# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of twelve weeks of physical activity with Ginkgobiloba supplementation on the serum levels of brain-derived neurotrophic factor and elderly patients lifestyle

## Protocol summary

**Study aim**
The effect of twelve weeks of physical activity with Ginkgobiloba supplementation on the serum levels of brain-derived neurotrophic factor and elderly patients lifestyle

**Design**
The clinical trial consisted of a control group, with parallel, randomized groups, 40 subjects in each group and 10 in each group.

**Settings and conduct**
The purpose of this study was to determine the effect of 12 weeks of aerobic and resistance exercise 5 days a week for 20 minutes and daily intake of Ginkgo biloba supplement on BDNF serum levels and quality of life in 40 elderly people aged 60-75 years in Tehran. In this study, Kit Elisa, Quality of Life questionnaire and Physical Activity Questionnaire were used.

**Participants/Inclusion and exclusion criteria**
inclusion criteria: Old and healthy people 60 to 75 years old, who do not suffering from heart, bone, brain, kidney, liver, respiratory and hormonal diseases. Be inactive and do not do any physical activity during the week. Do not have a medical ban on exercising or taking ginkgo Biloba supplements exclusion criteria: Using Cigarette or drug, antioxidant supplements or various anti-inflammatory drugs

**Intervention groups**
Ginkgo biloba supplementation exercise group, Ginkgo biloba supplementation exercise control group

**Main outcome variables**
Brain derived neurotrophic factor (BDNF) serum level and quality of life

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20191223045864N1**
Registration date: **2020-01-31, 1398/11/11**
Registration timing: **retrospective**

Last update: **2020-01-31, 1398/11/11**
Update count: **0**

**Registration date**
2020-01-31, 1398/11/11

**Registrant information**

**Name**
shadi Jalalian
**Name of organization / entity**
Science an research branch of Islamic azad university
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-01-21, 1397/11/01

**Expected recruitment end date**
2019-02-09, 1397/11/20

**Actual recruitment start date**
2019-02-12, 1397/11/23

**Actual recruitment end date**
2019-03-06, 1397/12/15

**Trial completion date**
2019-07-16, 1398/04/25

**Scientific title**
The effect of twelve weeks of physical activity with

Ginkgobiloba supplementation on the serum levels of brain-derived neurotrophic factor and elderly patients lifestyle

**Public title**
The effect of twelve weeks of physical activity with Ginkgobiloba supplementation on the serum levels of brain-derived neurotrophic factor and elderly patients lifestyle
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
An elderly person with age 60 to 70 Having Iranian nationality Speaking in persian Being completely cautious during this study Having communication ability Having ability to answer the questionnaires. living in Tehran. Being inactive and do not have any physical activity or exercise during the week Do not have any known mental illness (psychosis)
**Exclusion criteria:**
Active people based on the questionnaire Opt out of answering the questionnaire while doing the job and interview Refrain from running the exercise or supplement you are looking for Unwanted things have happened
**Age**
From **60 years** old to **75 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
Actual sample size reached: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The randomization method was simple, individual, and sealed using envelopes. So that the names of ten subjects were written in four envelopes and in each one. Then, each of the intervention and control groups was assigned A, B, C, D codes and randomly assigned to one of the training, supplement, exercise, and control groups. Making the envelope, it was determined in which group each of the subjects belonged.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Sport Sciences Research institute of Iran
**Street address**
No.3, 5th Ave, Miremad St, Motaharri St
**City**
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**Province**
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**Postal code**
1587958711
**Approval date**
2019-07-01, 1398/04/10
**Ethics committee reference number**
IR.SSRC.REC.1398.116

## Health conditions studied

**1**

**Description of health condition studied**
aging
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Brain derived neurotrophic factor serum level
**Timepoint**
Before the intervention and 48 hours after the end of the 12-week exercise and supplementation interventions
**Method of measurement**
Serum Concentration Measurement Using ELISA Laboratory Kit

## Secondary outcomes

**1**

**Description**
Quality of Life
**Timepoint**
Before the intervention and 48 hours after the end of the 12-week exercise and supplementation interventions
**Method of measurement**
SF-36 Quality of Life Questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Exercise including 5 minutes warm-up and 5 minutes of balance and walking movements

and 5 minutes of progressive resistance training and 5 minutes of cooling which were performed for a total of 20 minutes for 5 days a week for 12 weeks. The training method was progressive and according to the level of ability of individuals. With 0.5, 0.75, 1.5 and 1.5 kg weights and 8 repetitive bands for knee extension, flexion and lift, hip extension, flexion, arm back and ankle support movements from sitting to standing. The probability of increasing the number of repetitions could be increased up to 12 times with the Borg pressure scale of 12 to 14. Balance and aerobic movements included walking, lifting on toes, lifting on heels, knee lifting, standing on one leg, shifting body weight in different directions, standing on two legs with or without the help of a chair.

**Category**

N/A

**2**

**Description**

Intervention group: Fasting subjects received a daily dose of 240 mg of ginkgo biloba supplement for 12 weeks.

**Category**

N/A

**3**

**Description**

Intervention group: Exercise including 5 minutes warm-up and 5 minutes of balance and walking movements and 5 minutes of progressive resistance training and 5 minutes of cooling which were performed for a total of 20 minutes for 5 days a week for 12 weeks. The training method was progressive and according to the level of ability of individuals. With 0.5, 0.75, 1.5 and 1.5 kg weights and 8 repetitive bands for knee extension, flexion and lift, hip extension, flexion, arm back and ankle support movements from sitting to standing. The probability of increasing the number of repetitions could be increased up to 12 times with the Borg pressure scale of 12 to 14. Balance and aerobic movements included lifting on toes, lifting on heels, knee lifting, standing on one leg, shifting body weight in different directions, standing on two legs with the help of a chair and without walking. Intervention group: Fasting subjects received a daily dose of 240 mg of ginkgo biloba supplement for 12 weeks and used 200 mg of ginkgo biloba mark made of French Vitarmonil.

**Category**

N/A

**4**

**Description**

Control group: A placebo was given daily for 12 weeks with a cellulose capsule that was similar in color to the contents of the ginkgo biloba capsule.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Sceince and Research branch of Islamic Azad University

**Full name of responsible person**

Shadi Jalalian

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## Sponsors / Funding sources

**1**

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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?**

Yes

**Title of funding source**

Sceince and Research branch of Islamic Azad University

**Proportion provided by this source**

50

**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**
Sceince and Research branch of Islamic Azad University,
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no more information
**Study Protocol**
No - There is not 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**
Not applicable
**Data Dictionary**
Not applicable