Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the effectiveness of pharmacotherapy with sertraline versus Glaser reality therapy in social anxiety disorder in medical sciences students

Protocol summary

Study aim
Comparison of the effectiveness of sertraline, glassser reality therapy alone or simultaneously on social anxiety

Design
This study is a quasi-experimental study with pre-test and post-test design. First, 75 students with social anxiety will be selected by convenience sampling method and then will be randomly divided into three groups.

Settings and conduct
It will be performed on medical students with social anxiety in 1400.

Participants/Inclusion and exclusion criteria
Criteria for entering the sample into the research: Earn the required score in the social anxiety test and diagnose social anxiety Interest in participating in training sessions Failure to participate in concurrent research Criteria for excluding samples from research: Absence for more than two sessions Sickness Reluctance to continue participating in research taking medication Addiction The patient is undergoing other non-drug treatment

Intervention groups
In the present study, patients will be divided into three groups. Group 1: Glasser reality therapy II: Glasser reality therapy and sertraline drug Group 3: Sertraline drug therapy

Main outcome variables
social anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191106045356N4**
Registration date: **2021-04-21, 1400/02/01**
Registration timing: **prospective**
Last update: **2021-04-21, 1400/02/01**
Update count: **0**

Registration date
2021-04-21, 1400/02/01

Registrant information

Name
Mohsen Zabihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of pharmacotherapy with sertraline versus Glaser reality therapy in social anxiety disorder in medical sciences students

Public title
Comparison of the effectiveness of pharmacotherapy with sertraline versus Glaser reality therapy in social anxiety disorder

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Earn the required score in the social anxiety test and diagnose social anxiety
Exclusion criteria:
Absence for more than two sessions Addiction
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the samples in each group, the subjects are divided into three groups A, B and C using the RAN() function of Excel software, and according to the type of intervention, drug use and participation in mental training classes. It is a treatment, there is no possibility of blindness, there is no intervener and the subjects, and only the statistical analyst does not know what kind of intervention was done by each group.
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
thics committee of ʾShahid Sadoughi University of Medical Sciences
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۹۷۸۴۷۷
Approval date
2020-11-10, 1399/08/20
Ethics committee reference number
IR.SSU.MEDICINE.REC.1399.168

Health conditions studied

1

Description of health condition studied
Social anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Social anxiety score
Timepoint
Before and after treatment
Method of measurement
standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Venlafaxine treatment will receive sertraline (50 mg daily) for 28 days, after which they will answer the questionnaire questions. In order to evaluate the effect of time on maintaining the effect of the intervention, after two months, the subjects will be asked to answer the research questionnaires again. Finally, the data will be statistically analyzed using spss24 software and multivariate analysis of covariance.
Category
Treatment - Drugs

2

Description
Intervention group: Participate in Glasser reality therapy classes in 8 sessions of 1.5 hours and two sessions per week. At the end of the sessions, all groups will answer the questions of the relevant questionnaire. In order to evaluate the effect of time on maintaining the effect of the intervention, again after two months from the last session, the subjects will be asked to answer the research questionnaires again. Finally, the data will be statistically analyzed using SPSS24 software and multivariate analysis of covariance. Summary of Glasser reality therapy therapy sessions are: introduction and introduction, introduction and purpose of the group and the number of sessions, introduction of members to each other and expressing their expectations of each other, expression of group rules. Completing the pre-test, presenting the homework, reviewing the homework of the previous session, teaching 5 basic needs from

Glasser's point of view and the concept of responsibility and selection, categorizing 5 demands related to the homework of the previous week in these 5 categories by members, submitting homework, reviewing homework of the previous session, Behavior machine training and the effect of thoughts and actions on emotions and bodily changes in the form of behavior machine using members' views, examining social anxiety and examining emotions and bodily changes when social anxiety occurs, presenting homework, reviewing the previous session, teaching the desirable world And the role of desires in creating the desired world and its difference with behavior and basic needs, examining the costs of social anxiety and its importance in life and consulting members about ways to improve it using reality therapy, homework presentation, homework review of the previous session , Give a text to members to present in the meeting and receive feedback, repeat the exercise and review, present the assignment, review the assignment of the previous session, give a long text that requires group cooperation to members to present in the meeting as a group and receive feedback Repeat the exercise and review, present the homework, review the homework of the last session. Investigating the role of excuses in achieving goals. Teaching Seven Destructive Behaviors and Seven Effective Behaviors to Satisfy Needs. Introduction to preparing members for the final session, presenting assignments, reviewing previous session assignments, summarizing, receiving feedback from group members on all sessions, and results in their lives. Final, post-test tagging

Category

Behavior

3

Description

Intervention group: Venlafaxine treatment and Glasser reality therapy will use both types of interventions simultaneously and, like the other two interventions, a questionnaire will be used to evaluate them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Univesity of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available