Catalase)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140907019082N10**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **2**

##### Registration date

2021-02-20, 1399/12/02

##### Registrant information

##### Name

Mahdieh Abbasalizad Farhangi

##### Name of organization / entity

Department of Community Nutrition School of Nutrition

##### Country

Iran (Islamic Republic of)

##### Phone

+98 413357580

##### Email address

abbasalizadm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-10, 1399/12/20  
**Expected recruitment end date**  
 2021-12-07, 1400/09/16  
**Actual recruitment start date**  
 empty  
**Actual recruitment end date**  
 empty  
**Trial completion date**  
 empty

**Scientific title**  
 The effect of aerobic physical activity alone and in combination with hemp seed powder consumption on biophysical, metabolic and neurological parameters in sedentary young men

**Public title**  
 The effect of aerobic physical activity and cannabis powder consumption in sedentary young men

**Purpose**  
 Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Male age 18-40 low active Inclination to participate in the study  
**Exclusion criteria:**  
 Use any medication or diet and exercise supplements for at least 2 months before the start of the study  
 Respiratory disease Cardiovascular disease and hypertension Diabetes Thyroid disease Nervous disease Skeletal muscle disease Autoimmune disease Skeletal and joint problems

**Age**  
 From **18 years** old to **40 years** old

**Gender**  
 Male

**Phase**  
 3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
 Target sample size: **48**

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

**Randomization description**  
 In this study, we will use block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all the blocks is the same and we will have 4 blocks in this four-group experiment. The randomization tool is also used from the site [www.sealedenvelope.com](http://www.sealedenvelope.com), which is a site for generating random sequences, in addition to simple randomization, is able to generate random sequences by blocking method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on study participants, so that the assigned group is not

known before the individual is assigned. Using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are placed in the envelopes respectively. Are placed. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

In this study, the main researchers (including students, supervisors, and advisors) as well as participants will be unaware of the type of supplement (hemp seed or placebo) received by each group. The person in charge of preparing the supplement packs (who is completely unrelated to the study) will be asked to assign a three-digit code to each of the two powders (hemp seed and placebo) and, until the end of the study and data analysis, Keep the codes with you.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Research Ethics Committee of Tabriz University of Medical Sciences

##### **Street address**

Research & Technology Dept, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golghast St.

##### **City**

tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

516614711

#### **Approval date**

2021-02-03, 1399/11/15

#### **Ethics committee reference number**

IR.TBZMED.REC.1399.1015

### **Health conditions studied**

## 1

### **Description of health condition studied**

Sedentary men

### **ICD-10 code**

### **ICD-10 code description**

## **Primary outcomes**

## 1

### **Description**

Biophysical indicators (balance, strength, mental function)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

stabilometer, dynamometer, VTS

## 2

### **Description**

Neurological factors BDNF and NPY

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 3

### **Description**

Fasting Blood Glucose (FBG)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

Laboratory evaluation

## 4

### **Description**

Serum level of Insulin

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 5

### **Description**

Lipid profile

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

Laboratory evaluation

## 6

### **Description**

Insulin resistance index

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

Using formula

## 7

### **Description**

Renal function indicators (total iron-binding capacity, creatinine, urea, uric acid)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 8

### **Description**

Serum electrolytes (total iron-binding capacity, magnesium, iron, calcium, phosphorus)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 9

### **Description**

high-sensitivity C-reactive protein

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 10

### **Description**

Liver function (ALT, AST, direct bilirubin, ALP, albumin, total bilirubin, total protein)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 11

### **Description**

Lactate dehydrogenase activity

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 12

### **Description**

Creatine kinase activity

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## 13

### **Description**

testosterone

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## **14**

### **Description**

Sex hormone binding globulin

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## **15**

### **Description**

Oxidative stress status (MDA, SOD, GPX, TAC, Catalase)

### **Timepoint**

Baseline and 8 weeks after intervention

### **Method of measurement**

ELIZA

## **Secondary outcomes**

### **1**

#### **Description**

Anthropometric indices

#### **Timepoint**

Baseline and 8 weeks after intervention

#### **Method of measurement**

Seca Scale, stadiometer and strip meter

### **2**

#### **Description**

Body composition

#### **Timepoint**

Baseline and 8 weeks after intervention

#### **Method of measurement**

With the body composition analyzer

## **Intervention groups**

### **1**

#### **Description**

Intervention group: People in the physical activity group with supplements, take 2 capsules of hemp seed powder a day, one before lunch and one the night before bed, and also work out on a treadmill three times a week.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group: Instead of hemp seed, people in the physical activity group will take a capsule containing cornstarch, which is similar to a supplement, before lunch and at night before going to bed, and will also work out on a treadmill three times a week.

#### **Category**

Treatment - Other

### **3**

#### **Description**

Intervention group: . People in the supplement group take 2 capsules of hemp seed powder a day, one before lunch and one the night before bed.

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Control group: People in the control group will also take capsules containing cornstarch, which will be similar to the supplement, before lunch and at night before bed.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Faculty of Nutrition, Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Mahdieh Abbasalizad Farhangi

##### **Street address**

Tabriz - Golgasht St. - Attar Neyshabouri St. - Faculty of Nutrition and Food Sciences

##### **City**

tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

۵۱۶۶۶۱۴۷۱۱

##### **Phone**

+98 41 3335 7580

##### **Email**

nutritionfaculty@tbzmed.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohammad Samiei

##### **Street address**

Golgasht St. / Tabriz University of Medical Sciences

##### **City**

tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614711

##### **Phone**

+98 41 3335 7310

##### **Email**

research-vice@tbzmed.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Mohammad Rezaei

**Position**

Master student in sports nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

خیابان گلگشت، خیابان عطار نیشابوری، دانشکده تغذیه و علوم غذایی

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

۵۱۶۶۶۱۴۷۱۱

**Phone**

+98 41 3335 7580

**Email**

alimrezaei4@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Mahdiah Abbasalizad Farhangi

**Position**

Associate Professor of Nutrition Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 7582

**Fax**

+98 41 3334 0634

**Email**

Abbasalizad\_m@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Mohammad Rezaei

**Position**

Master student in sports nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

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Tabriz

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East Azarbaijan

**Postal code**

۵۱۶۶۶۱۴۷۱۱

**Phone**

+98 41 3335 7580

**Email**

Alimrezaei4@gmail.com

## 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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable