Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Effectiveness of the Unified Protocol with Treatment as Usual for Children with Attention Deficit/Hyperactivity Disorder (ADHD) Comorbid with Emotional Disorders

Protocol summary

Study aim
The effectiveness of the Unified Protocol in children with attention deficit hyperactivity disorder

Design
A randomized clinical trial with a control group, parallel groups, on 60 children diagnosed with ADHD. Randomization was performed using R software to generate random allocation lists.

Settings and conduct
This study will be conducted at two healthcare centers affiliated with Zanjan University of Medical Sciences (Shahid Beheshti Hospital and Shafiee Clinic). Patients visiting these centers who have been diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) by their treating psychiatrist will be referred to the principal investigator if they meet the inclusion criteria. Patients will be randomly assigned to intervention and control groups using block randomization methods.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Children aged 8–12 years with a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) and at least one emotional disorder. Exclusion Criteria: Presence of suicidal thoughts or plans, intellectual disability, autism spectrum disorders, specific learning disorders, language disorders, or any acute physical illness.

Intervention groups
Intervention Group: Receives Unified Protocol for Children (UP-C), a group cognitive-behavioral intervention for children's emotional problems, with mindfulness and emotion regulation. Includes 12 weekly 90-minute sessions by psychologists in a clinic, with interactive training and homework, over 4 months. Control Group: Receives standard pharmacological treatment (methylphenidate or atomoxetine), with doses (0.3-1 mg/kg for methylphenidate) and frequency (1-2 times daily) set by a psychiatrist, over 4 months, without group psychological intervention.

Main outcome variables
Neuroticism; emotion regulation; attention problems; impulsivity; anxiety; depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250504065589N1**
Registration date: **2025-07-10, 1404/04/19**
Registration timing: **prospective**

Last update: **2025-07-10, 1404/04/19**
Update count: **0**

Registration date
2025-07-10, 1404/04/19

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of the Unified Protocol with Treatment as Usual for Children with Attention Deficit/Hyperactivity Disorder (ADHD) Comorbid with Emotional Disorders

Public title

Investigating the Effectiveness of the Unified Protocol for Children Attention-Deficit/Hyperactivity Disorder (ADHD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) and at least one emotional disorder based on the Semi-Structured Diagnostic Interview for Schizophrenia and Mood Disorders in Children and Adolescents Across the Lifespan (K-SADA-PL DSM-5) Having at least a third-level secondary education for mothers Willingness to participate in group therapy sessions Receiving a fixed dose of medication for one month prior to the start of the study

Exclusion criteria:

having serious suicidal thoughts Suffering from mental retardation, autism spectrum disorders, specific learning disabilities, language disorders, and any type of acute physical illness Parent's mental disability, learning disabilities, and mental illness that leads to impaired understanding of treatment tools and protocols

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize participants, the random sequence will be generated using a block randomization method with a block size of 4 using R software (version 4.3.2). This process will be performed by an independent statistician who will not be involved in the implementation of the intervention or the evaluation of the data. Sixty children with ADHD will be randomly assigned in a 1:1 ratio to either the intervention (Unified Protocol) or treatment as usual (TAU) groups. To ensure no bias, the group allocations will be kept in opaque sealed envelopes and will only be opened after the participant has enrolled and completed the initial assessment by the study coordinator. This procedure will ensure that the investigators responsible for the intervention and evaluation remain unaware of the group allocation until the end of the study.

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

Research Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

University Headquarters Building No. 2. Shahid Beheshti University of Medical Sciences and Health Services. Erabi Street. Shahid Chamran Highway Tehran

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Approval date

2024-10-08, 1403/07/17

Ethics committee reference number

IR.SBMU.MSP.REC.1403.424

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

Neuroticism score in the Big Five personality Questionnaire- Children Version

Timepoint

Measuring neuroticism at the beginning of the study (before the intervention), at the end of the eighth session, and one week after the intervention

Method of measurement

Big Five Personality Questionnaire- Children Version

2

Description
Emotion regulation score in the Child and Adolescent Emotion Regulation Questionnaire
Timepoint
Measuring emotion regulation at the beginning of the study (before the intervention starts), at the end of the eighth session, and one week after the intervention
Method of measurement
Child and Adolescent Emotion Regulation Questionnaire

3

Description
Attention deficit score in the attention problems subscale of the Child Behavior Checklist
Timepoint
Measurement of attention problem at the beginning of the study (before the intervention), at the end of the eighth session, and one week after the intervention
Method of measurement
Attention problems subscale of the Child Behavior Checklist

4

Description
Impulsivity score in the Hirschfield Impulsivity Scale
Timepoint
Measurement of impulsivity at the beginning of the study (before the intervention), at the end of the eighth session, and one week after the intervention
Method of measurement
Hirschfield Impulsivity Scale

5

Description
Anxiety score in Spence Child Anxiety Scale
Timepoint
Measuring anxiety at the beginning of the study (before starting the intervention), at the end of the eighth session, and one week after the intervention
Method of measurement
Spence Child Anxiety Scale

