Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of aquatic and karate training on stereotypical behaviors, sleep habits and balance in children with Autism spectrum disorder

Protocol summary

Study aim
Improvement the stereotypical behavior, sleep habits and balance of children with autism spectrum disorder with aquatic and karate exercise

Design
30 children aged 8-14 years with autism spectrum disorder were selected using available sampling method. They will randomly divided into two intervention groups and one control group.

Settings and conduct
Aquatic exercise intervention will be carried out in the welfare pool of the city of Rasht. Karate training intervention will be held at Ansar karate Club.

Participants/Inclusion and exclusion criteria
age (8 to 14) sex (male) having autism spectrum disorder not having co-morbid disability

Intervention groups
first intervention group: aquatic exercise second intervention group: karate training control group

Main outcome variables
Stereotypical behaviors; sleep habits; balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180626040242N1**
Registration date: **2018-07-31, 1397/05/09**
Registration timing: **retrospective**

Last update: **2018-07-31, 1397/05/09**
Update count: **0**

Registration date
2018-07-31, 1397/05/09

Registrant information

Name
Fahimeh Adibsaber
Name of organization / entity
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Iran (Islamic Republic of)
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+98 13 3375 2906
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-30, 1396/11/10

Expected recruitment end date
2018-02-19, 1396/11/30

Actual recruitment start date
2018-01-30, 1396/11/10

Actual recruitment end date
2018-04-09, 1397/01/20

Trial completion date
empty

Scientific title
Comparison of the effect of aquatic and karate training on stereotypical behaviors, sleep habits and balance in children with Autism spectrum disorder

Public title
Comparison of the effect of aquatic and karate training on stereotypical behaviors, sleep habits and balance in children with Autism spectrum disorder

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
age (8 to 14 years old) sex (male) not having co-morbid disability parents consent

Exclusion criteria:
Receiving specialized treatment in addition to the usual treatment during study

Age
From **8 years** old to **14 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
through drawing (The participants' names were written on paper and selected through simple random draw for the two intervention groups and a control group)

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
Medical Sciences Division-Research Ethics Committee

Street address
Azad University of Rasht, Lakan Boulevard

City
Rasht

Province
Guilan

Postal code
۴۱۴۷۶۵۴۹۱۹

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

Ethics committee reference number
IR.IAU.RASHT.REC.1396.131

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder

ICD-10 code
F84.0

ICD-10 code description
Childhood autism

Primary outcomes

1

Description
stereotypical behaviors

Timepoint
A week before and after 10 weeks of intervention

Method of measurement
Gars-2 stereotypical behaviors subscale

2

Description
sleep habits

Timepoint
A week before and after 10 weeks of intervention

Method of measurement
Children’s Sleep Habits Questionnaire

3

Description
Balance

Timepoint
A week before and after 10 weeks of intervention

Method of measurement
Stabliometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: aquatic exercise (10 weeks, two session per week, 60 minutes including, 5 minutes warm up, 20 minutes aerobic exercise, 20 minutes strength training, 10 minutes free swimming and 5 minutes cool down)

Category
Treatment - Other

2

Description
Intervention group: Karate training (10 weeks, two session per week, 60 minutes each session, including 10 minutes warm up, 45 minutes of kata technique training and 5 minutes of cool down).

Category
Treatment - Other

3

Description
Control group: without training

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan Autism Association
Full name of responsible person
Mehdi Zahedi Kalashtari
Street address
second Fooladloo, Saffari Ave, Bisoton Ave
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4193191933
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoomeh Shojaei
Street address
Islamic Azad university of Science and Research Branch, Shohadaye Hesarak Boulevard, University Square, the end of Ashrafi Esfahani Highway
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+98 44 8651 7982
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e5shojaei@yahoo.com
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
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Fahimeh Adibsaber
Position
a faculty member
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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

Consulting and coordination with the supervisor

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available