

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effectiveness of Interpersonal Psychotherapy in Patients with Social Anxiety Disorder with Comorbid Depressive Symptoms: Symptoms Reduction, Interpersonal Problems and Quality of Life Improvement, and Change of Therapeutic Mediators.

Protocol summary

Study aim

Effectiveness of interpersonal psychotherapy on symptoms reduction, improvement of function, change of therapeutic mediators and quality of life in patients with social anxiety disorder with comorbid Depressive Symptoms

Design

This is a Randomized Controlled Trial (RCT) in which randomization software will be used to assign 20 patients to intervention and control groups randomly.

Settings and conduct

This study will be conducted in the psychology clinic of Taleghani hospital. Having done diagnostic interview, patients suffering from social anxiety disorder with comorbid depressive symptoms will be assigned to the intervention or control group randomly. Prior to the treatment and in pre-test, baseline assessments will be conducted. Then, patients in the treatment group will participate in weekly 12-session individual interpersonal psychotherapy, whereas there will be no intervention to the control group. Participants in the treatment group will complete the whole measures in session 3, 6, 9, and 12 and patients in the control group will answer these measures again only after 12 weeks. Finally, all participants will complete measures in a 2-month follow-up. It is worth mentioning that in order to comply with the ethical principles, all participants in the control group will also receive interpersonal psychotherapy after follow-up.

Participants/Inclusion and exclusion criteria

Participants: Patients with social anxiety disorder with comorbid depressive symptoms
Include Criteria: being Diagnosed with social anxiety disorder with comorbid depressive symptoms; being aged 15-50 years' old; being educated at least at middle school level; participants should not have received any psychological

interventions within the past 3 years or any pharmacotherapy at least one month before the baseline assessment until the end of follow-up; not being diagnosed with psychiatric disorders which necessitate urgent treatments and having motivation and satisfaction to participate in the research. Exclude Criteria: primary and main diagnosis of mood disorders or other anxiety disorders; presence of psychiatric disorders requiring urgent treatments; meeting full criteria of personality disorders, except those of avoidance personality disorder; suicidal ideation or extreme thinking about self-harm; having IQ below the normal range; missing more than 3 sessions of psychotherapy and participation in another treatment plan simultaneously.

Intervention groups

Intervention group: A group of patients who will receive a 12-session individual interpersonal psychotherapy.

Control group: A group of patients who will not receive any kinds of psychotherapy within the period when participants in the intervention group are getting interpersonal psychotherapy.

Main outcome variables

social anxiety; fear on negative evaluation; depression; interpersonal difficulties; quality of life; social support; interpersonal stress; emotion regulation strategies; difficulties in emotion regulation; interpersonal skills.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161110030822N1**

Registration date: **2018-02-24, 1396/12/05**

Registration timing: **prospective**

Last update: **2018-02-24, 1396/12/05**
Update count: **0**
Registration date
2018-02-24, 1396/12/05

Registrant information
Name
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-06, 1396/12/15
Expected recruitment end date
2018-04-19, 1397/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Interpersonal Psychotherapy in Patients with Social Anxiety Disorder with Comorbid Depressive Symptoms: Symptoms Reduction, Interpersonal Problems and Quality of Life Improvement, and Change of Therapeutic Mediators.

Public title
Effectiveness of Interpersonal Psychotherapy in Patients with Social Anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Minimum education should be middle school grade. Participants should not have received psychological interventions over the past 3 years or drug treatment at least one month before the baseline measurement stage until the end of the follow-up. The absence of psychiatric disorders necessitates urgent treatments such as substance use disorders, alcohol use disorder and psychotic disorders. Having the motivation and satisfaction to participate in the research. Diagnosis of social anxiety disorder with comorbid depressive symptoms
Exclusion criteria:
Primary diagnosis of mood disorders and other anxiety disorders The presence of psychiatric disorders requiring immediate treatment such as substance use disorders, alcohol use disorder and psychotic disorders. Having complete criteria for personality disorders, except for avoidance personality disorder Suicide Ideation or extreme thinking about self harm IQ below the normal

range Missing more than 3 sessions of psychotherapy participate simultaneously in another treatment plan
Age
From **15 years** old to **50 years** old
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the sample group and explaining the research objectives and methods and before obtaining informed consent, patients will be randomized using randomized software in two groups of interpersonal psychotherapy and control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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19839-63113

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.SBMU. MSP.REC.1396.172

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes**1****Description**

social anxiety symptoms

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Social Phobia Inventory and Brief Fear of Negative Evaluation Scale

2**Description**

Beck Depression Inventory-II Score

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Beck Depression Inventory-II

3**Description**

Interpersonal Problems

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Inventory of Interpersonal Problems

4**Description**

Quality of Life

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

The World Health Organization Quality of Life

5**Description**

Social Support

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Social Support Appraisals Scale

6**Description**

Interpersonal Stress

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Life Distress Inventory and a researcher-made questionnaire

7**Description**

Emotion Regulation

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Emotion Regulation Questionnaire and Difficulties in Emotion Regulation Scale

8**Description**

Interpersonal Skills

Timepoint

Before the intervention and the third, sixth, ninth sessions, after the intervention and follow up

Method of measurement

Interpersonal Communication Skills Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group: Patients with social anxiety disorder participating in 12 weekly and individually sessions and receive interpersonal psychotherapy. Control Group: Patients with social anxiety disorder who are in the waiting list and do not receive intervention.

Category

Behavior

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

Taleghani Hospital

Full name of responsible person

Hamid Amiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamid Amiri

Position
Resident
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The title of the data will be "the effectiveness of interpersonal psychotherapy on social anxiety disorder". All data can be shared after making participants anonymous.

When the data will become available and for how long

Six months after publishing results, everything will be accessible.

To whom data/document is available

The data from this research will be accessible only to mental health researchers and those who are working in academic and scientific institutions.

Under which criteria data/document could be used

With respect to ethical considerations, the data from this research can be used for other research purposes. It is also possible to conduct any statistical analyses. All these processes require correspondence and coordination.

From where data/document is obtainable

All applicants can contact Mr. Hamid Amiri through one of the following ways: 1. Email address: hamid.amiri@sbm.ac.ir 2. Phone number: +98 21 23031548 3. Address: Department of Clinical Psychology, Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

What processes are involved for a request to access data/document

Within 10 working days after correspondence or a phone call, your request will be answered and the data will be sent to a valid email submitted by the applicant.

Comments