

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the Creatine adjunct effect on athletes mood and affect in body building clubs: a randomized clinical trial

Protocol summary

Summary

1- Objectives: To evaluate the effect of Creatine on athletes mood and affect 2- Design: 44 male athletes in a body building club in Nahavand city. 3- Setting and conduct: the athletes were randomized to the study and placebo groups by using random numbers table. 4- Participants including major eligibility criteria: male athletes between 16-66 year old, without history of medical and psychiatric disorder or drug and alcohol consumption during past 3 months, were enrolled to the study. 5- Intervention: The study group received 5 gram Creatine daily for 6 months, and the placebo group received placebo (wheat flour) for the same time. Both groups completed 2 questionnaires (Beck depression scale and PANAS) in weeks 0, 3 and 6. 6- Main outcome measures: Athletes mood and affect

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040521609N1**

Registration date: **2015-06-27, 1394/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-27, 1394/04/06

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Iran university of medical sciences; Investigator

Expected recruitment start date

2013-12-12, 1392/09/21

Expected recruitment end date

2014-02-22, 1392/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Creatine adjunct effect on athletes mood and affect in body building clubs: a randomized clinical trial

Public title

The effect of Creatine adjunct on Athletes Mood and Affect.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: age between 16-60, male gender; regular daily physical exercise; not having history of allergy to Creatine; not having history of medical disease such as heart disease, renal disorder, thyroid disease or cancer; not having history of psychiatric drug consumption or OTC usage or drug and alcohol abuse during past 3 months; not having history of axis 1 psychiatric disorders. Exclusion criteria: allergy to Creatine; any medical complication during the study.

Age

From **16 years** old to **60 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The participants were randomized to the study and placebo groups by using random numbers table. Each participant received a random number and the researcher was not aware of each athlete's group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical science

Street address

keshavarz street, Ghods Ave., Tehran University

City

Tehran

Postal code

1417613151

Approval date

2013-09-22, 1392/06/31

Ethics committee reference number

130/1301/92/5

Health conditions studied

1

Description of health condition studied

Psychiatric conditions

ICD-10 code

F32

ICD-10 code description

Depression

Primary outcomes

1

Description

The score of mood

Timepoint

Before the intervention, 3 weeks after beginning of intervention, 6 weeks after beginning of intervention

Method of measurement

Beck depression scale

2

Description

The score of affect

Timepoint

Before the intervention, 3 weeks after beginning of intervention, 6 weeks after beginning of intervention

Method of measurement

PANAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the athletes were received 5 gram Creatine Monohydrate (from Karen pharmaceutical company) in 7 capsules, administered orally, daily for 6 weeks.

Category

Treatment - Drugs

2

Description

The placebo group received wheat flour capsule (7 capsules daily) for the same time (6 weeks) and the same appearance (Creatine capsule) in intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

YARAN body building club

Full name of responsible person

Amir Salehi

Street address

Before Miri St., Hafez Ave., Nahavand

City

Nahavand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Iran university of medical sciences

Full name of responsible person

Seyed Ali Javad Mousavi

Street address

Hemmat highway, Iran university of medical sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Iran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran university of medical sciences

Full name of responsible person

Mehrdad Eftekhari

Position

Vice chancellor for research, Iran University of medical sciences, Medicine college

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran institute of psychiatry

Full name of responsible person

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Assistant professor

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Person responsible for updating data

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psychiatric resident

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty