Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The efficacy of Cognitive Behavioral Group Therapy, Psychodrama and the Combination of Both for the Treatment of Social Anxiety Disorder in a Randomized Controlled Trial

Protocol summary

Summary

The present study aims to compare cognitive behavioral therapy, psychodrama and their combination in group format as treatments for social anxiety disorder and compare them to a wait list condition in a randomized controlled trial.Study one is a randomized controlled trial (RCT) and it will compare four conditions, a waitlist and three group therapies for SAD. The Structured Clinical Interview for DSM-IV-TR (Farsi Version) (SCID-I; First, Spitzer, Gibbon, & Williams, 2012), conducted by an experienced interviewer, will be used to determine the diagnosis. We will have 144 social anxious patients in four conditions. CBGT (n=36), psychodrama (n=36), the psychodrama-CBGT (n=36) and a waitlist group (n=36). The three active groups will undergo 12 sessions of treatment; every session lasts 2.5 hours with 6 patients and one therapist (male for women and female for men), whereas the control group will not receive any active treatment during this period. For the three active arms only, a follow-up measurement will be done 6 months after the intervention. Given that depression is also highly co morbid with social anxiety disorder, the influence of co morbid major depression disorder on treatment outcome will be assessed. The conditions will be compared on social anxiety symptoms as primary outcome and quality of life as secondary outcome. Mediation analysis will test whether changes per conditions are mediated by specific processes: increased spontaneity in psychodrama; decreased social cost and probability for cognitive behavioral group therapy; decreased social avoidance as a joint mediator and both sets of mediators for the combined treatment. Finally, role reversal is a fundamental technique in psychodrama that provides the opportunity to play the role of others that leads to a shift in patients' perspective toward the other. The short term effectiveness of role reversal technique in psychodrama will be examined as a single session experiment for social anxiety disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016032321385N1**
Registration date: **2016-05-26, 1395/03/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-26, 1395/03/06

Registrant information

Name

Hanieh Abeditehrani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Cognitive Behavioral Group Therapy, Psychodrama and the Combination of Both for the Treatment of Social Anxiety Disorder in a Randomized Controlled Trial

Public title

The efficacy of Cognitive Behavioral Group Therapy, Psychodrama and the Combination of Both for the Treatment of Social Anxiety Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A primary diagnosis of social anxiety disorder according to SCID I, age 18 to 65 years, ability to read and understand the questionnaire and the interview and a written consent for this study. Exclusion Criteria: Comorbid with psychotic or bipolar disorder, or a lifetime history of schizophrenia or bipolar disorder, high suicidality risk, antisocial or borderline personality disorder, comorbid diagnosis of substance abuse or dependence, unwilling to stablize medication for entire duration of the study based on clinical interview.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block randomization with computer randomized allocation to four conditions of equal proportions. The six cohorts will be n=24, with n=6 allocated to each condition. The evaluators are blind the allocation of patients to interventions and waitlist group. State there that randomization will be conducted by an independent researcher at the University of Amsterdam.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Science

Street address

Khajerashid four way, AyatollaKashani Bolivar

City

Hamedan

Postal code

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

IR.UMSHA.REC.1394.521

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Fear of scrutiny by other people leading to avoidance of social situations. More pervasive social phobias are usually associated with low self-esteem and fear of criticism. They may present as a complaint of blushing, hand tremor, nausea, or urgency of mi

Primary outcomes

1

Description

social anxiety

Timepoint

before intervention,in the middle (after 6th session)

Method of measurement

The Liebowitz Social Anxiety interview (LSAS; Liebowitz, 1987) . Brief Fear of Negative Evaluation Scale (BFNE; Rodebaugh et al., 2004; Weeks et al., 2005)

Secondary outcomes

1

Description

quality of life

Timepoint

before intervention, after intervention, 6-month follow-up

Method of measurement

The Quality of Life Inventory (QOLI; Frisch, Cornell, Villanueva, Retzlaff, 1992).

Intervention groups

1

Description

Cognitive behavioral group therapy (CBGT) (n=36), psychodrama (n=36), the psychodrama CBGT (n=36) and a wait list group (n=36). The three active groups will undergo 12 sessions of treatment; every session lasts 2.5 hours with 6 patients and one therapist (male for women and female for men), whereas the control group will not receive any active treatment during this period. For the three active arms only, a follow-up measurement will be done 6 months after the intervention. CBGT will be based on Heimberg and Becker's protocol (2002). It will include 12 weekly sessions; every session lasts 2.5 hours and will be given by two therapists. In the first session, the therapists explain the group's rules and present the cognitive behavioral therapy model of social anxiety and train cognitive restructuring with focusing on identification of automatic thoughts. Patients share their individual problems and goals. At the end of the first session, the therapists assign homework which is to record automatic thoughts during the following week. During the second session, the homework is reviewed and the therapists use the recorded automatic thoughts to identify thinking errors. The therapists will train the patients how to dispute automatic thoughts with rational responses. At the end of the session, the therapists assign homework to label thinking errors in identified automatic thoughts and prepare for initiation of in-session exposure. From 3rd session to 11th patients will practice in exposure in and between sessions with cognitive restructuring skills that learned. Choices of exposure situations depend on feared and avoided situations, which will be detected during interviews or treatment. Sometimes patients will need help to set the goals and they repeat the exposure with a more rational response to adapt themselves during anxiety provoking situations. The therapists assign to utilize cognitive restructuring before, during and after homework exposure every session for each patient. The last session is divided into two parts. During the first half the therapists do additional exposure and cognitive restructuring. During the second half the therapists review each patient's development during treatment and work on situations that may still be problematic.

