Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 nvestigating 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

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

Public title
effectiveness of integrated transdiagnostic therapy
Purpose
Treatment
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
Age
From **12 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **60**
Participants assigned randomly
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
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.
Placebo
Not used
Assignment
Parallel
Other design features
None

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical sciences
Street address
Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2022-01-26, 1400/11/06
Ethics committee reference number
IR.IUMS.REC.1400.999

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

3

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 tranactional 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
City
Tehran
Province
Tehran
Postal code
1343222305
Phone
+98 21 4456 7667
Email
Meysamnikdanesh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Mousavi Zadeh
Street address
No 8, Iran University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 4837
Fax
+98 21 8854 6783
Email
mousavizadeh.kiums@ac.ir
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
Street address
No 65, Block 3, Ekbatan, Tehran
City
Tehran
Province
Tehran
Postal code
1446789545
Phone
+98 919 484 9599
Email

meysamnikdanesh@gmail.com

Person responsible for scientific 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

Street address
No 65, Block 3, Ekbatan, Tehran

City
Tehran

Province
Tehran

Postal code
1446789768

Phone
+98 919 484 9599

Email
meysamnikdanesh@gmail.com

Person responsible for updating data

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

Street address
No 65, Block 3, Ekbata, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1447645678

Phone
+98 919 484 9599

Email
meysmnikdanesh@gmail.com

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