

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Group Behavioral Activation Therapy; Drug Therapy and Combination Therapy on Clinical Signs (Anxiety and Depression), Negative Evaluation and Quality of Life in Patients with Social Anxiety Disorder

Protocol summary

Study aim

This research studies the efficacy of group behavioral activation therapy and drug therapy and combined therapy on anxiety and depression, negative evaluation, and quality of life in patients with social anxiety disorder.

Design

In this study, in the specialty psychology center (2018-2017) 41 of these patients were randomly selected in volunteers. The instruments for measuring the variables of the research, including the Spin Social Anxiety Scale (2000), Depression Beck-2, the World Health Organization's Short Quality of Life Scale (1989), and the Consequences of the Wilson & Rapper Social Negative Events (2005)

Settings and conduct

Specialist Consulting and Psychotherapy Center

Participants/Inclusion and exclusion criteria

Entry criteria: Social Anxiety Disorder, residency in Mashhad, Degree higher than diploma , age between 18 to 40 years old Exit criteria: Specific Axis 1 Disorder, under the psychological or Medical treatment at the same time as research, disabling physical illness that it s possible to make problem for group research.

Intervention groups

" Behavioral activation therapy " " Drug therapy " " Combined therapy "

Main outcome variables

" Social anxiety " " depression " " fear of negative evaluation " " quality of life "

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038109N3**

Registration date: **2018-07-10, 1397/04/19**

Registration timing: **retrospective**

Last update: **2018-07-10, 1397/04/19**

Update count: **0**

Registration date

2018-07-10, 1397/04/19

Registrant information

Name

Mahdi Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-30, 1396/11/10

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

2018-05-11, 1397/02/21

Actual recruitment end date

2018-06-11, 1397/03/21

Trial completion date

empty

Scientific title

Effectiveness of Group Behavioral Activation Therapy; Drug Therapy and Combination Therapy on Clinical Signs (Anxiety and Depression), Negative Evaluation and

Quality of Life in Patients with Social Anxiety Disorder

Public title

"Evaluating Effectiveness of Group Behavioral Activation Therapy; Drug Therapy and Combined Therapy on Social Anxiety Disorder"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Social anxiety disorder based on diagnostic interview (DSM-V) Residence in Mashhad at the time of meeting group therapy Degree higher than diploma age between 18 to 40 years old

Exclusion criteria:

Having a specific axis of disorder by using a structured interview for DSM-V mental disorders Having a disabling physical illness that, it is possible to make problem for group research Being under the psychological or Medical treatment at the same time as research

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **48**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected in a targeted manner with a Diagnostic Interview according to DSM-V criteria and Spin Anxiety questionnaire score and randomly selected by two-way blind lottery in groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and the researcher did not know the division of the members into the groups and the participants were assigned to groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ebnesina Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9319797139

Approval date

2018-04-10, 1397/01/21

Ethics committee reference number

IR.MUMS.fm.REC.1396.489

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F93.2

ICD-10 code description

Social anxiety disorder of childhood

Primary outcomes

1

Description

Social Anxiety Scale with Spin Questionnaire

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Spin Social Anxiety Scale (2000)

2

Description

Depression Scale with Beck Questionnaire

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Beck Depression Inventory

3

Description

Fear of Negative Assessment with Wilson & Rappi's Consequences of Social Incidents (2005)

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Wilson & Rappi's Consequences of Social Incidents (2005)

4

Description

Quality of Life Score with the World Health Organization

Short Life Style Quality Scale (1989)

Timepoint

Pre-test - Post-test - Follow up

Method of measurement

World Health Organization Quality of Life Scale (1989)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combined behavioral group activation therapy by taking placebo: The behavioral group therapy trend in group sessions were held for the experimental group based on Menal Guelan, during of sessions, which the basic principles of behavioral activation, the recording of their daily activities program within a week, And its application in the face of avoiding enjoyable and mastering activities and And tabulating these activities and assessing skills, choosing, examining, joining, observing results, never give up too. Also, motivation skills, responsiveness, appropriate alternatives, coping methods and overcome stimuli, responses, avoidance patterns, self-esteem skills, self-expression, and courageous training and discussion.

Category

Treatment - Other

2

Description

Intervention group: Group supportive treatment with paroxetine. Each of the participants in the drug treatment group took paroxetine seven times a week. According to psychiatrist, for avoiding side effects, three to four days in the first week, they took half a dozen paroxetine at night. Also, throughout the course of treatment, the contact numbers were given to the participants to contact and notify in case of possible side effects. Except for drowsiness in the first nights of taking medication, no particular complications were reported. were reported.

Category

Treatment - Drugs

3

Description

Intervention group: Combined behavioral group activation therapy with paroxetine. In combined group therapy, behavioral activation therapy was performed according to the behavioral activation group therapy guidelines that described in the behavioral therapy intervention, simultaneously with the treatment of a daily dose of paroxetine.

Category

Treatment - Other

4

Description

Control group: Waiting list

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Adora Specialist Consulting and Psychotherapy Center, Mashhad

Full name of responsible person

Dr. Farnaz Abharzanjani

Street address

No. 111, between Janbaz Ave and Samaneh Ave; Ferdowsi Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
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Dr. Mahdi Amiri
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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information of the clients is confidential and its controversy with secrecy in the context of psychotherapy is contradictory

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available