

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of Cognitive Behavioral Group therapy's Efficacy Versus Hypnotherapy on decreasing signs of social phobia and patients' brain/behavioral systems changes.

Protocol summary

Summary

After volunteers sign up for participation in the study through a public invitation across all Zanjan universities and higher education institutes and also by referral of other psychiatrists and clinical psychologists they will be tested for social phobia and checked for inclusion and exclusion criteria through questionnaires and diagnostic interview. After that the participants will be assigned randomly in two groups. Each group will receive a different treatment (Cognitive-behavioral group therapy and hypnotherapy). Both treatments will take place in a format of group therapy. First group will receive 6 therapy sessions of CBGT and the protocol is derived from Morrise et al protocol at Dalhousie University of Canada. Second group will receive 4 therapy sessions of hypnotherapy which the protocol was made by the researcher and has the approval licence and supervision through the study from the Iranian Scientific Society of Clinical Hypnosis. Participants will be assessed in two stages of pre-test and post-test by following questionnaire (DASS-21, SAD, SPIN, BAI, WHOQOL-BREF, GWPQ, FNES-B). At the end of treatment courses the data will be statistically analyzed and the results will be published by confidentiality concerns.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121425523N1**
Registration date: **2017-01-15, 1395/10/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-15, 1395/10/26

Registrant information

Name

Golnaz Forouzandehfar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cognitive Behavioral Group therapy's Efficacy Versus Hypnotherapy on decreasing signs of social phobia and patients' brain/behavioral systems changes.

Public title

Comparison of Cognitive Behavioral Group therapy's Efficacy Versus Hypnotherapy on decreasing signs of social phobia and patients' brain/behavioral systems changes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Having DSM-5 diagnostic criteria for social phobia 2. Getting psychiatric diagnosis of Social Phobia based on diagnostic interviews by Psychiatrist or Clinical Psychologist. 3. Subject's Score on SPIN questionnaire 4. Participants should not have received any treatments 6 month prior to beginning of the study. 5. participants should not received any medication one month prior to beginning of the study. 6. Participants should have a minimum age of 18 and maximum age of 50 years old. 7. Participants Should be at least on a undergraduate program. 8. Participants should agree to participation principals of the study and sign a written consent. Exclusion criteria: 1. having a psychotic disorder and or substance abuse based on diagnostic interview. 2. having full criteria of personality disorder diagnosis on Axis II based on diagnostic interview. 3. Being absent for more than one session of therapy course.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhuri
Eslami Blv, Azadi Squ, Zanjan, Iran

City

Zanjan

Postal code

Approval date

2016-05-04, 1395/02/15

Ethics committee reference number

IR.ZUMS.REC.1395.36

Health conditions studied

1

Description of health condition studied

Social phobia

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes

1

Description

Social Phobia

Timepoint

Before intervention, after intervention, 1 month after
intervention

Method of measurement

SPIN questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

before intervention, after intervention, one month after
intervention

Method of measurement

DASS-21 Questionnaire

2

Description

physiologic symptoms of Anxiety

Timepoint

before intervention, after intervention, one month after
intervention

Method of measurement

BAI Questionnaire

3

Description

Anxiety

Timepoint

before intervention, after intervention, one month after
intervention

Method of measurement

DASS-21 Questionnaire

4

Description

Avoidance Signs of Anxiety

Timepoint

before intervention, after intervention, one month after
intervention

Method of measurement

SAD Questionnaire

5

Description

general function

Timepoint

before intervention, after intervention, one month after intervention

Method of measurement

GAF Scale

6

Description

quality of life

Timepoint

before intervention, after intervention, one month after intervention

Method of measurement

WHOQOL- BREF Questionnaire

7

Description

Brain/Behavioral System changes

Timepoint

before intervention, after intervention, one month after intervention

Method of measurement

GWPQ Questionnaire

8

Description

fear of negative evaluation

Timepoint

before intervention, after intervention, one month after intervention

Method of measurement

FNESB Questionnaire

Intervention groups

1

Description

Experimental Group 1: Cognitive-behavioral group therapy for social phobia Following Protocol is going to be used: A Brief Cognitive-Behavioral Treatment for Social Anxiety Disorder Eric P. Morris, David Mensink, and Sherry H. Stewart Dalhousie University Session 1: Following the questionnaires, introductions are made, An overview of the coming sessions is discussed and any questions were addressed, Feared Situations Questionnaire, developed by the authors, is administered, Discussion of Thoughts/Situations on the board. The board can be divided into two columns; on the left, the automatic thoughts are recorded, using examples from the class and on the right, the types of situations that elicit the thought, An introduction to how thoughts affect the subsequent physiological reactions

and behaviors is presented on the board, Introduce the Vertical Arrow Technique on the board, Homework: Think about distorted thoughts you have during one anxiety provoking social situation that occurs between now and next session. Session 2: 1) Review Homework, 2) The 10 Burns cognitive distortions are introduced, with the goal of providing the clients with examples of the types of thinking errors they were making, 3) Administer Feared Situations Questionnaire. This questionnaire was designed to provide the therapists with a better idea of which types of situations elicit the most social evaluative fear in the clients, 4) The Steps for Moderating Negative Feelings worksheet, developed by the authors, is administered, which explicitly outlines the process of identifying, analyzing, and correcting negative thoughts, Homework. Session 3: 1) Discuss homework, 2) Continue developing automatic thoughts and replies on the board, 3) The concept of safety behaviors/cognitions is introduced with several examples provided by the therapist, Homework. Session 4: The purpose of this session is to talk about self esteem, To help the clients better understand the construct of self-esteem, several worksheets are administered. Session 5 and 6: Based on their responses from the feared situations questionnaire, a number of feared scenarios can be listed on a handout and administered to the group. This handout is given to the group to provide a few examples of the types of situations they could role play in the session. Role plays are to be geared towards creating an anxiety provoking situation specific to the individual clients, Clients are randomly chosen to participate in a role play in front of the group, The role plays typically last approximately 10min with about 15min of preparation time, The Subjective Units of Distress (SUD) ratings are taken just prior to commencing the role play and are recorded on the board. SUD ratings are a simple tool used to provide a rough approximation of the client's anxiety level. SUD ratings typically consist of a vertical line with "0" at the bottom and "100" at the top and clients are told that 100 is the most anxious they have been while 0 is the least anxious, Following the completion of the role play, the clients are asked about the automatic thoughts they experienced and whether they had applied any of their cognitive strategies to these thoughts. Feedback is also elicited from the group on the client's performance (the feedback is typically positive and encouraging).

Category

Treatment - Other

2

Description

Experimental Group 2: Group Hypnotherapy for social phobia the following group will receive 4 sessions of hypnotherapy within 4 weeks and the protocol is self-structured and approved by The Iranian Scientific Society of Clinical Hypnosis. session 1: Administration of PMR (Progressive Muscle Relaxation) and Relaxation training, Records of the session will be given to participants for further practice as homework. session 2: recognition of primary symptoms, Imagery Inductions, records of session 1 and 2 will be given to participants for further practice. session 3: Emotional Modelling, cognitive

reconstruction and behavior modification through mental visualization, conditioning, as homework records of session 1, 2 and 3 will be given to participants for further practice. session 4: repetition of the conditioning, repetition of 3rd session, answering participants questions, asking them for feedback.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

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Zanzan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanzan University of Medical Sciences

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

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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