

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the efficacy of face-to-face and online Transdiagnostic therapy on anxiety severity, related transdiagnostic factors and therapeutic alliance in people with Sub-clinical symptoms of anxiety disorders

Protocol summary

Study aim

Comparison of the efficacy of face-to-face and online Transdiagnostic therapy on anxiety severity, related transdiagnostic factors and therapeutic alliance in people with Sub-clinical symptoms of anxiety disorders

Design

The clinical trial will be randomized using the random function of Excel software

Settings and conduct

The intervention is individual and will be done in 12 sessions. Sessions will last 45 minutes. According to the protocol, the medals will be implemented as well as the number of sessions determined for each medal.

Participants/Inclusion and exclusion criteria

having subclinical anxiety symptoms based on Beck's anxiety questionnaire (scoring 8-25) age range between 18-50 years not suffering from severe psychiatric disorders (psychotic spectrum, bipolar disorder) not consuming drugs and alcohol in the last three months Not receiving cognitive-behavioral interventions for at least eight sessions in the last five years not receiving drug therapy within a month before the start of the intervention the interest of the participants to participate in the research based on the provisions of the written consent: Having drug or alcohol addiction suffering from severe psychiatric disorders (schizophrenia and bipolar disorder)

Intervention groups

In this study, 12 45-minute therapy sessions will be conducted for the members of the intervention group. In the first intervention group, these sessions will be held in person, and in the second group, they will be held online. The main focus in the sessions is on cognitive reconstruction, awareness of bodily sensations, awareness of the present moment, teaching the concepts of contradictory behavior and the three

components of emotion, which include thoughts, bodily sensations, and behavior.

Main outcome variables

Anxiety intensity, anxiety sensitivity, negative repetitive thoughts, positive and negative affect and therapeutic alliance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230117057142N1**

Registration date: **2023-02-09, 1401/11/20**

Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **0**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

Zeinab Hasanpour pirstasti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-08, 1401/12/17
Expected recruitment end date
 2023-06-20, 1402/03/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of the efficacy of face-to-face and online Transdiagnostic therapy on anxiety severity, related transdiagnostic factors and therapeutic alliance in people with Sub-clinical symptoms of anxiety disorders

Public title
 Comparison the effectiveness of face-to-face and online psychotherapy on mild anxiety

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 having subclinical anxiety symptoms based on Beck's anxiety questionnaire (scoring 8-25) age range between 18-50 years not suffering from severe psychiatric disorders (psychotic spectrum, bipolar disorder) not consuming drugs and alcohol in the last three months Not receiving cognitive-behavioral interventions for at least eight sessions in the last five years not receiving drug therapy within a month before the start of the intervention the interest of the participants to participate in the research based on the provisions of the written consent
Exclusion criteria:
 Having drug or alcohol addiction suffering from severe psychiatric disorders (schizophrenia and bipolar disorder)

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The samples are randomly assigned to two test groups. Random allocation is done using Excel software. For this purpose, in the first column, we enter 22 numbers 1 and 22 numbers 2 (respectively indicating the group (online and face-to-face integrative meta-diagnostic treatment group). Then in the second column, we generate 44 random numbers using the RAND() function. The data Based on the column values, we include random numbers sorted (ascending or descending). With this sorting, the order of placement of numbers 1 and 2 will also change and be placed randomly. Based on the order

of appearance of numbers 1 and 2, the samples are assigned to two groups.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 None of the subjects will be informed about the randomization and interpretation process of the groups.

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

2023-01-11, 1401/10/21

Ethics committee reference number

IR.ZUMS.REC.1401.298

Health conditions studied

1

Description of health condition studied

Social phobias

ICD-10 code

F40.1

ICD-10 code description

Social phobias

2

Description of health condition studied

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

3

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

4

Description of health condition studied

Other mixed anxiety disorders

ICD-10 code

F41.3

ICD-10 code description

Other mixed anxiety disorders

5

Description of health condition studied

Phobic anxiety disorders

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

6

Description of health condition studied

Agoraphobia, unspecified

ICD-10 code

F40.00

ICD-10 code description

Agoraphobia, unspecified

Primary outcomes

1

Description

Score in Beck's Anxiety Questionnaire

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 برای

Method of measurement

Beck's anxiety questionnaire will be used for the variable of anxiety, and the subject's score in the range of 8-25 indicates the presence of subclinical symptoms of anxiety.

