Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of short-term psychodynamic psychotherapy versus Sertraline in reducing the symptoms of social phobia in Tehran University students

Protocol summary

Summary

The aim of this quasi-experimental study was comparing the effectiveness of short-term psycho-dynamic psychotherapy (McCullough method) with the pharmacotherapy (sertraline) in reducing symptoms of social phobia. The study population was the male students of Tehran University. Students who were diagnosed with social phobia, based on structural clinical interview,and had not received medical care or psychotherapy for the treatment of this disorder in the past six months were accepted in this study. Forty-five male students of Tehran University with social phobia criteria randomly were assigned to three groups: 1- psycho-dynamic therapy, 2-pharmacotherapy, 3- waiting list. psychotherapy group received 25 individually psychotherapy sessions (each session lasting 45 minutes) according to McCullough's treatment Manual. In this group were considered two sessions for initial assessments, 21 sessions for the treatment and two sessions for final assessments and termination. Pharmacotherapy group received 12 weeks of treatment with sertraline and the waiting list group did not receive treatment for eight weeks. Psychotherapy was conducted by a doctoral student in clinical psychology and pharmacotherapy was carried out by a psychiatrist. Assessments were conducted using the Structural Clinical Interview for DSM-IV-TR, the demographic questionnaire, Social Phobia Inventory, Clinical Global Impression severity and improvement scales and Global assessment of Functioning scale. Members of each group were individually assessed four times during the treatment process. The data were gathered from December 22th, 2011 to June 19th, 2012.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103011328N1**
Registration date: **2012-12-09, 1391/09/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-09, 1391/09/19

Registrant information

Name

Mehryar Nader Mohammadi Moghaddam

Name of organization / entity

Tehran University of Medical Sciences, Tehran Psychiatric Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1668

Email address

m-nadermohammadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Counseling Center

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-30, 1391/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of short-term psychodynamic psychotherapy versus Sertraline in reducing the symptoms of social phobia in Tehran University students

Public title
Effectiveness of psychotherapy in the treatment of social phobia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: having social phobia criteria based on the SCID; SPIN score greater than or equal to 24; age between 18 to 50 years; Exclusion criteria: psychotic disorders; obsessive - compulsive disorder; bipolar disorder; organic brain injury; addiction to drugs and alcohol; impaired impulse control; Cluster A and B personality disorders; disorder on Axis III; history of attempt and suicidal ideation; history of violent behavior; psychotherapy for social phobia over the last 6 months; If there are any other psychotic disorders (except stated in the first clause), primary complaint is not symptoms of social phobia.

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

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

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
Tehran University of Medical Sciences

Street address
Tehran University of Medical Science, Sixth Floor, Ghods St, Keshavarz Blvd.

City
Tehran

Postal code
1417653761

Approval date
2012-10-20, 1391/07/29

Ethics committee reference number
1720/130/91/د

Health conditions studied

1

Description of health condition studied
social phobia

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
Severity of symptoms of social phobia- clinician rating

Timepoint
The psychotherapy Group at weeks 1, 8, 15, 23 and the medication group at weeks 1, 4, 8, 12, and the waiting list group at weeks1, 4, 6, 8

Method of measurement
clinical global impression - severity

2

Description
Severity of symptoms of social phobia- Patient rating

Timepoint
The psychotherapy Group at weeks 1, 8, 15, 23 and the medication group at weeks 1, 4, 8, 12, and the waiting list group at weeks1, 4, 6, 8

Method of measurement
social phobia inventory (SPIN)

3

Description
Improvement rate in symptoms of social phobia

Timepoint
The psychotherapy group at weeks 8, 15, 23 and the medication group at weeks 4, 8, 12, and the waiting list group at weeks 4, 6, 8

Method of measurement
Using the Clinical Global Impression of Improvement scale, CGI-I

Secondary outcomes

1

Description

Global Function

Timepoint

the Psychotherapy group at weeks 1, 23 and the medication group at weeks 1, 12 and the waiting list group at weeks1, 8

Method of measurement

Using the GAF Scale to assess the global functioning

Intervention groups

1

Description

The medication group were treated with Sertraline for 12 weeks. Sertraline was started at a dose of 50 mg and was added to it 50 mg per week until reached into maximum dose of 200 mg over 4 weeks. Treatment continued for eight weeks with a dose of 200 mg per day. Treatment was conducted by a psychiatrist.

Category

Treatment - Drugs

2

Description

Waiting list group did not receive treatment for eight weeks and were evaluated only 4 times.

Category

N/A

3

Description

Psychodynamic psychotherapy intervention group received 21 sessions (in addition to the primary and final evaluations and termination). Individual psychotherapy sessions were held twice per week, each session lasting 45 minutes. Psychodynamic interventions were performed based on McCullough’s treatment Manual. This type of treatment was composed of three main parts: defenses restructuring, affect restructuring and restructuring of sense of self/others.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University Counseling Center

Full name of responsible person

Mr Hasan Taghavi, MSc , responsible for boys dormitory counseling center

Street address

Yazdi Rasoulian Building, boys dormitory, North Kargar St., above Jalal Ale Ahmad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr Rahimnia

Street address

Shahid Hemmat Campus, Shahid Chamran and Sheikh Fazlullah Nuri Intersection, Shahid Hemmat West Highway

City

Tehran

Grant name

02/123700/91

Grant code / Reference number

برنامه 30121

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Science

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

Tehran psychiatric institute

Full name of responsible person

Mehryar nader Mohammadi moghaddam

Position

Ph.D student in clinical psychology

Other areas of specialty/work

Street address

No 1, Shahid Mansouri Alley, niayesh St, Sattarkhan Ave, Postal Code: 1445613111 POBox: 441 to 145

City

Tehran

Postal code

1443813444

Phone

+98 21 6655 1515

Fax

+98 66551668

Email

m-nadermohammadi@razi.tums.ac.ir

Web page address

ندارد

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran university of medical science , Tehran psychiatric institute

Full name of responsible person
Dr Mohammad Kazem Atef Vahid

Position
Ph.D in clinical psychology

Other areas of specialty/work

Street address
No 1, Shahid Mansouri Alley, niayesh St, Sattarkhan Ave, Postal Code: 1445613111 POBox: 441 to 145

City
Tehran

Postal code
1443813444

Phone
+98 21 6655 1655

Fax
+98 21 6655 1668

Email
kazemv@yahoo.com

Web page address
ندارد

Person responsible for updating data

Contact

Name of organization / entity
Tehran Psychiatric Iinstitute

Full name of responsible person
Mehryar Nader Mohammadi Moghaddam

Position
Ph.D student in clinical Psychology

Other areas of specialty/work

Street address
No 1, Shahid Mansouri Alley, niayesh St, Sattarkhan Ave, Postal Code: 1445613111 POBox: 441 to 145

City
Tehran

Postal code
1443813444

Phone
+98 21 6655 1655

Fax
+98 21 6655 1668

Email
m-nadermohammadi@razi.tums.ac.ir

Web page address
ندارد

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