

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative effects of cognitive behavioral therapy focused on intolerance of uncertainty and pharmacotherapy among patients with generalized anxiety disorder

Protocol summary

Summary

The purpose of the study: comparative effects of cognitive behavioral therapy focused on intolerance of uncertainty and pharmacotherapy among patients with generalized anxiety disorder. Design of the study: random. The study population: included all patients referred to private and public institutions are the city of Sanandaj, Iran by clinicians and psychiatrist receive GAD diagnose. The main inclusion criteria of the study: the age range of between 18 to 35 years; female gender; GAD diagnosis according to DSM-5 criteria. The main exclusion criteria of the study: comorbidity with other mental disorders; psychotic symptoms (hallucinations, delusions); having a physical illness. The sample size is 30, based on clinical interviews and diagnostic criteria for DSM-5 diagnosis of GAD are receiving. Interventions studied: group I (CBT), group II (pharmacologic treatment) took the intervention: 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020626397N1**
Registration date: **2016-03-06, 1394/12/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-06, 1394/12/16

Registrant information

Name

Negar Beheshti

Name of organization / entity

University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 4502

Email address

n.beheshti@hum.uok.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Kurdistan

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of cognitive behavioral therapy focused on intolerance of uncertainty and pharmacotherapy among patients with generalized anxiety disorder

Public title

Compare psychological and pharmacological treatment of generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 35 years old; female gender; diagnosis of GAD according to DSM-5 criteria, and that so far have not received any treatment, including psychological and medical treatments.
Exclusion criteria: comorbidity with other mental

disorders; psychotic symptoms (hallucinations, delusions); having a physical illness.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

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

Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Abidar St.

City

Sanandaj

Postal code

6618634683

Approval date

2016-02-03, 1394/11/14

Ethics committee reference number

MUK.REC.1394.309

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, after the intervention and 1 month after intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

1

Description

Intolerance of Uncertainty

Timepoint

Before the intervention, after the intervention and 1 month after intervention

Method of measurement

Intolerance of Uncertainty Scale

2

Description

Worry

Timepoint

Before the intervention, after the intervention and 1 month after intervention

Method of measurement

Penn State Worry Questionnaire-Why Worry-II-Questionnaire

3

Description

Cognitive Avoidance

Timepoint

Before the intervention, after the intervention and 1 month after intervention

Method of measurement

Cognitive Avoidance Questionnaire

4

Description

Negative Problem Orientation

Timepoint

Before the intervention, after the intervention and 1 month after intervention

Method of measurement

Negative Problem Orientation Questionnaire

Intervention groups

1

Description

Type of intervention: a cognitive behavioral intervention group (intervention intolerance of uncertainty) is carried out which consists of twelve weekly 60-minute sessions.

Category

Behavior

2

Description

Control group: group medication (anti-anxiety medications appropriate dose, under the Psychiatric) is performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University Counseling Center

Full name of responsible person

Dr. Mehdi Zemestani

Street address

pasdaran Blv.Sanandaj

City

Sanandaj

2

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Dr. Farzin Rezai

Street address

Zhyna building, Safari crossroad, Azadi Square, Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Kurdistan

Full name of responsible person

Mehdi Zemestani

Street address

University of Kurdistan, Pasdaran Blvd.

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Kurdistan

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Kurdistan

Full name of responsible person

Negar Beheshti

Position

Master student

Other areas of specialty/work

Street address

University of Kurdistan, Pasdaran Blvd.

City

Sanandaj

Postal code

Phone

+98 83 3835 4502

Fax

Email

ne.beheshti@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Kurdistan

Full name of responsible person

Mehdi Zemestani

Position

PhD in Psychology

Other areas of specialty/work

Street address

University of Kurdistan, Pasdaran Blvd.

City

Sanandaj

Postal code

Phone

+98 87 0912 4374

Fax

Email

m.zemestan@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Kurdistan

Full name of responsible person

Negar Beheshti

Position

Master student

Other areas of specialty/work

Street address

University of Kurdistan, Pasdaran Blvd.

City

Sanandaj

Postal code

Phone

+98 83 3835 4502

Fax

Email

ne.beheshti@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty