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
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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
None

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

Country
Iran (Islamic Republic of)

Postal code
141763761

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

Ethics committee reference number
1720/130/91/

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 weeks 1, 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 weeks 1, 4, 6, 8

Method of measurement
social phobia inventory (SPIN)

Secondary outcomes

1

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

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
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/other.
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
Country
Iran (Islamic Republic of)

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
Country
Iran (Islamic Republic of)
Grant name
02/123700/91
Grant code / Reference number
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
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Person responsible for scientific
inquiries

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Full name of responsible person
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Position
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Other areas of specialty/work

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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