Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of culturally adapted game-based behavioral activation therapy (CA-BAPT) and cognitive behavioral therapy in reducing anhedonia among adolescents

Protocol summary

Study aim
To evaluate the effectiveness of Culturally Adapted Behavioral Activation Play Therapy (CA BAPT) compared with Cognitive Behavioral Therapy (CBT) in reducing anhedonia and improving adolescent mental health outcomes

Design
Two arm parallel group pragmatic cluster quasi experimental study with clinic level allocation; non randomized allocation after clinic pair matching; single blind outcome assessment; total sample size 900; phase not applicable

Settings and conduct
Conducted in 30 community mental health clinics; assessments at baseline; posttreatment at week 12; 3 month follow up; outcome assessors and statistical analysts were blinded to group allocation and participants were asked not to disclose their condition during assessments

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adolescents aged 13 to 18 years with moderate to high anhedonia based on the Snaith Hamilton Pleasure Scale; able to read Persian; written consent from the adolescent and a parent or legal guardian. Exclusion criteria: active psychotic disorders; severe cognitive or developmental impairment; concurrent participation in other psychological treatments

Intervention groups
Intervention group received twelve 60 minute group sessions of CA BAPT integrating behavioral activation skills with culturally relevant play based activities; two parent psychoeducation sessions Control group received twelve 60 minute group CBT sessions based on a standardized adolescent protocol

Main outcome variables
Anhedonia severity based on the Snaith Hamilton Pleasure Scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251116068014N3**
Registration date: **2026-04-05, 1405/01/16**
Registration timing: **prospective**

Last update: **2026-04-05, 1405/01/16**
Update count: **0**
Registration date
2026-04-05, 1405/01/16

Registrant information
Name
khatereh Arbabi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-04-21, 1405/02/01
Expected recruitment end date
2026-05-04, 1405/02/14
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of culturally adapted game-based behavioral activation therapy (CA-BAPT) and cognitive behavioral therapy in reducing anhedonia among adolescents

Public title
Effect of culturally adapted behavioral activation play therapy on adolescent mental health

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adolescents aged 13 to 18 years Moderate to high levels of anhedonia based on the Snaith–Hamilton Pleasure Scale Ability to read and understand Persian Written informed consent obtained from the adolescent Written informed consent obtained from a parent or legal guardian Willingness to participate in group based psychological sessions

Exclusion criteria:
Presence of active psychotic disorders Severe cognitive impairment or severe developmental disorder interfering with effective participation Concurrent participation in other psychological or psychotherapeutic interventions Inability to cooperate with study assessments based on clinical judgment

Age
From **13 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **900**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Because of the nature of group-based psychological interventions, blinding of participants and therapists will not be feasible, and participants will be aware that they are taking part in a research study. However, outcome assessors, the data management team, and statistical analysts will be kept blinded to group allocation. Data will be collected by assessors who will not be informed about the type of intervention delivered at each center, and participants will be instructed not to disclose their intervention type during assessments. Statistical analyses will be conducted using coded data without identification of group allocation. The principal investigator and therapists will not be blinded to group allocation due to their operational roles in delivering the interventions. No independent data safety monitoring committee will be established because the study will be non-pharmacological and designed to involve minimal psychological risk.

Placebo
Not used

Assignment
Parallel

Other design features
This study will be conducted as a pragmatic cluster-based study in service delivery centers, and the unit of allocation will be the center or clinic. Due to operational constraints within routine service settings, cluster-level randomization will not be performed, and allocation of clusters will take place after matching centers based on cluster size, geographic location, baseline mean anhedonia, and gender ratio, while also considering service delivery feasibility. Assessments will be conducted at four time points, including baseline, end of intervention, and a three-month follow-up. To enhance reporting transparency, the study will be reported in accordance with the TREND guideline for nonrandomized evaluations and the StaRI framework addressing real-world implementation and delivery considerations. Analyses will follow the intention-to-treat principle, missing data will be handled using multiple imputation, and intervention effects will be estimated using multilevel mixed models accounting for the cluster structure, with matching variables controlled for in the models.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Medical Sciences, Islamic Azad University, Qom

Street address
No. 33, Rasoulian Street, Zabti Street, Heravi Avenue, Tehran, Iran

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Approval date
2025-11-05, 1404/08/14

Ethics committee reference number
IR.IAU.QOM.REC.1404.123

Health conditions studied

1

Description of health condition studied

Anhedonia in adolescents

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anhedonia severity score in adolescents based on the Snaith Hamilton Pleasure Scale

