Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country

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 Disordercombined 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
City
Tehran
Province
Tehran
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 visaul 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, fallow 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

Dr. Katayun Khoushabi

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2

Recruitment center

Name of recruitment center

Cognitive Rehabilitation Clinic of Shahid Beheshti University

Full name of responsible person

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Cognitive Rehabilitation Clinic of Shahid Beheshti University, student boulevard,shahriyari squer, yaman street,chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Person responsible for general inquiries

Contact

Name of organization / entity

Institute of Cognitive and Brain sciences of Shahid Beheshti University

Full name of responsible person

Solmaz Soluki

Position

PhD student in Cognitive Psychology and Occupational Therapist

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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