

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Efficacy effect of integrated transdiagnostic treatment on reducing the symptoms in individuals with general anxiety disorder and its co-morbidity

Protocol summary

Study aim

Determination of the efficacy of integrated transdiagnostic treatment on reducing the symptoms in individuals with general anxiety disorder and its co-morbidity

Design

Clinical trial with control ,Not blind, randomized

Settings and conduct

Farabi Hospital in Kermanshah-Patients receive 12 sessions of integrated transdiagnostic treatment individually.

Participants/Inclusion and exclusion criteria

The main inclusion criterion:The person has a generalized anxiety disorder as the primary diagnosis
The main inclusion criteria:The current diagnosis of any mental disorder is consistent in Diagram 1 and 2 based on a psychiatrist's diagnostic interview, with the exception of emotional disturbances

Intervention groups

12 patients receive transdiagnostic and drug treatment, and 12 receive drug treatment.

Main outcome variables

Symptoms of generalized anxiety disorder and its co-morbidity

General information

Reason for update

Acronym

UTT

IRCT registration information

IRCT registration number: **IRCT20120619010063N7**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **retrospective**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

Registration date

2018-05-11, 1397/02/21

Registrant information

Name

Kheirollah Sadeghi

Name of organization / entity

Kermanshah University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy effect of integrated transdiagnostic treatment on reducing the symptoms in individuals with general anxiety disorder and its co-morbidity

Public title

Efficacy transdiagnostic therapy in the treatment of generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 18 years of age Have at least 3rd grade education A person experiences generalized anxiety disorder as the primary diagnosis based on a psychiatrist's diagnosis and a diagnostic interview by a psychologist Motivation and satisfaction for participation during treatment and research implementation

Exclusion criteria:

The current diagnosis of any mental disorder is consistent in Diagrams 1 and 2 based on a psychologist's diagnostic interview, with the exception of emotional disturbances The current risk of suicide Not receiving psychological treatment in the past year Abuse history or substance dependence currently and over a year before the start of treatment Unwillingness to attend research meetings

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups (simple randomization), Twenty-four patients with generalized anxiety disorder using random numbers table assigned to one of the intervention or control groups. Patients are assigned individually in groups.

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

Ethic's committee of Kermanshah University of Medical Sciences

Street address

Headquarter, Shahid Beheshti Blvd , Kermanshah

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Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-02-14, 1396/11/25

Ethics committee reference number

KUMS.REC.1396.617

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

genralized anxiety

Timepoint

pre-test, post-test, two months follow up

Method of measurement

Penn State Worry Questionnaire.

Secondary outcomes

1

Description

Depression

Timepoint

pre-test, post-test, two months follow up

Method of measurement

Beck Depression Inventory - Second Edition

2

Description

social anxiety

Timepoint

pre-test, post-test, two months follow up

Method of measurement

Social Interaction Anxiety Scale

3

Description

Health Anxiety

Timepoint

pre-test, post-test, two months follow up

Method of measurement

Short Form-Health Anxiety Inventory

4

Description

sleep quality

Timepoint

pre-test, post-test, two months follow up

Method of measurement

Pittsburgh Sleep Quality Index

5

Description

work and Social Adjustment

Timepoint

pre-test, post-test, two months follow up

Method of measurement

work and Social Adjustment Scale

Intervention groups

1

Description

Intervention group: 12 sessions of integrated transdiagnostic treatment of Barlow and colleagues-It has 5 main sections(Teaching awareness of emotions, cognitive flexibility, emotional avoidance and emotion-driven behaviors , awareness and tolerance of physical sensations and facing the emotions in the position) and 3 sub-sections (Increased motivation and passion for change and participation in treatment,train the nature of emotions and review the progress of treatment and strategies to prevent relapse) and target key aspects of emotional processing and regulation of emotional experiences. treatment sessions are done weekly and within 3 months. Patients are simultaneously treated with approximately the same drugs, such as benzodiazepines

Category

Behavior

2

Description

Control group: no intervention (Medicine alone)-Patients are only treated with approximately the same drugs as benzodiazepines.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Mohsen Mohammadpour

Street address

Kermanshah-Shahid Shiroodi Blvd.-Imam Reza

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Grant name

Kermanshah University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohsen Mohammadpour

Position

MSc

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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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

The participants are unclear

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

No - There is not 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