

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effectiveness of applied behavioral analysis program and sensory enrichment on improving executive functions to Autistic children in Zahedan city 2018- 2019 .

Protocol summary

Study aim

Examine the effectiveness of the apply behavior analysis program and sensory enrichment on improve the executive functions in autistic children.

Design

This study included 24 autistic children in aged 3_6 years ,that selected randomly by random sampling and randomly assigned into three equal groups. All three groups had pre-test, intervention and post-test.post-test.

Settings and conduct

Research in the field of developmental neurological disorder (autism) in the autism center of the Well-being organization in Zahedan, Sistan-Baluchestan province. The sample is selected of the Autism Children's Society of this Center and divided into three groups, and each group will have a pre-test, intervention, and post-test. In the first group, the parent cares for the apply behavioral analysis and runs on his child. The second group of children's home environment is enriched by various sensory stimuli in five main areas. And in the third group, the parent sees and implements the apply behavioral analysis program, and the child's home environment is enriched by various sensory stimuli. And in all three groups, the impact of these interventions is measured on executive functions

Participants/Inclusion and exclusion criteria

Enter: Autistic children in 3 to 6 years old. Having educated parents. Filling in the Satisfaction Questionnaire. out: Having mental retardation. The autism children with sever body disability and epilepsy.

Intervention groups

This study consists of three intervention groups. For the first group, the Applied Behavioral Analysis Program is implemented by the trained care parent. The second group is enriching the child's environment From the aspects of sensory stimuli in all five sensory areas. The third group includes both interventions.

Main outcome variables

The components of executive functions that include: 1. Inhibition of response. 2-Planning. 3.Shifting of behavioral .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190420043334N1**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **retrospective**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Asghar Khaqani Yamchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 4216 3329

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-10-25, 1397/08/03
Actual recruitment end date
2018-11-17, 1397/08/26
Trial completion date
2019-04-19, 1398/01/30

Scientific title
The effectiveness of applied behavioral analysis program and sensory enrichment on improving executive functions to Autistic children in Zahedan city 2018- 2019

Public title
The effectiveness of applied behavioral analysis and sensory enrichment on improving executive functions.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Autistic children 3 to 6 years old referring to the Autism Center. Having educated parents Filling in the Satisfaction Questionnaire for attending meetings.

Exclusion criteria:
Having mental retardation. The autism children with sever body disability and epilepsy.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**
Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, Random number table will be used. According to the 24- sample size of the statistical population (children aged 3 to 6 are at the center of autism) will be selected, then with doing lottery they will be placed in 3 equal groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this research, each person is his own control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Blvd.doctor hesabi

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743175

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.ZAUMS.REC.1397.139

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Executive functional of behavior planning.

Timepoint

The variable, first time before the program is measured, and the final measurement will be 14 weeks after intervention.

Method of measurement

Standard inventory for behavioral rating of executive function of preschool children in parental form.

2

Description

Executive functional of behavior inhibition.

Timepoint

The variable, first time before the program is measured, and the final measurement will be 14 weeks after intervention.

Method of measurement

Standard inventory for behavioral rating of executive function of preschool children in parental form.

3

Description

Executive functional of behavior shifting.

Timepoint

The variable, first time before the program is measured, and the final measurement will be 14 weeks after

intervention.

Method of measurement

Standard inventory for behavioral rating of executive function of preschool children in parental form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The applied behavioral analysis program will be implemented to children by trained parent for 12 weeks.

Category

Rehabilitation

2

Description

Intervention group 2: The sensory enrichment program will be implemented to children by trained parent for 12 weeks.

Category

Rehabilitation

3

Description

Intervention group 3: Both the applied behavior analysis and sensory enrichment programs will be implemented to children by trained parent for 12 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism center of welfare organization of Zahedan City, Sistan and Baluchestan Province.

Full name of responsible person

Asghar Khaqani Yamchi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Deputy of research and technology of Zahedan University of Medical Sciences.

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Grant name

No

Grant code / Reference number

ندارد

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

Yes

Title of funding source

Zahedan University of Medical Sciences

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

Zahedan University of Medical Sciences

Full name of responsible person

Asghar Khaqani Ymchi

Position

Msc, student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Title and more details about the data/document

In this clinical trial whole research data upload to other researchers.

When the data will become available and for how long

2019/06/21-2020/06/21

To whom data/document is available

All researcher children.

Under which criteria data/document could be used

For clinical and research.

From where data/document is obtainable

The journal of publication paper.

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

You can email request and researcher will provide for you.

Comments

Nothing.