

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Moderating role of locus of control on the effectiveness of Cognitive - Behavior Therapy and Relaxation in 30 patients with generalized anxiety disorder

Protocol summary

Summary

Locus of control is one of the known personality variables, refers to judgment of causality or causation's embodied of events, necessary for the prognosis of psychotherapies. The aim of this study was to investigate the relationship between locus of control and therapeutic effect of cognitive-behavior therapy and relaxation, in patients with Generalized Anxiety Disorder. For this purpose, 30 patients who have been diagnosed with generalized anxiety disorder by clinical interview using DSM-IV-TR, using convenience sampling chose and assigned randomly into two groups, one experimental and one control group each contains 15 members. For one of the groups during twelve sessions (one hour a week) cognitive behavior therapy and for the other group eight sessions (one hour a week) relaxation training applied. At the start and the end of the process, they tested on the Rotter Locus of Control scale and Beck Anxiety inventory. Result analyzed according to the patient's locus of control using ANCOVA to determine the role of locus of control in the therapeutic effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052517839N1**

Registration date: **2014-08-15, 1393/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name

Hiwa Karimi

Name of organization / entity

Kurdistan University

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Myself

Expected recruitment start date

2013-01-19, 1391/10/30

Expected recruitment end date

2013-04-19, 1392/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Moderating role of locus of control on the effectiveness of Cognitive - Behavior Therapy and Relaxation in 30 patients with generalized anxiety disorder

Public title

Role of locus of control on the effectiveness of Cognitive - Behavior Therapy in patients with generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 45 years, minimum education 9th, and clinical diagnosis of

generalized anxiety disorder according to the DSM-IV-TR. Exclusion criteria included: Drug addiction, physical disease, and personality disorders.

Age

From **18 years** old to **45 years** old

Gender

Both

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

Method of randomization: After selecting 30 patients using convenience sampling, the first patient using coin assigned in cognitive - behavior group. Consequently, second patient assigned in the relaxation group, third in cognitive - behavior Group and so on ...

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University

Street address

Kurdistan University, Pasdaran Ave. Pasdaran Blvd.
Sanandaj

City

Sanandaj

Postal code

6617715175

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

112/9518

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances.

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and immediately after intervention

Method of measurement

Beck anxiety inventory

2

Description

Locus of control

Timepoint

Before intervention and immediately after intervention

Method of measurement

Rotter locus of control scale

Secondary outcomes

empty

Intervention groups

1

Description

Cognitive - Behavior therapy applied during twelve sessions, one hour a week and based on Beck's cognitive therapy. At the end of each session, homework gave to patients and the beginning of the next session the performance and results discussed.

Category

Behavior

2

Description

Relaxation training applied during eight sessions, one hour a week based on Ost's applied relaxation. At the end of each session, homework gave to patients and the beginning of the next session the performance and results discussed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Marivan Welfare center

Full name of responsible person

Aram Ranginkaman

Street address

Behzisti Ave. Ebadat Blvd. Mariwan Welfare center

City

Mariwan

2**Recruitment center****Name of recruitment center**

Tolo Counseling Center

Full name of responsible person

Fatah Rezaie

Street address

Beside Maharat driving education center, Ebadat Blvd. Mariwan

City

Mariwan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kurdistan University

Full name of responsible person

Abdollah Salimi

Street address

Vice chancellor for research, Kurdistan University, Pasdaran Ave. Pasdaran Blvd. Sanandaj

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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

Vice chancellor for research, Kurdistan University

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**

Kurdistan University

Full name of responsible person

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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