Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of face-to-face Transdiagnostic Treatment (Unified Protocol) on Emotion Regulation, Experiential Avoidance, Social Adjustment, and Resilience in Students with Test Anxiety

Protocol summary

Study aim

The study aims to investigate the effectiveness of face-to-face transdiagnostic group therapy on test anxiety in students, focusing on emotion regulation, experiential avoidance, social adjustment, and resilience."

Design

This study is a parallel-group, double-blind (assessor and statistical analyst-blinded), randomized controlled trial conducted on 40 female students in grades 10 to 12 in Zanjan City. Web-based randomization was utilized for the randomization process in this study."

Settings and conduct

This study is a double-blind clinical trial conducted in Zanjan city among female high school students in grades 10 to 12. After obtaining the necessary approvals and randomly selecting schools, 40 students with moderate to severe test anxiety are divided into two groups: in-person treatment, and waitlist contrl group.Data collectors and outcome assessors remain unaware of group assignments to maintain objectivity and accuracy of the results.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age: 15 to 18 years Moderate to severe test anxiety No severe psychiatric disorders No Cognitive Behavioral Therapy (CBT) received in the past five years. Stability of effective medications (if applicable) Exclusion Criteria Absence from more than three consecutive sessions Lack of satisfaction with treatment Worsening of individual problems Non-participation in assessment stages

Intervention groups

Face-to-Face Transdiagnostic Treatment Group: In-person sessions focus on managing exam anxiety and enhancing emotional skills using the UP Control Group: Participants receive no intervention during the study period.

Main outcome variables

reduce test anxiety and experiential avoidance ,Improving emotion regulation skills, Increasing social adjustment and resilience in students

General information

Reason for update

Due to the lack of approval from the Ministry of Education (or: educational authorities) to conduct the protocol online, the protocol was implemented solely face-to-face."

Acronym

IRCT registration information

IRCT registration number: **IRCT20250121064456N1**
Registration date: **2025-01-24, 1403/11/05**
Registration timing: **prospective**

Last update: **2025-06-01, 1404/03/11**
Update count: **1**

Registration date

2025-01-24, 1403/11/05

Registrant information

Name
Iran Andaroon
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3501 2534
Email address
andaroonnegin80@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-09, 1404/01/20

Expected recruitment end date
2026-03-11, 1404/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of face-to-face Transdiagnostic Treatment (Unified Protocol) on Emotion Regulation, Experiential Avoidance, Social Adjustment, and Resilience in Students with Test Anxiety

Public title
effectiveness of face-to-face psychotherapy on test anxiety
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1.Participants must be between the ages of 15 and 18. 2.They should experience moderate to severe test anxiety. 3.Participants must have no history of severe psychiatric disorders. 4. They should not have received cognitive-behavioral therapy in the past five years 5.If applicable, participants must have stable psychotropic medication. 7.Informed consent must be obtained from participants for their participation in the study, as outlined in the written consent form
Exclusion criteria:
1.Having Autism Spectrum Disorder. 2.Having a chronic illness.
Age
From **15 years** old to **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a parallel-group, double-blind (assessor and analyst-blinded), randomized controlled trial, targeting female students in grades 10 to 12 in Zanjan City. In this section, we will provide a detailed explanation of the randomization process using web-based randomization. Randomization Method (Sampling & Screening) Cluster Sampling & Screening: Initially, two city districts and then two schools will be randomly selected. Students will be screened using the Sarason Test Anxiety Questionnaire, followed by K-SADS-PL diagnostic interviews for those with moderate (scores 13-20) or severe (score 20+) anxiety. Randomization Units and Selection Randomization Units: Eligible students are the units. From the screened pool, 40 eligible students will be randomly selected using web-based randomization and will complete baseline questionnaires (Sarason, STAI, DERS, AAQ-II, Sinha & Singh Adjustment, CD-RISC). Stratified Randomization Stratified Randomization: Stratified randomization will not be employed in this study. However, if necessary, strata based on characteristics like anxiety levels or age could be considered. Randomization Tool Web-Based Randomization: Web-based randomization will be utilized for both the random selection of the 40 participants and their subsequent random assignment. This tool ensures transparent, online, bias-reducing allocation. Random Sequence Generation and Group Allocation Random Sequence & Allocation: After selection and baseline assessment, the 40 participants will be randomly assigned via web-based randomization to one of two groups: the in-person transdiagnostic integrative therapy group (n=20) or the waitlist control group (n=20). The in-person group will be divided into two sub-groups of 10 for facilitation. Allocation Concealment and Blinding Allocation Concealment & Blinding: The web-based randomization sequence will be concealed until assignment. Outcome assessments will be by a blind assessor, and data analysis by a blind analyst. Therapists and participants will be aware of group assignments.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding of Data Collectors Individuals responsible for data collection will remain unaware of the group assignments. This ensures that the data collection process is conducted without bias. Blinding of Outcome Assessors Those evaluating the results of the study will also be blind to the group assignments. This is crucial for maintaining objectivity in the assessment of outcomes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences , Mahdavi Blv, shahrak karmandan
City
zanjan
Province
Zanjan
Postal code

