

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of integrated cognitive-behavioral therapy with transdiagnostic treatment on symptoms of patients with generalized anxiety disorder comorbid with depression

Protocol summary

Study aim

Comparison of the effectiveness of integrated cognitive-behavioral therapy with Transdiagnostic Treatment on symptoms of patients with generalized anxiety disorder comorbid with depression

Design

Competitive validation of a two-group quasi-experimental design (group 1): integrated treatment intervention group and (group 2): single diagnostic treatment group in a single case with different subjects and continuous assessment. Targeted and random sampling in two groups using random numbers.

Settings and conduct

Once the baseline in the research variables was determined, in the next stage, the interventions were performed individually in one-hour weekly sessions. Subjects in both groups were evaluated to follow the results of treatment in the time intervals of the third, sixth, eighth and tenth sessions (completion of treatment sessions) and one-month follow-up with research scales.

Participants/Inclusion and exclusion criteria

Education cycle and age range 20 to 55 years, the main and primary diagnosis of generalized anxiety disorder based on diagnostic interview and generalized anxiety questionnaire, having symptoms of depression syndrome based on diagnostic interview and depression questionnaire, no disease or other psychiatric diagnosis other than Generalized Anxiety Disorder And Depression. Reluctance and satisfaction from participating in the study were also conditions for not entering the study.

Intervention groups

Integrated cognitive-behavioral therapy; transdiagnostic treatment

Main outcome variables

Anxiety, worry and depressive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200918048749N1**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **retrospective**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

Farzad Ghaderi

Name of organization / entity

University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 83 5835 0709

Email address

f.ghaderi@edu.ui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2020-02-20, 1398/12/01

Scientific title

Comparison of the effectiveness of integrated cognitive-behavioral therapy with transdiagnostic treatment on symptoms of patients with generalized anxiety disorder comorbid with depression

Public title

Comparison of the effectiveness of integrated cognitive-behavioral therapy with transdiagnostic treatment on symptoms of patients with generalized anxiety disorder comorbid with depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Third grade middle school education Age range 20 to 55 years Main and initial diagnosis of generalized anxiety disorder based on diagnostic interview and generalized anxiety questionnaire Having sub-syndromic symptoms of depression based on diagnostic interview and depression questionnaire No illness or psychiatric diagnosis other than generalized anxiety disorder and depression

Exclusion criteria:

Dissatisfaction and unwillingness to participate in research work

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Actual sample size reached: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

University of Isfahan

Street address

University of Isfahan, Daneshgah street

City

isfahan

Province

Isfahan

Postal code

8174673441

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.UI.REC.1398.013

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Generalized anxiety disorder symptoms

Timepoint

Third, sixth, eighth and tenth sessions and one month follow-up

Method of measurement

GAD-7 scales

2

Description

Worry

Timepoint

Third, sixth, eighth and tenth sessions and one month follow-up

Method of measurement

Penn State Worry Questionnaire (PSWQ)

3

Description

Depression

Timepoint

Third, sixth, eighth and tenth sessions and one month follow-up

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Integrated cognitive behavioral therapy. One-hour weekly sessions of integrated cognitive-behavioral therapy in a single case

Category

Behavior

2

Description

Intervention group: Transdiagnostic treatment. One-hour weekly Transdiagnostic treatment sessions on a case-by-case basis.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Isfahan

Full name of responsible person

Farzad ghaderi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, University of Isfahan

Full name of responsible person

Dr Rasoul Roknizadeh

Street address

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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

Deputy of Research, University of Isfahan

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

University of Isfahan

Full name of responsible person

Farzad Ghaderi

Position

student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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)**

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

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data related to the main outcomes of the study without mentioning the demographic characteristics of the subjects

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Academic researchers after authentication

Under which criteria data/document could be used

Requesting the use of data is permitted only for use in cross-cultural surveys or meta-analysis studies.

From where data/document is obtainable

The request should be sent to Farzad Ghaderi's email address. email: ghaderi68@yahoo.com

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

Data information will be provided to individuals via email after the application is evaluated.

Comments