Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of an Educational Intervention Based on Dialectical Behavior Therapy on Alexithymia and Anxiety in Adolescents with Autism

Protocol summary

Study aim
To investigate the effectiveness of an educational intervention based on Dialectical Behavior Therapy in reducing alexithymia and anxiety in adolescents with Autism Spectrum Disorder (ASD).

Design
This is a quasi-experimental study with a pretest–posttest design and a control group, with participants randomly allocated to intervention and control groups.

Settings and conduct
The study will be conducted in exceptional schools in Borazjan. After participant selection and random allocation into two groups, a pretest will be conducted. The intervention group will receive a structured group-based educational intervention based on Dialectical Behavior Therapy, while the control group will continue its usual school program. A posttest will be conducted for both groups after completion of the intervention.

Participants/Inclusion and exclusion criteria
Adolescents with Autism Spectrum Disorder (ASD) attending exceptional schools in Borazjan Official diagnosis of Autism Spectrum Disorder, being within the adolescent age range, ability to participate in group sessions, parental consent, and no concurrent similar interventions. Lack of an official ASD diagnosis, being outside the adolescent age range, inability to participate in group sessions, lack of parental consent, or concurrent receipt of similar interventions.

Intervention groups
One intervention group of 26 adolescents with ASD receiving an educational intervention based on Dialectical Behavior Therapy (DBT), and one control group of 26 participants receiving no intervention and continuing their usual school program.

Main outcome variables
Alexithymia Anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260816070681N1**
Registration date: **2026-09-25, 1405/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-25, 1405/07/03**
Update count: **0**

Registration date
2026-09-25, 1405/07/03

Registrant information
Name
Naznin Joomhoori
Name of organization / entity
Country
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Phone
+98 77 3424 4860
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-09-13, 1405/06/22
Expected recruitment end date
2026-10-06, 1405/07/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Effectiveness of an Educational Intervention Based on Dialectical Behavior Therapy on Alexithymia and Anxiety in Adolescents with Autism

Public title

Investigating the Effect of Dialectical Behavior Therapy Training on Alexithymia and Anxiety in Adolescents with Autism

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having an official diagnosis of Autism Spectrum Disorder (ASD) based on educational and diagnostic records. Being within the adolescent age range Being enrolled in exceptional schools in Borazjan. Having the ability to participate in group intervention sessions. Providing informed parental consent for participation in the study. Not receiving other similar interventions concurrently.

Exclusion criteria:

Lack of an official diagnosis of Autism Spectrum Disorder Being outside the adolescent age range Inability to participate in group sessions Lack of parental consent, Concurrent receipt of similar interventions.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

After identifying and selecting eligible participants, they will be randomly allocated in equal numbers to two groups: an intervention group and a control group (26 participants in each group). After identifying and selecting eligible participants and obtaining informed consent from their parents, each participant will be assigned a code. The participants will then be allocated equally to the intervention and control groups using simple randomization and a random number table, with 26 participants assigned to the intervention group and 26 participants assigned to the control group. Following random allocation, the intervention group will receive the educational intervention based on Dialectical Behavior Therapy, while the control group will continue to receive the routine school program during the intervention period

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 Islamic Azad University, Marvdasht Branch

Street address

Marvdasht–Persepolis Road, Islamic Azad University, Marvdasht Branch

City

Marvdasht

Province

Fars

Postal code

7371113119

Approval date

2026-06-08, 1405/03/18

Ethics committee reference number

IR.IAU.M.REC.1405.209

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder (ASD)

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Alexithymia refers to difficulty in identifying, describing, and distinguishing one's own and others' emotions. In this study, alexithymia will be assessed using the Toronto Alexithymia Scale (TAS-20), with higher scores indicating greater alexithymia. Anxiety refers to the level of anxiety symptoms in adolescents. In this study, anxiety will be assessed using a standardized anxiety questionnaire appropriate for the adolescent age group.

Timepoint

Pre-test: Before the beginning of the educational interventionPost-test: Immediately after completion of the educational intervention

Method of measurement

Alexithymia will be measured using the Toronto Alexithymia Scale (TAS-20), consisting of 20 items rated on a 5-point Likert scale. Higher scores indicate greater alexithymia. Anxiety will be measured using an age-appropriate anxiety questionnaire assessing cognitive, emotional, and physical anxiety symptoms. Higher scores indicate greater anxiety.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group-based educational intervention based on Dialectical Behavior Therapy (DBT) will be provided in 8 sessions, each lasting 90 minutes, for adolescents with autism. The intervention includes training in distress tolerance, mindfulness, emotion regulation, and interpersonal effectiveness skills. The aim is to improve alexithymia and reduce anxiety.
Category
Behavior

2

Description
Control group: The control group will not receive any educational intervention during the intervention period and will continue the usual school program.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Exceptional Schools of Borazjan
Full name of responsible person
Ahmad Arabzadeh
Street address
Aftab Aramesh Specialized Counseling and Psychological Services Clinic, next to Nobat Clinic, Chamran Street, Borazjan
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Arabzadehdr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ruhollah Arshadi
Street address
Bushehr – Municipality Square – Beginning of Shahid Raisali Delvari Boulevard – Velayat Building (Islamic Azad University of Bushehr Province and Bushehr Branch)
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info@bushehr.iau.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Ruhollah Arshadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared because there is no plan to make individual-level data publicly available. Participant confidentiality and privacy will be maintained, and study results will be reported only in aggregate form.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable