Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
Phone
+98 83 1826 0700
Email address
khsadeghi@kums.ac.ir

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

City

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 Hospital- Medical school
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 5925
Email
mohammdpour5711@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Headquarte, Shahid Beheshti Blvd, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 5925
Email
fnajafi@kums.ac.ir
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
Street address
Kerma Hospital- nshah-Shahid Shiroodi Blvd.-Imam Reza Medical School
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 5925
Email
mohammdpour5711@gmail.com

Person responsible for scientific 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
Street address
Kermanshah-Shahid Shiroodi Blvd.-Imam Reza Hospitantel- Medical School
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 5925
Email
mohammdpour5711@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Kheirollah Sadeghi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Kermanshah-Shahid Shiroodi Blvd.-Imam Reza Hospital- Medical School
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 5925
Email
khirollahsadeghi@yahoo.com

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