6

Description
Depression score in the Children Depression Inventory
Timepoint
Measuring depression at the beginning of the study (before starting the intervention), at the end of the eighth session, and one week after the intervention
Method of measurement
Children Depression Inventory

Secondary outcomes

1

Description
Parental burnout score in the Parental Burnout Questionnaire
Timepoint
Measuring parental burnout at the beginning of the study (before starting the intervention), at the end of the eighth session, and one week after the intervention
Method of measurement
Parental Burnout Questionnaire

Intervention groups

1

Description
Intervention Group: Participants in the intervention group, in addition to receiving standard pharmacological treatment prescribed by a psychiatrist based on clinical protocols, will participate in a group-based psychological intervention program grounded in the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Parents. This protocol is a modified version of the transdiagnostic cognitive-behavioral therapy originally developed by David Barlow and colleagues in 2011 for adults, which was later adapted and tailored in 2021 by Ehrenreich and colleagues for implementation with children and their parents.The primary objective of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Parents is to improve emotional regulation skills, strengthen mindfulness, identify and restructure maladaptive thoughts, and enhance emotional resilience in both children and their parents. This therapeutic approach, through its transdiagnostic focus, targets a wide range of emotional difficulties such as anxiety, depression, and challenges in emotional regulation, rather than focusing on a single specific disorder. It aims to address the shared underlying psychological mechanisms across various emotional problems.The psychological intervention consists of twelve weekly group sessions, each lasting ninety minutes, conducted over a four-month period at the university’s psychology clinic. These sessions are designed to be interactive and include direct skill instruction, role-playing, group exercises, and homework assignments for both children and their parents. The structure of the sessions is as follows:Sessions 1 to 3: Teaching foundational concepts of emotional regulation and mindfulness, including deep breathing exercises and attention-focusing techniques;Sessions 4 to 6: Identifying maladaptive thoughts and training in cognitive restructuring techniques for both children and parents;Sessions 7 to 9: Practicing problem-solving strategies and managing emotional responses in challenging or stressful situations;Sessions 10 to 12: Strengthening emotional resilience and reviewing learned skills with a focus on consolidation and generalization to everyday life.Sessions will be facilitated by licensed clinical psychologists who have completed specialized training in the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Parents. Each group

will consist of six to eight child–parent dyads to ensure effective interaction and close clinical supervision.The intervention will make use of a comprehensive set of materials, including the educational package for the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Parents (comprising a therapist’s manual and separate worksheets for children and parents); visual aids for teaching emotions (such as illustrated emotion cards and educational posters); progress evaluation tools (such as standardized questionnaires for assessing emotional regulation and psychological symptoms, including child anxiety and depression measures).To reinforce the learning process, homework assignments will include mindfulness exercises, daily tracking of thoughts and emotions using structured worksheets, and joint parent–child activities aimed at practicing the acquired skills. These assignments will be reviewed in subsequent sessions by the psychologists, who will provide individualized feedback. In addition to the psychological intervention, participants will receive standard pharmacological treatment based on the diagnosis made by the psychiatrist. Since the focus of this study is on the psychological intervention component, detailed information regarding the pharmacological treatment—such as the name of the medication, chemical composition, dosage, and method of administration—is determined according to standard clinical protocols under the supervision of the treating physician and is treated as a controlled variable in this study. Precise data about the medications (including brand name, manufacturer, and dosage) is documented in each participant’s medical file and will be reported in the study results if deemed necessary. The entire psychological intervention spans a period of four months. Standardized psychometric assessments will be conducted at three points in time: at baseline, mid-intervention (after session six), and post-intervention (after session twelve), in order to evaluate improvements in emotional regulation and reductions in psychological symptoms among participants.

Category

Treatment - Other

2

Description

Control group: Participants in the control group receive only standard medication for Attention Deficit Hyperactivity Disorder (ADHD). Prescription medications include methylphenidate (Ritalin) or atomoxetine (Strattera), which are prescribed individually according to the psychiatrist's assessment. The dosage for methylphenidate is between 0.3 and 1 mg per kilogram of body weight per day, and for atomoxetine is 0.5 to 1.2 mg/kg per day. The dosage is adjusted between 1 and 2 times per day according to the psychiatrist's opinion. The medications are purchased through reputable and licensed pharmacies, manufactured by well-known companies, and their use is under the regular supervision of a child psychiatrist and in coordination with the parents. In this group, no group psychological intervention is performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Zanjan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
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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
Yes - There is 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
Title and more details about the data/document
Information related to the main result or similar items will be shared.
When the data will become available and for how long
The access period will begin 6 months after the publication of the results.
To whom data/document is available
Researchers employed at academic and scientific institutions.
Under which criteria data/document could be used
For use in articles
From where data/document is obtainable
Roya Ahmadizadeh Shahid Beheshti University of Medical Sciences ahmadizadeh1390@gmail.com
What processes are involved for a request to access data/document

Data for academic applications will typically be sent within one month of the request email.

Comments