Category

Treatment - Other

2

Description

Psychodrama will include 12 weekly sessions. Each session lasts 2.5 hours. In this study we have one therapist as a director.Every psychodrama session is divided into three stages: warming up, action and sharing. The warming up or ice broking stage facilitates a safe, supportive and creative atmosphere to patients at the beginning of every session. Patients introduce themselves and do physical interaction games until ice breaks. After that, the individual who will act as the protagonist needs to be identified. The director can select the protagonist based on the preparation in warming-up stage or ask who is ready to work as a volunteer. In the acting stage, the director creates a scene with the protagonist, in which a problem is played. The protagonist can select the auxiliary ego. The patients can play a childhood experience from the past, or a feared situation in future, or some feared situations in the present. All are played "here and now"; freely, spontaneously and creatively. Catharsis usually takes place in the action stage. Sharing or closure is a time for patients to discuss the effects of acting the scene on them and share their feelings and thoughts with the group.There are several techniques that the director can utilize to solve the protagonist's problems. 'Role reversal' offer protagonists an opportunity to take the role of the other person to see themselves from other's perspective. In 'doubling' a patient of the group plays the protagonist's inner self and gives a voice to the protagonist's feelings, thoughts or needs, so that the protagonist can become aware of his or her inner experiences. The auxiliary ego plays the role of the protagonist for a short time in a technique called 'mirroring'. It can help patients to observe themselves through the auxiliary ego. 'Soliloquy' is a monologue in which the patients can express their thoughts and feelings to the audience. In the 'empty chair' technique, the protagonist can talk to an imaginary person as represented by an empty chair (Moreno & Fox, 1987; Blatner, 2000).

Category

Treatment - Other

3

Description

Psychodrama CBGT.This intervention also has 12 weekly sessions and every session lasts 2.5 hours with one therapists. In the first session, the therapists explain the group's rules and present the combining CBGT and psychodrama model of social anxiety and train cognitive restructuring with focusing on identification of authomatic thoughts. Patients share their individual problems and goals. At the end of the first session, the therapists assign homework which is to record automatic thoughts during the following week. During the second session, the homework is reviewed and the therapists use the recorded automatic thoughts to identify thinking errors. The therapists will train the patients how to dispute automatic thoughts with rational responses. At the end of the session, the therapists assign homework to label thinking errors in identified automatic thoughts and prepare for initiation of in-session exposure. Session 3 to 11 are divided into three stages: warming up, action and sharing. The warming up or ice broking stage facilitates a safe, supportive and creative atmosphere to patients at the beginning of every session. Patients introduce themselves and do physical interaction games until ice breaks. After that, the individual who will act as the protagonist needs to be identified. The director can select the protagonist based on the preparation in warming up stage or ask who is ready to work as a volunteer. In the acting stage, the director creates a scene with the protagonist, in which a problem is played. The protagonist can select the auxiliary ego. The patients can play a childhood experience from the past, or a

feared situation in future, or some feared situations in the present. All are played “here and now”; freely, spontaneously and creatively. Catharsis usually takes place in the action stage. patients will practice in exposure and role playing in and between sessions with cognitive restructuring skills that learned and do exposure with the psychodrama techniques as described above: double, role reversal, soliloquy, mirroring and empty chair. The protagonist can select auxiliary ego to act. Sometimes patients will need help to set the goals and they repeat the exposure with a more rational response to adapt themselves during anxiety provoking situations. Sharing or closure is a time for patients to discuss the effects of acting the scene on them and share their feelings and thoughts with the group. At the end of each sessions, Therapists assign homework exposure similar to those practice in the group and encourage them to utilize cognitive restructuring before, during and after homework exposure every session for each patient. The last session is divided into two parts. During the first half the therapists do additional exposure, role playing and cognitive restructuring. During the second half the therapists review each patient’s development during treatment and work on situations that may still be problematic.

Category
Treatment - Other

4

Description
wait-list group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mental Health North West Tehran
Full name of responsible person
Hanieh Abeditehrani
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No16, First Soroosh, Sattarkhan St
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2

Recruitment center
Name of recruitment center
Mental Health Clinics
Full name of responsible person
Hanieh Abeditehrani
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No13, Iranian Building, Iranpars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ministry of Science, Research and Technology of Iran
Full name of responsible person
Deputy of Scholarship and Students Affairs in Abroad of IR
Street address
No 27, Forsatejonobi Avenue, Ferdosi Square
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ministry of Science, Research and Technology of Iran
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

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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