Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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,

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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 Squre, 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 questionnare

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 Squre, 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
Tehran

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