

# 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

Iran (Islamic Republic of)

###### Phone

+98 29903262

###### Email address

f\_momeni@sbu.ac.ir

##### 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**

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**

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## Person responsible for updating data

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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*