Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Jul 2019

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.
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**
     - 1417653761
   - **Approval date**
     - 2012-10-20, 1391/07/29
   - **Ethics committee reference number**
     - 1720/130/91/

**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 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)

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 weeks 1, 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 to 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

**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**
empty

**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 PBox: 441 to 145

**City**
Tehran

**Country**
Iran (Islamic Republic of)

**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
Country
Iran (Islamic Republic of)
Postal code
1443813444
Phone
+98 21 6655 1655
Fax
+98 21 6655 1668
Email
kazemv@yahoo.com
Web page address
n/D

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
Country
Iran (Islamic Republic of)
Postal code
1443813444
Phone
+98 21 6655 1655
Fax
+98 21 6655 1668
Email
m-nadermohammadi@razi.tums.ac.ir
Web page address
n/D

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