

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The comparison of the efficacy of Metacognitive therapy, Applied Relaxation, Buspirone and Venlafaxine in the treatment of women with Generalized Anxiety Disorder.

Protocol summary

Summary

The purpose of this study is comparison of the efficacy of Metacognitive therapy, Applied Relaxation, Buspirone and Venlafaxine in the treatment of women with Generalized Anxiety Disorder. Single-case experimental design will be used in this study. The study sample will include women with generalized anxiety disorder (GAD) referred to counseling centers and psychiatric clinics in Tabriz. 16 women will be selected by the purposive sampling and replaced at random into four metacognitive therapy treatment groups, Applied Relaxation, Venlafaxine and Buspirone. Inclusion criteria: age, at least 18 years and maximum 50 years; generalized anxiety disorder diagnoses based on structured clinical interview based on DSM-VI-TR and confirm the diagnosis according to a psychiatrist or clinical psychologist; having a minimum qualification cycle and ability to read and write and speak fluently. Exclusion criteria: psychotic disorder; obsessive - compulsive disorder; drug dependence; epilepsy syndrome and using any recreational drug and mental health three months before the first treatment session. All patients will be treated for 12 weeks and 3 months will also follow up. Possible outcome would be the treatment of anxiety and worry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204239544N1**
Registration date: **2012-05-06, 1391/02/17**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-06, 1391/02/17

Registrant information

Name

Asghar Arfaee

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1557 2628

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arfaia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Psychiatry and Behavioral Sciences Research Center -
Tabriz University of Medical Sciences

Expected recruitment start date

2012-06-04, 1391/03/15

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of Metacognitive therapy, Applied Relaxation, Buspirone and Venlafaxine in the treatment of women with Generalized Anxiety Disorder.

Public title

the effect of psychotherapy and pharmacotherapy on anxiety

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Age, at least 18 years and maximum 50 years; generalized anxiety disorder diagnoses based on structured clinical interview based on DSM-VI-TR and confirm the diagnosis according to a psychiatrist or clinical psychologist; having a minimum qualification cycle and ability to read and write and speak fluently. Exclusion criteria: psychotic disorder; obsessive - compulsive disorder; drug dependence; epilepsy syndrome and using any recreational drug and mental health three months before the first treatment session.

Age
 From **18 years** old to **50 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **16**

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

Tabriz University of Medical Sciences Ethics Committee

Street address

University Sq

City

Tabriz

Postal code

Approval date

2011-12-19, 1390/09/28

Ethics committee reference number

5/4/7636

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 (i.e. it is

Primary outcomes

1

Description

Anxiety

Timepoint

Before treatment, after treatment, 3 month after treatment

Method of measurement

Beck anxiety inventory

Secondary outcomes

1

Description

Worry

Timepoint

Before treatment, after treatment, 3 month after treatment

Method of measurement

Pennsylvania State Worry Questionnaire

Intervention groups

1

Description

relaxation therapy, 12 weekly session,

Category

Behavior

2

Description

meta cognitive therapy, 12 weekly session,

Category

Behavior

3

Description

Buspirone, 10 mg oral tablet, three times a day for three months.

Category

Treatment - Drugs

4

Description

venlafaxine, 75 mg oral tablet, three times a day for three months.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dr. Arfaie

Full name of responsible person

Dr. Arfaie

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Counseling Center of Allameh Amini

Full name of responsible person

Hossein Gholizadeh

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Clinical Psychiatric Research Center- tabriz university of medical science

Full name of responsible person

Mrs. Alizadeh

Street address

El goli st. Razi hospital, department of psychiatry

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Clinical Psychiatric Research Center- tabriz university of medical science

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

Welfare organization

Full name of responsible person

Hossein Gholizadeh

Position

Master of science - psychologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Welfare organization

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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