

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigating the pattern of transdiagnostic related to emotion regulation of adolescents with high-risk behavior and effectiveness of integrated transdiagnostic therapy on reduction of their anxiety, depression, and emotional dysregulation

Protocol summary

Study aim

The aim is investigating the pattern of transdiagnostic related to emotion regulation of adolescents with high-risk behavior and the effectiveness of integrated transdiagnostic therapy on the reduction of their anxiety, depression, and emotional dysregulation

Design

This study is conducted in the form of a clinical trial with a control group, with parallel groups, double-blind, randomized on 60 patients. The randomization method is a simple randomization method using the table of random numbers.

Settings and conduct

Azadi Urban Comprehensive Center. Using the table of random numbers, patients are randomly divided into two groups: The experimental group and the control group. Even numbers are considered for the experimental group and odd numbers are for the control group. Random allocation is done by the researcher and the clinical caregiver and data analyzer are unaware of the allocation of patients.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of anxiety based on Diagnostic and Statistical Manual of Mental Disorders (DSM); No use of Vitamin D3 before the study; Lack of any psychotherapy during the last 2 months. Exclusion Criteria: seizure; Systolic blood pressure over 12 Drug allergy.

Intervention groups

Patients receive 1 30-minute transdiagnostic training session every week for 12 weeks.

Main outcome variables

Anxiety, Depression, Emotional dysregulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230128057255N1**

Registration date: **2023-06-27, 1402/04/06**

Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**

Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

meysam nikdanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4468 3203

Email address

meysamnikdanesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-03, 1402/05/12

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	None
Scientific title Investigating the pattern of transdiagnostic related to emotion regulation of adolescents with high-risk behavior and effectiveness of integrated transdiagnostic therapy on reduction of their anxiety, depression, and emotional dysregulation	Secondary Ids empty
Public title effectiveness of integrated transdiagnostic therapy	Ethics committees <u>1</u>
Purpose Treatment	Ethics committee Name of ethics committee Ethics committee of Iran university of medical sciences
Inclusion/Exclusion criteria Inclusion criteria: Diagnosis of anxiety based on Diagnostic and Statistical Manual of Mental Disorders (DSM) No use of Vitamin D3 before the study Lack of any psychotherapy during last 2 months Exclusion criteria: seizure Systolic blood pressure over 12 Drug allergy	Street address Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran
Age From 12 years old to 17 years old	City Tehran
Gender Both	Province Tehran
Phase N/A	Postal code 14496-14535
Groups that have been masked - Investigator - Data analyser	Approval date 2022-01-26, 1400/11/06
Sample size Target sample size: 60 More than 1 sample in each individual Number of samples in each individual: 60 Participants assigned randomly	Ethics committee reference number IR.IUMS.REC.1400.999
Randomization (investigator's opinion) Randomized	Health conditions studied <u>1</u>
Randomization description The randomization method is a simple randomization method. The unit of randomization is individual. Using the table of random numbers, patients are randomly divided into two groups: The experimental group and the control group. Even numbers are considered for the experimental group and odd numbers are for the control group. Random allocation is done by the researcher and the clinical caregiver and data analyzer are not aware of the allocation of patients.	Description of health condition studied Anxiety
Blinding (investigator's opinion) Double blinded	ICD-10 code F41.9
Blinding description Treatment allocation was concealed from the therapist and the data analyzer who specified patients by using random table, and opaque, and sealed envelopes. participants pick up envelopes inside the box randomly which are in an unspecified wrapper. They are aware of which experimental group they were assigned to.	ICD-10 code description Anxiety disorder, unspecified
Placebo Not used	<u>2</u>
Assignment Parallel	Description of health condition studied Depression
Other design features	ICD-10 code F32
	ICD-10 code description Depressive episode
	<u>3</u>
	Description of health condition studied Emotional dysregulation
	ICD-10 code F93
	ICD-10 code description Emotional disorders with onset specific to childhood
	Primary outcomes

1

Description

Anxiety symptoms

Timepoint

Assessment of anxiety at the beginning of the study (before the intervention), weeks 4, 8 and 12

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients do not receive any intervention during the 12 weeks.

Category

Behavior

2

Description

Intervention group: Patients receive 1 30-minute transactional training session every week for 12 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadi Urban Comprehensive center

Full name of responsible person

Dr gholam hossein Alishiri

Street address

No 87, Azadi street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Mousavi Zadeh

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No 8, Iran University of Medical Sciences, Tehran, Iran

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Web page address

<https://iums.ac.ir/>

Grant name

none

Grant code / Reference number

none

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

Private

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

Meysam Nikdanesh

Position

phd 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

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

Only part of the data, such as information related to main outcome or like that, can be share.

When the data will become available and for how long

Start of access, 6 months after publishing the results

To whom data/document is available

Only people working in academic institutions could apply.

Under which criteria data/document could be used

People who are conducting clinical trials in this field could apply.

From where data/document is obtainable

By referring to the electronic address:

s.hasanvandi@alzahra.ac.ir

What processes are involved for a request to access data/document

The applicant can receive information by registering the exact personal details.

Comments