Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Investigating the effect of computer learning and diary on the self-regulation and emotional adjustment in teenagers with attention deficit hyperactivity disorder

Protocol summary

Study aim
Determining the level of self-regulation and emotional adaptation in adolescents with attention deficit hyperactivity disorder using computer learning and diary methods

Design
The upcoming clinical trial has a randomized control group with one-way blinded factorial groups, which was used for randomization usingGPower's Random Allocation software.

Settings and conduct
After the sampling, the participants will go to the neurofeedback department of Ibn Sina Psychiatric Hospital and will be trained with RihaCam cognitive rehabilitation software in the presence of a psychologist and a doctor, and they will receive a semi-structured diary. It should be noted that the pre-test and post-test will also be conducted.

Participants/Inclusion and exclusion criteria
Inclusion criteria Adolescents from the age of 11 to 19 years with ADHD diagnosed by a specialist in child and adolescent psychiatry Ability to read and write Not having vision, hearing, muscle and physical problems Not suffering from known concomitant diseases such as schizophrenia, autism, low IQ Not using drugs according to the information received from parents Family and patient satisfaction Exclusion criteria Lack of physical and mental ability to continue treatment Drug use during the intervention Not participating in more than two intervention sessions

Intervention groups
In the intervention group, the computer learning method will be used using Rihacom software and the self-management tool of the diary, and after the end of the intervention, emotion regulation training sessions will be provided for the control group.

Main outcome variables
Evaluation of changes in self-regulation and emotional adjustment of participants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231019059769N1**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date
2023-12-07, 1402/09/16

Registrant information

Name
Fatemeh zahra Janbabanezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-21, 1402/09/30

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of computer learning and diary on the self-regulation and emotional adjustment in teenagers with attention deficit hyperactivity disorder

Public title

Investigating the effect of computer learning and diary on the self-regulation and emotional adjustment in teenagers with attention deficit hyperactivity disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescents from the age of 11 to 19 years with ADHD diagnosed by a specialist Ability to read and write Not having vision, hearing, muscle and physical problems Not suffering from known concomitant diseases such as schizophrenia, autism, low IQ Not using drugs according to the information received from parents Family and patient satisfaction

Exclusion criteria:

Inability to read and write Substance use Having bipolar schizophrenia and autism

Age

From **11 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of replacement blocks will be allocated in 6 blocks of 6 with the Random Allocation software according to the attached list. Thus, with the available sampling method, the patients who refer to Ibn Sina Hospital will be included in the study according to the entry criteria and according to the attached table. which is explained by G power, the first patient enters the intervention group according to the block of 6, the next 3 patients enter the control group, and the last two patients also enter the intervention group It should be mentioned that the allocation is considered in the form of 6 blocks, in each block 3 patients will be in the intervention group and 3 patients will be in the control group, and it will continue up to 36 people, which will actually be 6 blocks of 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is one-sided blind, the person analyzing the information does not have access to the separation of the control and intervention groups when checking the results of the pre- and post-questionnaires, so they do not know which group the results of the analysis belong to, but the researcher and the participant He knows that the intervention has been done for him. Therefore, in this way, the bias will be as much as possible.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Nursing and Midwifery Faculties, Management and Medical Information - Shiraz Uni

Street address

Shiraz town, Shiraz University of Medical Sciences Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-10-28, 1402/08/06

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.095

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description

Self regulation

Timepoint

The effect of computer learning and diary on self-regulation and emotional adjustment before immediately and 1 month after the intervention

Method of measurement

Miler-brown self regulation Questionnaire

Secondary outcomes

1

Description
Emotional adjustment
Timepoint
Effect of computerised learning and time diary on emotional adjustment before immediate and 1month after intervention
Method of measurement
Rabio Emotional adjustment Questionnaire

Intervention groups

1

Description
In addition to routine treatment, the intervention group will receive RIHACOM cognitive-rehabilitation interventions and event recording. Interventions will be carried out for patients using Rihakam cognitive-rehabilitation software for 10 sessions of 45 minutes for 5 weeks. During the first session, how to use the diary book and complete it, how to perform rehabilitation exercises will be taught. In these interventions, the response control module of Rihakam software will be used, which includes four stages: training warm-up, main test and cooling down. The first and second stages last 1 minute each, which is a response exercise based on the patient's attention. 90 seconds later, the main test begins. This test is based on mental performance and automatic adaptation of the software so that based on the reaction time, immediately after seeing the command variable of the software, the participant must click on the running exercise which is in Farsi language. Exercises are graded from 0 to 130 based on performance, so a higher score indicates better performance. In each session, the performance of the participant is saved in the software, and based on that training level, the next session begins. In the second and subsequent sessions, based on the person's performance in the previous session with the automatic evaluation of the device, the next steps are performed with different degrees of difficulty for the person. This work continues up to 10 sessions. During these 10 sessions and up to one month after the end of the intervention, the participants will be asked to express their emotional performance during the day in the form of a daily diary, including guidelines for use, goals, introduction of emotion, behavior and impulsive behavior. that these booklets will be collected and analyzed weekly. The main content of the booklet is in the form of tables, including columns such as days of the week, time and place of the event, and rows containing emotion-oriented behaviors such as verbal violence, behavioral violence, delaying the response to the stimulus, impulsive behavior, the will to complete the work, motivation. Starting work, smoking, using virtual space, etc. After the end of the interventions, these booklets will be completed and then collected by the participant as a follow-up tool for the patient.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebn Sina Hospital
Full name of responsible person
Dr Sarah Dehbozorgi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad Hashem Hashempour
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Shiraz town , Blvd Zand, Namazi square
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Phone
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nurs_midwif@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ladan Zarshenas

Position

Professor

Latest degree

Ph.D.

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

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

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

Title and more details about the data/document

clinical report

When the data will become available and for how long

4month

To whom data/document is available

Research team

Under which criteria data/document could be used

—

From where data/document is obtainable

Conductor of the research project

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

As needed refer to analytic reports

Comments