

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of hydrotherapy on serum serotonin and BDNF in children with Autism spectrum disorders

#### Protocol summary

##### Study aim

Determining the effect of eight weeks hydrotherapy on the serotonin and Brain-derived neurotrophic factor (BDNF) level in children with Autism.

##### Design

These clinical trial includes training and control group that has been randomly divided into two groups. The sample size is 32 and participants are the children with autism in Kahrizak charity.

##### Settings and conduct

Research in Kahrizak Charity Organization has been done after getting parents and children written consent. Then, a pre-test has been performed , after 2 months of hydrotherapy, a post-test has been performed. blinding has been done for testers, including psychologists and lab technician.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of autism, 6 to 14 years old, male gender, tolerance to motion, lack of motor problem.  
Non-inclusion criteria: Having other diseases , Skin problems

##### Intervention groups

The subjects of the present study has been randomly divided into 2 groups , including training groups (n=16) and control group (n=16). The training group has carried out three sessions of eight weeks (two months) and a 60-minutes Halliwick program. The control group has also conducted their routine activities during the study.

##### Main outcome variables

Main source variables included : Serotonin and Brain-derived neurotrophic factor Serum

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039330N1**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **retrospective**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

##### Registration date

2018-11-22, 1397/09/01

##### Registrant information

###### Name

hadi farahani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3342 2153

###### Email address

hadifarahani@phd.iaurasht.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-02, 1396/10/12

##### Expected recruitment end date

2018-03-14, 1396/12/23

##### Actual recruitment start date

2018-01-02, 1396/10/12

##### Actual recruitment end date

2018-03-14, 1396/12/23

##### Trial completion date

empty

##### Scientific title

Effect of hydrotherapy on serum serotonin and BDNF in children with Autism spectrum disorders

##### Public title

Effect of hydrotherapy on serotonin and BDNF in children with Autism spectrum disorders

##### Purpose

Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children with Autism Spectrum Disorders Age of 6 to 14 years Male gender Exercise Tolerance  
**Exclusion criteria:**  
Movement problem Having other diseases Skin problems

**Age**  
From **6 years** old to **14 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **32**  
Actual sample size reached: **32**

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

**Randomization description**  
Individuals in the groups have been matched based on autism severity , then randomly divided to two groups (experimental and control) by research randomizer software.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
For assesment of autism severity two psychologists and for blood test a laboratory expert have been acquired. 2 psychologists and a laboratory technician evaluated all participants without knowing the grouping and by number encoding at the beginning and at the end of the research.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Islamic Azad University Rasht Branch  
**Street address**  
Islamic Azad University Rasht Branch  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**

4147654919

**Approval date**  
2017-09-19, 1396/06/28

**Ethics committee reference number**  
IR.IAU.RASHT.REC.1395.104

## Health conditions studied

### 1

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

## Primary outcomes

### 1

**Description**  
Serum Serotonin  
**Timepoint**  
Serotonin measurements before and after 2 months of hydrotherapy  
**Method of measurement**  
Elisa kit (zellbio) Germany

### 2

**Description**  
Serum Brain-derived neurotrophic factor  
**Timepoint**  
Brain-derived neurotrophic factor measurements before and after 2 months of hydrotherapy  
**Method of measurement**  
Elisa kit (zellbio) Germany

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
Intervention group: 24 sessions of hydrotherapy in 2 months. 3 sessions per week for 60 minutes and the Halliwick method is used for this study.  
**Category**  
Rehabilitation

### 2

**Description**  
Control group: This group did not do any additional activity during the 2 months of the study.  
**Category**  
Rehabilitation

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Kahrizak Charity Foundation

**Full name of responsible person**

Dr. Afshin Vejdani

**Street address**

Esfahaniha Street, Golestanak Road, Mohammad Shahr

**City**

Karaj

**Province**

Alborz

**Postal code**

31845167

**Phone**

+98 26 3630 9171

**Fax**

+98 26 3630 1859

**Email**

Kahraj@kahrizak.com

**Web page address**

http://kahrizak.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Alireza Elmiye

**Street address**

Islamic Azad University Rasht Branch

**City**

Rasht

**Province**

Guilan

**Postal code**

۴۱۴۷۶۵۴۹۱۹

**Phone**

+98 13 3342 2153

**Email**

info@iaurasht.ac.ir

**Web page address**

http://iaurasht.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Hadi Farahani

**Position**

Teacher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

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## Person responsible for updating data

### Contact

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data includes the main consequence of the unidentifiable sharing of people.

**When the data will become available and for how long**

The beginning of the access period is one year after the publication of the results.

**To whom data/document is available**

The data can only be sent to researchers.

**Under which criteria data/document could be used**

Terms include academic emails as well as academic specifications and the reason for requesting data.

**From where data/document is obtainable**

Email: hadifarahani111@gmail.com Tel. 00989123642069

**What processes are involved for a request to access data/document**

First send the required information and then send the document information after confirmation.

**Comments**