Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of the Unified Protocol for Transdiagnostic Treatment on Improving Symptoms and Psychological and Neuropsychological Indices in Adults with Attention-Deficit/Hyperactivity Disorder Comorbid with other Emotional Disorders: a Clinical Trial Study

Protocol summary

Study aim
Determining the effectiveness of Unified Protocol for transdiagnostic treatment on improving symptoms and psychological and neuropsychological indicators in adults with attention-deficit/hyperactivity disorder (ADHD) comorbid with other emotional disorders.

Design
A clinical trial with one waitlist group and one experimental group is designed as a double-blind, randomized study using the minimization method, with a sample size of 34 participants.

Settings and conduct
The allocation of participants will be carried out by a person other than the therapist. The minimization method and coin toss will be used for participant allocation. Referrals to the treatment and waitlist groups will be made by the Counseling Center University of Kurdistan and mental health specialists.

Participants/Inclusion and exclusion criteria
Inclusion criteria: meeting the diagnostic criteria for adult attention-deficit/hyperactivity disorder (ADHD) and a comorbid emotional disorder, consent to participate in the study, and being at least 18 years old. Exclusion criteria: receiving any other psychological treatment, having any personality disorder or being diagnosed with any psychiatric disorder (except for emotional disorders), substance abuse and use of medication related to the disorder, and being absent from more than two therapy sessions.

Intervention groups
Adults with attention-deficit/hyperactivity disorder (ADHD) accompanied by emotional disorders will be randomly assigned to two groups: a treatment group and a waitlist control group. The treatment consists of up to 12 sessions, each lasting 45 minutes, targeting emotional experiences. The waitlist group will receive a similar treatment after the study concludes.

Main outcome variables
Adult ADHD؛ Depression and Anxiety؛ Difficulty in Emotion Regulation؛ Frustration Intolerance؛ Anxiety Sensitivity؛ Inhibition؛ Persistent Inattention؛ Risky Decision-Making

General information

Reason for update

Acronym
UP

IRCT registration information
IRCT registration number: **IRCT20250522065850N1**
Registration date: **2025-06-11, 1404/03/21**
Registration timing: **prospective**

Last update: **2025-06-11, 1404/03/21**
Update count: **0**

Registration date
2025-06-11, 1404/03/21

Registrant information

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Name of organization / entity
The University of Kurdistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-15, 1404/03/25
Expected recruitment end date
2025-11-21, 1404/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of the Unified Protocol for Transdiagnostic Treatment on Improving Symptoms and Psychological and Neuropsychological Indices in Adults with Attention-Deficit/Hyperactivity Disorder Comorbid with other Emotional Disorders: a Clinical Trial Study

Public title
The Effectiveness of Unified Protocol for Transdiagnostic Treatment in adults with attention-deficit/hyperactivity disorder comorbid with other emotional disorders.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having diagnostic criteria for Adult ADHD and a comorbid emotional disorder Age range of 18 to 35 years Full consent to participate in the research Not receiving other therapeutic interventions concurrently with the present study
Exclusion criteria:
The presence of other psychological disorders and personality disorders except for the mentioned emotional disorders Absence from more than two therapy sessions Having a history of substance and psychotropic drug abuse
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
After adults with comorbid Attention Deficit Hyperactivity Disorder (ADHD) and emotional disorders are selected based on the inclusion and exclusion criteria, they will be assigned to the treatment and waitlist groups using the minimization method. The purpose of this method is to control for the gender variable. For example, if the first participant is female, she will be assigned to group one. If the second participant is male, he will also be assigned to group one. If the third participant is female, she will be assigned to group two, and the remaining participants will be allocated in the same way, ensuring that gender is balanced across the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
A clinical interview will be conducted by a clinical specialist to assess the inclusion and exclusion criteria. After that, participants will be randomly assigned to the treatment group and the waitlist group. The allocation of participants will be carried out by someone other than the therapist.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research
Street address
University of Kurdistan, Organizational Central Building, Third Floor, Pasdaran Blvd., Sanandaj, Kurdistan Province, I.R.
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Postal code
6617715175
Approval date
2025-05-17, 1404/02/27
Ethics committee reference number
IR.UOK.REC.1404.011

Health conditions studied

1

Description of health condition studied
Adult Attention-Deficit/Hyperactivity Disorder (ADHD)
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
The ADHD score on the Adult ADHD Self-Report Scale (ASRS).
Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Adult ADHD Self-Report Scale (ASRS)

2

Description

Depression score on the Beck Depression Inventory (BDI_II)

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Beck Depression Inventory (BDI_II)

3

Description

The anxiety score in the Beck Anxiety Inventory.

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Beck Anxiety Inventory - BAI

4

Description

Frustration tolerance score on the Harrington Frustration Discomfort Scale.

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Harrington Frustration Discomfort Scale

5

Description

Anxiety Sensitivity score in the Anxiety Sensitivity Index (ASI) questionnaire

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Anxiety Sensitivity score in the Anxiety Sensitivity Index (ASI) questionnaire

6

Description

Emotion Regulation score on the Emotion Regulation Questionnaire (ERQ) by Gross.

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Emotion Regulation Questionnaire (ERQ) by Gross

7

Description

Response inhibition score on the Go/No-Go task

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Go/No-Go task

8

Description

Risky decision-making score in the Iowa Gambling Task

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Iowa Gambling Task

9

Description

Sustained attention score in the Continuous Performance Test (CPT)

Timepoint

Before treatment; after treatment; one months after the completion of treatment.

Method of measurement

Continuous Performance Test (CPT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Unified Protocol for Transdiagnostic Treatment. The unified protocol for transdiagnostic treatment for emotional disorders consists of up to 12 sessions of 45 minutes each. This treatment targets emotional experiences by fostering emotional awareness and cognitive flexibility; identifying emotion-driven behaviors and replacing them with adaptive behaviors; recognizing and preventing emotional avoidance; increasing awareness of and exposure to bodily sensations; and modulating and confronting emotions in context.

Category

Treatment - Other

2

Description

Control group: The waitlist group will receive the unified protocol for transdiagnostic treatment. After the intervention group's follow-up sessions are completed, the unified protocol for transdiagnostic treatment, similar to that of the first intervention group, will be administered to the waitlist group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Kurdistan
Full name of responsible person
Farzad Nasiri
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
The University of Kurdistan

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
The University of Kurdistan
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Maryam Khazaei Soltanabadi
Position
Master's student
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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)
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
Yes - There is a plan to make this available
Title and more details about the data/document
A portion of the data includes information related to the primary outcome that can be shared.
When the data will become available and for how long
The start of access will be one year after the publication of the results.
To whom data/document is available
The data will be accessible only to researchers employed at academic institutions.
Under which criteria data/document could be used
Requests to use the data are only permitted for use in cross-cultural reviews or meta-analyses.
From where data/document is obtainable
To obtain the documentation, they can contact via email at f.nasiri@uok.ac.ir.
What processes are involved for a request to access data/document
Data information will be provided to individuals via email or mail after the request has been evaluated.
Comments