Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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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
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 updating data

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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