Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of Transdiagnostic Cognitive-Behavioral Therapy Protocol on Reducing Subclinical Symptoms of Anxiety and Depression, Improving Emotion Regulation, Resilience and Spiritual Health in Students

Protocol summary

Study aim
Determining the effectiveness of transdiagnostic cognitive-behavioral therapy protocol on reducing preclinical symptoms of anxiety and depression, improving emotion regulation, resilience and spiritual health in students

Design
A randomized, randomized controlled clinical trial on 56 patients.

Settings and conduct
In this research, after receiving the code of ethics from the ethics committee of Shahid Beheshti University of Medical Sciences, sample people are selected based on the Inclusion criteria, and then after the initial interview according to SCID-5-RV and declaring their willingness to participate in the meetings, explanations They are given about research. All participants complete the DASS, CERQ, CD-RISC, SWB, and CFI questionnaires before starting the treatment during the introductory session and then immediately after the course and 2 months later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having preclinical anxiety and depression symptoms based on the cut-off point of a score of 18 and above in the DASS-42 subscale and a score of 16 and above in the anxiety subscale of the DASS-42 scale, Not suffering from severe psychiatric disorders, Not using drugs and alcohol in the last three months. Willingness to participate in research. Exclusion criteria: receiving cognitive-behavioral interventions for at least 8 sessions in the last 1 year.

Intervention groups
Intervention group: includes all students of Farhangian University of Tehran province who receive integrated transdiagnostic treatment as a group in 14 sessions of 60 minutes on a weekly basis. The control group includes students who do not receive any intervention.

Main outcome variables
Connor and Davidson Resilience Scale (CD-RISC), Cognitive Emotion Regulation Questionnaire (CERQ), Depression- Anxiety- Stress Scale (DASS), Cognitive flexibility scale (CFI), Spiritual well-being questionnaire (SWB)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211223053494N4**
Registration date: **2023-05-11, 1402/02/21**
Registration timing: **prospective**

Last update: **2023-05-11, 1402/02/21**
Update count: **0**

Registration date
2023-05-11, 1402/02/21

Registrant information

Name
Jafar Sarani yaztappeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-31, 1402/03/10
Expected recruitment end date
2023-08-11, 1402/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Transdiagnostic Cognitive-Behavioral Therapy Protocol on Reducing Subclinical Symptoms of Anxiety and Depression, Improving Emotion Regulation, Resilience and Spiritual Health in Students

Public title
The Effectiveness of Transdiagnostic Cognitive-Behavioral Therapy Protocol on Subclinical Symptoms of Anxiety and Depression, Emotion Regulation, Resilience and Spiritual Health
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
having preclinical anxiety and depression symptoms based on the cut-off point of a score of 18 and above in the DASS-42 subscale and a score of 16 and above in the anxiety subscale of the DASS-42 scale, Not suffering from specific or underlying physical diseases, Not suffering from severe psychiatric disorders such as bipolar spectrum disorders, psychotic spectrum disorders, and cognitive disorders. Not using drugs and alcohol in the last three months. Absence of speech or hearing problems Willingness to participate in research
Exclusion criteria:
absence of more than two sessions, receiving another similar psychological intervention at the same time as the current research, receiving cognitive-behavioral interventions for at least 8 sessions in the last 1 year, receiving psychiatric drugs at the same time as the intervention or within a month before the intervention, Lack of consent to continue the treatment during the intervention process, Aggravation of the person's problems during the intervention and the need to provide another intervention
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be simple randomization. The randomization unit is people. 56 student subjects will be divided into intervention and control groups by Microsoft Excel software using Rand function. Based on this, a table of random numbers is prepared and the Randbetween function is created, and the subjects are placed in two groups of 28 people according to the rows of this table.
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 Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me
Street address
Shahid Beheshti University of Medical Sciences, Shahid Chamran Evin Highwa
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Postal code
1985717443
Approval date
2022-09-11, 1401/06/20
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.407

Health conditions studied

1

Description of health condition studied
Anxiety, Depression, Emotion Regulation, Resilience and Spiritual Health
ICD-10 code
F54
ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Cognitive Emotion Regulation Score (CERQ) in the Garnevsky Questionnaire, Craig Vaspinhaven