Timepoint

Assessment at baseline before intervention; posttreatment at week 12; 3 month follow up

Method of measurement

Anhedonia severity measured using the Snaith Hamilton Pleasure Scale self report questionnaire validated for adolescents

Secondary outcomes

1

Description

Adolescent stress severity score

Timepoint

Assessment at baseline before intervention; posttreatment at week 12;3 month follow up

Method of measurement

Stress severity is measured using the Adolescent Stress Questionnaire, developed by Susan M. Byrne and colleagues, which has been validated for use in adolescent populations

2

Description

Psychological well being score in adolescents

Timepoint

Assessment at baseline before intervention; posttreatment at week 12; 3 month follow up

Method of measurement

Psychological well being is measured using the Mental Health Continuum Short Form self report questionnaire, developed by Corey L. M. Keyes, which has been validated for use in adolescent populations

3

Description

Resilience score in adolescents

Timepoint

Assessment at baseline before intervention; posttreatment at week 12;3 month follow up

Method of measurement

Resilience is measured using the Child and Youth Resilience Measure Revised, revised by Polly Jefferies and colleagues, and validated for use in adolescent populations

4

Description

Sleep hygiene score in adolescents

Timepoint

Assessment at baseline before intervention; posttreatment at week 12; 3 month follow up

Method of measurement

Sleep hygiene is measured using the Adolescent Sleep Hygiene Scale Revised, developed by Monika K. LeBourgeois and colleagues, and validated for use in adolescent populations

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive culturally adapted game-based behavioral activation therapy in a group format. The intervention will consist of twelve weekly 60-minute sessions that will be delivered by trained clinical psychologists. The intervention program will be based on behavioral activation principles and will use game-based, experiential, and interactive activities adapted to adolescents' cultural context and developmental stage. Core components will include increasing engagement in pleasurable and value-based activities, reducing avoidance patterns, strengthening social interactions, and facilitating emotional expression through structured group games and exercises. In addition, two structured parent sessions will be conducted, focusing on supporting adolescents' engagement in adaptive activities and reinforcing therapeutic goals within the family environment.

Category

Behavior

2

Description

Control group: Participants in the control group will receive group-based cognitive behavioral therapy. The intervention will consist of twelve weekly 60-minute sessions that will be delivered by trained clinical psychologists. The treatment will be designed based on the standard cognitive behavioral therapy protocol for adolescents, and its core components will include identification and modification of dysfunctional thoughts, training in emotion regulation skills, problem-solving skills, and strengthening adaptive coping strategies. Sessions will be conducted in a structured format in accordance with principles of group cognitive behavioral therapy.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
White Rose Psychological Chain Clinics affiliated with Imam Khomeini Relief Foundation

Full name of responsible person
Khatereh Arbabi

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No. 33, Rasoulian Street, Zabti Street, Heravi Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
White Rose Psychological Chain Clinics affiliated with Imam Khomeini Relief Foundation

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
White Rose Psychological Chain Clinics affiliated with Imam Khomeini Relief Foundation

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
White Rose Psychological Chain Clinics affiliated with Imam Khomeini Relief Foundation

Full name of responsible person
Khatereh Arbabi

Position
Psychotherapist

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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
Not applicable
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
De-identified individual participant data including primary and secondary outcome measures; data dictionary; study protocol; statistical analysis plan; analysis codes. All shared datasets will be fully anonymised and will not contain any direct or indirect identifiers.
When the data will become available and for how long
Data will be available starting 6 months after publication of the primary results and will remain accessible for a minimum period of 5 years.
To whom data/document is available
Qualified researchers affiliated with academic or research institutions who submit a reasonable and methodologically sound proposal.
Under which criteria data/document could be used
Data may be used solely for non-commercial scientific research purposes, including secondary analyses, meta-analyses, or methodological studies. Use of data requires approval of the study team, adherence to ethical standards, and signing of a data use agreement prohibiting re-identification and data redistribution.
From where data/document is obtainable
Requests should be submitted to the corresponding investigator via email. Contact details will be provided upon publication and are available through the affiliated research center.
What processes are involved for a request to access data/document
Applicants submit a written request including research objectives and analysis plan. Requests are reviewed by the study team within approximately 4 to 6 weeks. Upon approval and completion of a data use agreement, access to the requested materials will be granted.
Comments
No identifiable data will be shared. Data sharing will comply with ethical approvals and national regulations regarding research involving adolescents.