

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of The effectiveness between cognitive-behavior group therapy and mindfulness based cognitive therapy in improvement of females with generalized anxiety disorder

Protocol summary

Summary

Objectives: The aim of the present study was to compare the effectiveness of group Cognitive- Behavior (CBT) therapy (Borkovec model) and mindfulness based cognitive therapy (MBCT) in improving generalized anxiety disorder (GAD) in female participants. Design: An experimental design using pre and post-test and a four month follow up was used. The statistical population comprised of women with generalized anxiety disorder who had at least one primary school age daughter .The sample included 30 people. Participants' selection was based on availability and patients randomly arranged in two groups of CBT and MBCT. Setting and conduct: After arranging patients in the two groups and taking written consent for entering to the research, pretest was carried out pretest and after that, the both groups were treated. They carried out post-test at the end of therapy and 4 months follow up after finishing the therapy. Participants: Inclusion criteria were GAD diagnosis as the original and primary diagnosis and exclusion criteria was having personality disorder. Intervention: Intervention included two groups of cognitive behavior therapy and mindfulness based cognitive therapy. Main outcome measures: Primary outcome variables were GAD sign and symptoms, worry, cognitive avoidance, emotion regulation, quality of life, mindfulness attention, self-compassion, believes about worry, problem solving and relationship with child and there was no secondary outcome variables.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2012121711789N1**
Registration date: **2016-06-27, 1395/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Fereshte Momeni

Name of organization / entity

shahid beheshti university,

Country

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+98 29903262

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The effectiveness between cognitive-behavior group therapy and mindfulness based cognitive therapy in improvement of females with generalized

anxiety disorder

Public title

Comparison of the effectiveness between two treatment method in anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having diagnosed of GAD based on semi structured interview. Regarding the high co morbidity of GAD with other disorder, patient selected that have the primary diagnose of GAD; minimum level of the third grade of primary school. Exclusion criteria: having severe personality disorder; having the diagnose of psychotic or bipolar disorder; currently use of psychotherapy or medication; having the history of psychotherapy before the research; having disabling somatic decease; alcohol or substance addiction.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers was used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University

Street address

Shahid Beheshti University, Shahid Shahriari Squire, Velenjak, Chamran highway, Tehtan

City

Tehran

Postal code

Approval date

2012-05-23, 1391/03/03

Ethics committee reference number

10127/760/د

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

GAD sign and symptom

Timepoint

pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

GAD-7 questionnaire

2

Description

Worry

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

PSWQ

3

Description

Cognitive avoidance

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

CAQ

4

Description

Emotion regulation

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

DERS

5

Description

Quality of life

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

WHO- QOL- BREF

6

Description

Mindfulness attention

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

MAAS

7

Description

Self compassion

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

SCS

8

Description

Beliefs about worry

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

wwq-ll

9

Description

Problem solving

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

PSI

10

Description

Relationship with child

Timepoint

Pre treatment, after the termination of treatment, 4 months after the treatment

Method of measurement

CPRS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cognitive behavior group therapy that contains 10 sessions. Each session takes 90 minutes

and hold once a week.

Category

Behavior

2

Description

Intervention group 2: Mindfulness based cognitive group therapy contains 10 sessions. Each session takes 90 minutes and hold once a week. There was no control group.

Category

Behavior

3

Description

Control group: There was no control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Edalat girls primary school

Full name of responsible person

Zahra Mohammadi

Street address

Edalat street, Yasaman Squire, Velenjak, Evin, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Meshkat Girl Primary School

Full name of responsible person

Sude Aghamohamadian

Street address

Alvand alley, Ebrahimi street, Arash street, Jalal al ahmad highway, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

fereshte momeni

Street address

faculty of psychology, shahid beheshti university, velenjak Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Shahid Beheshti University

Full name of responsible person

Dr Fereshte Momeni

Position

Ph. D

Other areas of specialty/work

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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