4513956184

Approval date

2025-01-21, 1403/11/02

Ethics committee reference number

IR.ZUMS.REC.1403.287

Health conditions studied

1

Description of health condition studied

test anxiety

ICD-10 code

F40.1

ICD-10 code description

(اختلال اضطراب اجتماعی)

Primary outcomes

1

Description

test anxiety

Timepoint

The measurement will be done in three periods: before the intervention and after the end of the intervention and three months after the end of the intervention

Method of measurement

For the variable of test anxiety, a test anxiety questionnaire comprising 37 items will be utilized.

Secondary outcomes

1

Description

emotion regulation

Timepoint

The measurement will be done in three periods: before the intervention and after the end of the intervention and three months after the end of the intervention

Method of measurement

Difficulties in Emotion Regulation Scale (DERS):This scale was developed in 2004 by Gratz and Roemer with 36 items to assess the level of emotional dysregulation and to evaluate self-regulation strategies.

2

Description

Experiential avoidance

Timepoint

The measurement will be done in three periods: before the intervention and after the end of the intervention and three months after the end of the intervention

Method of measurement

This questionnaire was developed by Bond et al. in 2011 with 10 items to assess experiential avoidance.

3

Description

social adjustment

Timepoint

The measurement will be done in three periods: before the intervention and after the end of the intervention and three months after the end of the intervention

Method of measurement

Social Adjustment Questionnaire for Students (AISS29):This questionnaire was developed by Sinha and Singh in 1993 and consists of 20 items to measure social adjustment.

4

Description

resilience

Timepoint

The measurement will be done in three periods: before the intervention and after the end of the intervention and three months after the end of the intervention

Method of measurement

Connor-Davidson Resilience Scale (CD-RISC):The Connor-Davidson Resilience Scale consists of 25 items rated on a Likert scale from 0 (not true at all) to 5 (true nearly all the time).

Intervention groups

1

Description

Intervention group: The first intervention group will implement the face-to-face group therapy based on the Transdiagnostic Protocol (unified protocol) for adolescents. This protocol consists of 8 modalities and will be conducted over 12 sessions. The modalities of the protocol are as follows: Goal setting and motivation maintenance Understanding emotions Emotion awareness Cognitive flexibility Emotional behavior Understanding and confronting physical sensations Confronting emotions Reviewing skills and progressing towards goals while maintaining achievements The main focus of the protocol is on emotions and its three essential components: thoughts, bodily sensations, and behaviors. In the thoughts component, the focus is on teaching cognitive distortions and cognitive restructuring. In the bodily sensations component, techniques for awareness of physical sensations will be implemented. In the behavior component, concepts of triggers and opposing behaviors will be taught. Finally, techniques for confronting situational emotions and behavioral experiments will be conducted. The modalities will be carried out in 12 group sessions, each lasting 90 minutes.

Category

Treatment - Other

2

Description

Control group:In the control group, no intervention will be conducted. Participants will wait for treatment while monitoring the effectiveness of the therapy on reducing

test anxiety.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Schools in Zanjan City

Full name of responsible person

Negin Andaroon

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1578845136

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andaroonnegin80@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Negin Andaroon

Position

Master's Student

Latest degree

A Level or less

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Negin Andaroon

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Negin Andaroon

Position

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Latest degree

Bachelor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available