Secondary outcomes

1

Description

Repetitive negative thoughts: their main characteristic is being repetitive, disturbing and unwanted.

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 Repetitive negative thoughts variable, the Repetitive negative thoughts questionnaire will be used, which includes 10 questions.

2

Description

Anxiety sensitivity

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

The anxiety sensitivity questionnaire is a 16-item self-report questionnaire. The said questionnaire has 16 items and 3 subscales: physical concerns, fear of losing cognitive control, and fear of anxiety being observed by others.

3

Description

Positive and Negative Affect

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

The positive and negative affect scale is a 20-word instrument designed to measure two mood dimensions, namely positive affect and negative affect.

4

Description

therapeutic alliance

Timepoint

The client and therapist versions of the therapeutic alliance Questionnaire are completed in the 6th session and the 12th session.

Method of measurement

The Work Alliance Questionnaire is a questionnaire that includes two forms, client and therapist versions. Each version contains 12 questions and is scored on a Likert scale from 1 to 5. One of the most common tools for evaluating the quality of therapeutic alliance is the working alliance questionnaire

Intervention groups

1

Description

The first intervention group face-to-face Transdiagnostic treatment group: The intervention will be implemented face-to-face and based on the Transdiagnostic therapy (Unified protocol) for adults. This protocol has 8 modules that will be implemented in 12 sessions. The protocol modules are 1 (goal selection and maintaining motivation) 2 (understanding emotions) 3 (mindfulness of emotion) 4 (cognitive flexibility) 5 (emotional behavior) 6 (understanding and dealing with bodily

sensations) 7 (facing with excitement) 8 (reviewing skills and moving towards goals and maintaining achievements). The main focus of the protocol is on emotion and its three basic components, namely thoughts, physical sensations, and behavior. In the component of thoughts, the focus is on training mental errors and cognitive restructuring. In the component of bodily sensations, the techniques of awareness of bodily sensations are implemented. In the behavior component, training on the concepts of initiation and conflicting behavior is given. Finally, coping techniques with situational emotions and behavioral tests will be performed. Modals will be implemented during 12 sessions of 45 minutes for approximately 6 weeks. These modules will be distributed in the sessions according to the client's understanding and acceptance of the concepts and problems related to the preclinical symptoms of anxiety disorder, which is unique for each client.

Category

Treatment - Other

2

Description

The second intervention group, the online Transdiagnostic treatment group: the intervention will be implemented online and based on the Transdiagnostic therapy (Unified protocol) for adults. This protocol has 8 modules that will be implemented in 12 sessions. The protocol modules are 1 (goal selection and maintaining motivation) 2 (understanding emotions) 3 (mindfulness of emotion) 4 (cognitive flexibility) 5 (emotional behavior) 6 (understanding and dealing with bodily sensations) 7 (facing with excitement) 8 (reviewing skills and moving towards goals and maintaining achievements). The main focus of the protocol is on emotion and its three basic components, namely thoughts, physical sensations, and behavior. In the component of thoughts, the focus is on training mental errors and cognitive restructuring. In the component of bodily sensations, the techniques of awareness of bodily sensations are implemented. In the behavior component, training on the concepts of initiation and conflicting behavior is given. Finally, coping techniques with situational emotions and behavioral tests will be performed. Modals will be implemented during 12 sessions of 45 minutes for approximately 6 weeks. These modules will be distributed in the sessions according to the client's understanding and acceptance of the concepts and problems related to the preclinical symptoms of anxiety disorder, which is unique for each client.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

zeinab hasanpour pirbasti

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2

Recruitment center

Name of recruitment center

Suhrvardi Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

zeinab hasanpour pirbasti

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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