

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Dec 2021

### Dietary intervention for treating ADHD, a randomized controlled clinical trial

#### Protocol summary

##### Summary

This is a 4 week randomized controlled clinical trial investigating the adjuvant effect of diet recommendation with methylphenidate for treating 80 children with ADHD. Children will be assessed two time including at baseline and the week 4 using a DSM-IV ADHD checklist.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311303930N29**  
Registration date: **2013-12-22, 1392/10/01**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-22, 1392/10/01

##### Registrant information

###### Name

Ahmad Ghanizadeh

###### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1627 3070

###### Email address

ghanizad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciecnes

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2013-11-22, 1392/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Dietary intervention for treating ADHD, a randomized controlled clinical trial

##### Public title

Dietary intervention for treating ADHD, a randomized controlled clinical trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: children aged between 5 to 18 years old diagnosed with ADHD according to DSM-IV diagnostic criteria. Exclusion criteria: lack of providing written informed consent; serious uncontrolled medical condition such as hypothyroidism, serious interaction of recommended diet with a medical condition or methylphenidate.

##### Age

From **5 years** old to **18 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **80**

##### Randomization (investigator's opinion)

Randomized

##### Randomization description

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

--

**Approval date**

2013-09-22, 1392/06/31

**Ethics committee reference number**

CP-P-92-6001

**Health conditions studied****1****Description of health condition studied**

Hyperkinetic disorders- Attention deficit Hyperactivity disorder

**ICD-10 code**

F90

**ICD-10 code description**

Hyperkinetic disorders

**Primary outcomes****1****Description**

ADHD Rating Scale

**Timepoint**

baseline and week 4

**Method of measurement**

Interview

**Secondary outcomes**

empty

**Intervention groups****1****Description**

recommendation to reduce sugar intake for one month

**Category**

Behavior

**2****Description**

Control - without diet recommendation

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Street address**

Hafez Hospital

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Gholam Reza Hatam

**Street address**

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

**City**

Shiraz

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical sciences

**Full name of responsible person**

Behzad Hadad

**Position**

Medicine Student

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

Hafez Hospital

**City**

Shiraz

**Postal code**

--

**Phone**

+98 71 1627 3070

**Fax****Email**

behzad.haddad@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

Professor of Psychiatry

## Other areas of specialty/work

**Street address**

Hafez Hospital

**City**

Shiraz

**Postal code**

--

**Phone**

+98 71 1627 3070

**Fax****Email**

ghanizadeha@hotmail.com

**Web page address**

## Person responsible for updating data

### Contact

## 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*