Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The Comparison Of Efficacy Of Face-To-Face Unified Transdiagnostic Therapy With Internet-Based Unified Transdiagnostic Therapy In Reducing Symptoms And Improving The Function Of Adolescents With Depressive And Anxiety Disorders

Protocol summary

Study aim

1- Comparison of the effectiveness of unified face-to-face transdiagnostic treatment with unified Internet-based transdiagnostic treatment in reducing the symptoms of emotional disturbance in adolescents with anxiety and depressive disorders. 2. Comparison of the effectiveness of unified face-to-face and Internet-based transdiagnostic treatment in improving the functioning of adolescents with anxiety and depressive disorders.

Design

Clinical trial with control group, with parallel, randomized groups, on 45 patients. The "Random Allocation Law" method will be used for randomization.

Settings and conduct

First, based on a structured clinical interview by a clinical psychologist and psychiatrist, 45 people with one or more of the anxiety or depressive disorders (based on DSM5) were referred to a psychiatric clinic, hospital psychiatric clinics, or school counselors in the cities of Tehran, Karaj and Rasht have been selected and patients who have responded to the therapist's online call will be selected. Sampling will be purposeful and individuals will be assigned to 3 groups of face-to-face treatment, Internet-based treatment and control, 15 people in each group, after meeting the criteria for entering the research and the absence of criteria for leaving the research. People will be assigned in three groups at random.

Participants/Inclusion and exclusion criteria

patients with anxiety and depressive disorders.

Intervention groups

1- Unified face-to-face transdiagnostic treatment group: the group that receives face-to-face protocol of Ehrenreich et al. 2. Internet-based unified transdiagnostic treatment: the group that receives the unified treatment through a website (researcher-made). 3. Control group: the group that does not receive treatment at the same time as the two experimental groups.

Main outcome variables

Improve function, reduce the symptoms of anxiety and depressive disorders.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220226054129N1**
Registration date: **2022-03-05, 1400/12/14**
Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**
Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name
Nasim Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison Of Efficacy Of Face-To-Face Unified Transdiagnostic Therapy With Internet-Based Unified Transdiagnostic Therapy In Reducing Symptoms And Improving The Function Of Adolescents With Depressive And Anxiety Disorders

Public title

The Comparison of Face-To-Face Unified Transdiagnostic Therapy with Internet-Based Unified Transdiagnostic Therapy in Adolescents with Depressive and Anxiety Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The diagnosis and the main problem of the person, based on the clinical interview by a clinical psychologist or psychiatrist, is a mood or anxiety disorder (combination of psychiatric problems including conduct disorders, attention deficit-hyperactivity disorder, eating disorders, non-interfering with treatment drug abuse, are acceptable, if the main problem is anxiety or depression). The person has not had CBT treatment for anxiety or depression in the past. Age between 12 and 18 years. If the person is taking medication, a stable dose has been reached and it is necessary that this stable dose be obtained for SSRIs three months before the start of treatment and for benzodiazepines one month before the start of treatment. Access to high speed internet at home.

Exclusion criteria:

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: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, the method of "random allocation law" will be used for randomization. The researcher prepares 15 balls for group A, 15 balls for group B and 15 balls for group C and places them all in the lottery container. The balls are then randomly removed from the container without replacement and the sequence created is recorded.

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

Ethics committee of University of Social welfare and rehabilitation sciences

Street address

No. 9, P. 24, Pakzadnia Alley, West Mirzaee Zeynali Ave., North Sohrevardi Ave.

City

Tehran

Province

Tehran

Postal code

1576977619

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.USWR.REC.1399.167

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F30

ICD-10 code description

Major depressive disorder, recurrent

2

Description of health condition studied

Persistent mood disorders

ICD-10 code

F34

ICD-10 code description

Persistent mood [affective] disorders

3

Description of health condition studied

Phobic anxiety disorders

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

4

Description of health condition studied
Other anxiety disorders
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
The primary outcome is depression and is measured using the RCADS (Revised Child Anxiety and Depression Scale).
Timepoint
The beginning of the intervention, the end of the intervention, three months after the end of the intervention.
Method of measurement
RCADS (Revised Child Anxiety and Depression Scale)

2

Description
The primary outcome is anxiety and is measured using the RCADS (Revised Child Anxiety and Depression Scale).
Timepoint
The beginning of the intervention, the end of the intervention, three months after the end of the intervention
Method of measurement
RCADS (Revised Child Anxiety and Depression Scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the first group will receive treatment face to face. Treatment sessions will be individual, and unified transdiagnostic treatment will be conducted in eleven 45-minute sessions weekly. Unified transdiagnostic treatment of adolescent emotional disorders refers to the Ehrenreich May et al. (2017) protocol. The unified protocol consists of four main parts, which are: increasing emotional awareness, facilitating flexibility in assessments, identifying and preventing behavioral and emotional avoidance, and situational and internal exposure to emotion clues.
Category
Treatment - Other

2

Description
Intervention group: People in the second group will receive treatment based on the Internet and through a website. This treatment is also designed based on unified protocol of transdiagnostic treatment of emotional disorders for adolescence.
Category
Treatment - Other

3

Description
Control group: During this period, no intervention will be performed for the control group, but after the end of the treatment time, the members of the control group will also be treated.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Nezam Mafi Clinic
Full name of responsible person
Nasim Mousavi
Street address
Near Nezam Mafi Mosque, After Jannatabad, Ayatollah Kashani BLV.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Proportion provided by this source
10

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
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamid Poursharifi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
Not applicable

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

Not applicable

Data Dictionary

Not applicable