Timepoint
At the beginning of the study (before the intervention), after the intervention and 2 months after the intervention
Method of measurement
Cognitive Emotion Regulation Questionnaire (CERQ)

2

Description
Depression, anxiety and stress score in Lovibond and Lovibond scale
Timepoint
At the beginning of the study (before the intervention), after the intervention and 2 months after the intervention
Method of measurement
Depression- Anxiety- Stress Scale (DASS)

Secondary outcomes

1

Description
Spiritual well-being score in Paloutzian and Ellison questionnaire
Timepoint
At the beginning of the study (before the intervention), after the intervention and 2 months after the intervention
Method of measurement
Spiritual well-being (SWB)

2

Description
Cognitive flexibility score in Dennis scale
Timepoint
At the beginning of the study (before the intervention), after the intervention and 2 months after the intervention
Method of measurement
Cognitive flexibility scale (CFI)

3

Description
Connor and Davidson Resilience Scale (CD-RISC)
Timepoint
At the beginning of the study (before the intervention), after the intervention and 2 months after the intervention
Method of measurement
Connor and Davidson Resilience Scale (CD-RISC)

Intervention groups

1

Description
Intervention group: includes all students of Farhangian University of Tehran province who receive integrated transdiagnostic treatment as a group according to the protocol in 14 sessions of 60 minutes on a weekly basis. This treatment was designed by Barlow et al (2011). The content of the first session: (module one): improving motivation to engage in treatment, introducing motivation and discussing its importance for the outcome of treatment, helping the patient to evaluate the pros and cons of changing, helping the patient to evaluate the pros and cons of not changing, helping the patient to establish specific treatment goals, helping the patient to determine manageable steps to achieve the treatment goals. The second session (second module): psychological education and the logic of therapy, reviewing the assignment of the previous session, creating an overview of the functional and adaptive nature of emotions, presenting the three components of emotional experiences (thoughts, physical feelings and behaviors), introducing the concept of behaviors arising from emotions, Introducing the antecedents, responses and consequences of emotional experiences, discussing the learned responses of the third and fourth session (third module): emotional awareness training, reviewing the assignment of the previous session, introducing non-judgmental emotional awareness, introducing present-focused awareness, implementing emotional awareness exercises within the session, help To the patient to practice techniques using mood induction using music in the fifth and sixth session (fourth module): Cognitive Appraisal and Reappraisal, review of the assignment of the previous session, explanation of the mutual relationship between thoughts and emotions, introduction of automatic evaluations, introduction of mental traps common and helping the patient to identify them, introducing cognitive re-evaluation and helping the patient to practice it in order to increase flexibility in thinking, the seventh session (fifth module): emotional avoidance and behaviors arising from emotion, review of the assignment of the previous session, introducing the concept of emotional avoidance, Introducing the types of emotional avoidance strategies and discussing the contribution of these strategies in the negative cycle of emotional response, helping the patient to identify his emotional avoidance strategies, proving the contradictory effects of emotional avoidance, re-introducing the concept of behaviors arising from emotion and discussing them more deeply, introducing the logic of confrontation with behaviors arising from emotions, identifying behaviors arising from maladaptive emotions, the eighth session (sixth module): Awareness and Tolerance of Physical Sensations, reviewing the previous session's assignment, helping the patient to identify internal physical feelings related to emotions, helping the patient to gain more understanding From the role of internal physical feelings in creating an emotional response, performing symptomatic exercises designed to evoke uncomfortable physical feelings, sessions 9 to 13 (seventh module): Interoceptive and Situational Emotion Exposures, reviewing the assignment of the previous session, helping the patient to understand the purpose of emotional exposures. , helping the patient to create a hierarchy of emotional and situational avoidance, designing effective emotion coping exercises, helping

patients to face strong emotions through emotional coping exercises, the fourteenth session (eighth module): Accomplishments, Maintenance, and Relapse Prevention, Reviewing the assignment of the previous session, reviewing coping skills, reviewing treatment progress, identifying and fixing potential or common triggers, promoting the generalization of skills, and establishing goals for continuous improvement.

Category

Treatment - Other

2

Description

Control group: includes students who do not receive intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Jafar Sarani Yaztappeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti 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

Seyedeh Elnaz Mousavi

Position

Assistant Professor

Latest degree

Ph.D.

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

There is no more information.

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments