

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Designing and validating a cognitive rehabilitative program and determining its effect on the Spatial ability in children with Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim

Design and validation of cognitive rehabilitation program and evaluation of its effectiveness on spatial ability of children with attention deficit hyperactivity disorder

Design

Research is a semi experimental study with pretest-posttest design and control group. Thirty children diagnosed by a psychiatrist in a private office are selected by available sampling method in Tehran. Subjects were then randomly divided into two groups of 15 experimental and control

Settings and conduct

Children with ADHD are assessed for pre-testing. The experimental group are trained in ten difficulty levels two days a week through a package designed to enhance spatial ability factors. At the same time, the children in the control group are trained to the AREF emotional recognition intervention program. The intervention place is in the rehabilitation clinic of University.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the presence of hyperactivity disorder combined type, completion of the consent form, being in the range of 9 to 12 years and the Conners score higher than the cut point. Exclusion criteria include the presence of comorbid disorders and the use of Regular medication regimen

Intervention groups

The Spatial Ability Cognitive Rehabilitation Program is a set of computer rehabilitation tasks. In designing this package, eight factors of spatial ability based on progressive exercises are intervened. Tasks have ten difficulty levels that are adjusted based on the nature of each factor, the speed of presentation of the stimuli and their complexity. AREF cognitive rehabilitation program is used. This program includes training to recognize the emotional states of the face using graphic images.

Main outcome variables

Flexibility of Closure, Closure Speed, Perceptual Speed, Visualization, Spatial Relation, Spatial Orientation, Spatial Temporal and Wayfinding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201106049285N1**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Solmaz Soluki

Name of organization / entity

Institute for Cognitive and Brain Sciences, Shahid Beheshti University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-05-05, 1399/02/16

Actual recruitment start date

2020-02-09, 1398/11/20

Actual recruitment end date

2020-05-27, 1399/03/07

Trial completion date

2020-09-07, 1399/06/17

Scientific title

Designing and validating a cognitive rehabilitative program and determining its effect on the Spatial ability in children with Attention Deficit Hyperactivity Disorder

Public title

Effectiveness of a cognitive rehabilitative program on the Spatial ability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosing Attention Deficit Hyperactivity Disorder combined sub-type by psychiatrists according to the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition Filling consent form by parents Higher score of the Conner's Parent Rating Scale than the cut-off point Being in the age range of 9 to 12 years

Exclusion criteria:

Existing comorbid psychiatric disorders such as autism spectrum disorder, learning disorders, and so on. regular use of medication except for Methylphenidate

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: In order to randomize, first all subjects who meet the inclusion criteria are selected and each subject is given a code. Selected subjects should be homogeneous in terms of gender variable. For this purpose, after the subjects were matched in pairs in terms of the desired variable, a list of pairs of subjects is prepared and randomly one of the two elements paired by lottery by an uninformed person, to the control group and Another is assigned to the experimental group

Blinding (investigator's opinion)

Single blinded

Blinding description

After the subjects were matched in pairs, a list of pairs of subjects was prepared and one of the two paired elements was randomly assigned to the control group and the other to the experimental group. None of the subjects and their parents knew which of the two groups they belonged to.

Placebo

Used

Assignment

Parallel

Other design features

The study was approved by the ethical committee of the Shahid Beheshti University (ethical code: IR.SBU.ICBS.97/1022).

Secondary Ids

empty

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

the ethical committee of the Shahid Beheshti University

Street address

student boulevard, shahriyari squer, yaman street, chamran highway

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Postal code

1983969411

Approval date

2018-07-07, 1397/04/16

Ethics committee reference number

IR.SBU.ICBS.97/1022

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

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

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

The ability to apprehend and identify a visual pattern fast, without knowing in advance what the pattern is, when the pattern is disguised or obscured in some way

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the visual closure of Test of Visual Perception Skills are considered as variables

2

Description

The ability to find, apprehend, and identify a visual pattern fast, knowing in advance what is to be apprehended, when the pattern is disguised or obscured in some way

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the figure ground sub test of Test of Visual Perception Skills are considered as variables

3

Description

he ability to find a known visual pattern or accurately comparing one or more patterns in a visual field fast in which the patterns are not disguised or obscured

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the visual discrimination sub test of Test of Visual Perception Skills are considered as variables

4

Description

The ability to manipulate or transform the image of spatial patterns into other arrangements

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the paper folding task are considered as variables

5

Description

The ability to manipulate relatively simple visual patterns fast by whatever means (mental rotation, transformation, or otherwise)

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the mental rotation task are considered as variables

6

Description

The ability to the comprehension of the agreement of elements within a visual stimulus pattern and the aptitude to remain unconfused by the changing

orientation in which a spatial configuration may be presented

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC), and Reaction Time of correct responses (RT) in the picture task are considered as variables

7

Description

The ability to judge regarding a moving stimulus

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC) in the reception task, is considered as variable

8

Description

the ability to learn, remember and, follow a path in the environment

Timepoint

before intervention and next week and one month after intervention

Method of measurement

The Accuracy score (ACC) in the landmark memory, learning, and shortcut phases in the wayfinding task are considered as variabls

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Spatial Ability Cognitive Rehabilitation Program is a set of computer cognitive rehabilitation tasks designed to enhance the various factors of spatial ability. In designing this package, all eight factors related to spatial ability based on progressive exercises are intervened. All tasks have ten difficulty levels that are adjusted based on the nature of each factor, the speed of presentation of stimuli and their complexity, and the rules of the program. If the child can answer eighty percent of the items in a level correctly, he will go to a more difficult level. In designing cognitive rehabilitation exercises, important principles of cognitive rehabilitation have been considered, which are:

- Tasks are hierarchically organized and based on the child's response during the sessions become more difficult. Enhances performance.
- Homework can be repeated until the child reaches the desired level.
- The decision to develop the program is based on the child's performance and the presence of a therapist is needed to improve the homework. The duration of each session

was about sixty minutes, with the first five minutes being spent introducing the child to homework and the last ten minutes explaining homework to parents. At the same time and equal to the number of sessions intended for the rehabilitation of children in the experimental group, in order to control the relationship between the child therapist in determining the effectiveness of the rehabilitation package, the children in the control group underwent Aref intervention program. One week and then one month after the end of the treatment program, post-test was performed in both groups. After the assessments, the parents of the children in the control group were informed that they could benefit from free cognitive rehabilitation treatment if they wished.

Category

Rehabilitation

2

Description

Control group: the AREF cognitive rehabilitation program was used for the control group. This program includes training to recognize the emotional states of the face using graphic images. Each session consists of 150 face images with anterior and lateral views that the person must recognize the emotional state and feedback is provided to the person in the presence of the image. The intensity of the emotional manifestations gradually decreases in the next sessions. The first session is 100 percent intense and the last session is ten percent. In addition, the type of emotions during the treatment sessions is from easy to difficult and starts from happiness, anger and sadness and expands to six main emotions. The effectiveness of this treatment package has been shown to improve emotional recognition in normal children with autism.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Khoushabi's office

Full name of responsible person

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Institute of Cognitive and Brain sciences of Shahid Beheshti University

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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

Institute of Cognitive and Brain sciences of Shahid Beheshti University

Proportion provided by this source

20

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

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Person responsible for general inquiries

Contact

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Position
PhD student in Cognitive Psychology and Occupational Therapist

Latest degree
Master

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available