Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of transdiagnostic cognitive-behavioral therapy (TCBT) with mindfulness-based therapy (MBT) in reducing symptoms and comorbid problems of adolescents with attention deficit hyperactivity disorder (ADHD)

Protocol summary

Study aim

The general objective of this study is to assess and compare the effectiveness of transdiagnostic cognitive-behavioral therapy and mindfulness-based therapy in mitigating symptom severity related to attention deficit and hyperactivity/impulsivity. Additionally, we aim to address comorbid issues such as anxiety, depression, and emotional dysregulation among adolescents diagnosed with attention deficit hyperactivity disorder (ADHD).

Design

A parallel-group, randomized clinical trial will be conducted, involving 30 patients. Randomization will be achieved using a table of random numbers, and blinding procedures will be implemented.

Settings and conduct

Following participant selection and randomization, this study will be conducted at the Imam Khomeini Clinic in Tabriz. Blinding procedures will be implemented for participants, outcome assessors, and the individual responsible for statistical data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being diagnosed with ADHD disorder 2. Being in the age range of 14 to 17 years 3. Receiving a fixed dose of medicine from at least one month before the start of the study Non-inclusion criteria: 1. being diagnoesd with bipolar mood disorder 2. being diagnosed with psychotic disorders 3. being diagnosed with substance use disorder 4. Having serious suicidal thoughts 5. being diagnosed with conduct disorder

Intervention groups

First Intervention Group: Participants in this group will receive transdiagnostic cognitive-behavioral therapy (TCBT) over 20 sessions, each lasting 45 minutes. Second Intervention Group: Participants in this group will undergo mindfulness-based therapy (MBT) for 20 sessions, with each session also lasting 45 minutes.

Main outcome variables

symptoms of attention deficit and hyperactivity/impulsivity; severity of anxiety; severity of depression; Severity of emotional dysregulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240823062845N1**
Registration date: **2024-09-04, 1403/06/14**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-04, 1403/06/14**
Update count: **0**

Registration date

2024-09-04, 1403/06/14

Registrant information

Name

maryam sadighpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-26, 1403/06/05

Expected recruitment end date
2024-09-22, 1403/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of transdiagnostic cognitive-behavioral therapy (TCBT) with mindfulness-based therapy (MBT) in reducing symptoms and comorbid problems of adolescents with attention deficit hyperactivity disorder (ADHD)

Public title
Comparison of the effectiveness of transdiagnostic cognitive-behavioral therapy (TCBT) with mindfulness-based therapy (MBT) in reducing symptoms and comorbid problems of adolescents with attention deficit hyperactivity disorder (ADHD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adolescent with attention deficit hyperactivity disorder receiving a fixed dose of the drug from at least one month before the start of the study age 14-17
Exclusion criteria:
Being diagnosed with bipolar mood disorder Being diagnosed with psychotic disorders Being diagnosed with substance use disorder Having serious suicidal thoughts Being diagnosed with conduct disorder
Age
From **14 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will employ a simple randomization method to assign participants to two intervention groups. Simple randomization is chosen due to its appropriateness for the small sample size and its ability to provide unbiased assignment of participants to study groups. The unit of randomization will be the individual participant. Each eligible participant will be randomly assigned to MBCT group or the TCBT. The study will include a total of 30 participants, with 15 participants allocated to each of the two intervention groups. The randomization process will utilize the Random Allocation Software, a free Windows-based program specifically designed for randomization in clinical trials.The randomization will be conducted as follows: The Random Allocation Software will be downloaded from the official website (https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html) and installed on a computer. Within the software, two intervention groups will be specified: MBCT and TCBT. The total sample size of 30 will be entered into the software. The "Only one block" option will be selected to ensure simple randomization. The randomization sequence will be generated using the software's built-in random number generator. To maintain allocation concealment and prevent selection bias, the randomization sequence will be generated by a researcher not involved in participant recruitment or assessment.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, we will implement a partial blinding approach, specifically focusing on blinding the outcome assessor and data analyzer. This strategy is designed to minimize detection and analysis bias while acknowledging the practical limitations of blinding other parties involved in the study. Participants and healthcare providers will not be blinded to the treatment allocation. This is due to the nature of the interventions (MBCT and TCBT), which require active participation and specific therapeutic techniques that cannot be concealed from those delivering or receiving the treatment. The principal investigator will not be blinded to group allocation, as they will be overseeing the overall conduct of the study and ensuring proper implementation of both interventions.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
City
tehran
Province
Tehran
Postal code
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Approval date
2023-10-23, 1402/08/01

Ethics committee reference number
IR.IUMS.REC.1402.655

Health conditions studied

1

Description of health condition studied
attention deficit hyperactivity/impulsivity disorder
ICD-10 code
F90.0
ICD-10 code description
Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
Symptoms of attention deficit and hyperactivity/impulsivity based on Connors parent questionnaire
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Connors parent questionnaire

2

Description
Symptoms of attention deficit and hyperactivity/impulsivity based on the integrated visual and auditory continuous performance test
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
integrated visual and auditory continuous performance test

3

Description
Anxiety intensity
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Beck anxiety inventory

4

Description
Severity of depression
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Beck depression inventory

5

Description
Severity of emotional dysregulation
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Reactivity, intensity, polarity and stability scale

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: transdiagnostic cognitive-behavioral therapy. For this group, the unified protocol of transdiagnostic cognitive-behavioral therapy of Barlow et al. (2017) will be used. This intervention will include 20 individual treatment sessions, each of which will last 45 minutes. Specifically, the goal of this protocol is reducing the intensity and frequency of negative emotions. Unified protocol is designed to accomplish this goal through emotion-focused education, awareness techniques, cognitive strategies, problem-solving and an array of behavioral strategies, including a full-range of exposure and activation techniques.
Category
Treatment - Other

2

Description
The second intervention group: mindfulness-based therapy. The mindfulness protocol developed by Zylowska and Mitchell (2021) for individuals with ADHD will be applied to this intervention group. This approach involves 20 individual sessions, each lasting 45 minutes. The protocol aims to achieve three primary objectives: Disengaging from autopilot mode, enhancing attentional control and self-monitoring and cultivating a new perspective on internal experiences. These goals are achieved through teaching a variety of formal and informal mindfulness techniques, including mindfulness of thoughts, sounds, breathing, movement, kindness meditation, mindful listening and speaking and etc.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Parviz Shahabi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maryam Sadighpour

Position
Ph.D student

Latest degree
Master

Other areas of specialty/work
Psychology

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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
No - There is not 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
Yes - There is a plan to make this available
Title and more details about the data/document
The data entered in the statistical software in the form of SPSS file will be shared to the public through Figshare with a dedicated URL in the Data availability statement section. which according to the data dictionary should also be attached. Also, the results of the statistical analysis performed by the SPPS software will be available to the readers of the article. The study protocol will be attached to the article.
When the data will become available and for how long
The access time will be immediately after the results are printed.
To whom data/document is available
All people who are readers of the mentioned study.
Under which criteria data/document could be used
The mentioned data can be compared with the results of other studies. Also, these data will be available for meta-analyses.
From where data/document is obtainable
The data can be accessed in the form of attached files and internet addresses from figshare, which will be mentioned in the article itself.
What processes are involved for a request to access data/document
The data will be provided with the article and there is no need to send a direct request to the authors.
Comments