Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 83 5835 0709

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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
Isfehan

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
Street address
University of Isfahan, Daneshgah street
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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
University of Isfahan, Daneshgah street
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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

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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