

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effectiveness of Paroxetine on Anxiety, Depression, Fear of Negative Evaluation and Improvement of Quality of Life in Patients with Social Anxiety Disorder

Protocol summary

Study aim

The present study aimed to evaluate the efficacy of paroxetine on clinical symptoms of social anxiety, depression, fear of negative evaluation and quality of life in patients with social anxiety disorder.

Design

The Research Design includes pre-test, post-test and follow-up with the Experimental and Control Group

Settings and conduct

The statistical population of this study included all referrers to psychiatric services and private psychiatric clinics with the diagnosis of social anxiety disorder in the city of Mashhad. Twenty-four of these patients were selected in a targeted and accessible manner and randomly assigned to groups. Were ranked.

Participants/Inclusion and exclusion criteria

Participants: Patients with social anxiety disorder aged 18 to 20 years and minimum degree of diploma.
entrance: En Social anxiety disorder based on diagnostic interview (DSM-V) Residence in Mashhad at the time of meeting group therapy Degree higher than diploma age between 18 to 40 years old Exit: Having a specific axis of disorder by using a structured interview for DSM-V mental disorders Having a disabling physical illness that, it is possible to make problem for group research Being under the psychological or Medical treatment at the same time as research

Intervention groups

The Drug Treatment Group with Paroxetine

Main outcome variables

Social anxiety; depression; fear of negative evaluation; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038109N4**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **retrospective**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Mahdi Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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amirime@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-29, 1396/11/09

Expected recruitment end date

2018-02-28, 1396/12/09

Actual recruitment start date

2018-05-10, 1397/02/20

Actual recruitment end date

2018-06-10, 1397/03/20

Trial completion date

empty

Scientific title

The Effectiveness of Paroxetine on Anxiety, Depression, Fear of Negative Evaluation and Improvement of Quality

of Life in Patients with Social Anxiety Disorder

Public title
The Effectiveness of Paroxetine on Social Anxiety Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Social anxiety disorder based on diagnostic interview (DSM-V) Residence in Mashhad at the time of meeting group therapy Degree higher than diploma age between 18 to 40 years old
Exclusion criteria:
Having a specific axis of disorder by using a structured interview for DSM-V mental disorders Having a disabling physical illness that, it is possible to make problem for group research Being under the psychological or Medical treatment at the same time as research

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **24**
Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were selected in a targeted Manner with a Diagnostic Interview according to DSM-V Criteria and Spin Anxiety Questionnaire Score and randomly selected by two-way Blind Lottery in Groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The Participants and the Researcher did not know the Division of the Members into the Groups and the Participants were assigned to Groups.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Thics Committee of Mashhad University of Medical

Sciences
Street address
Ebnesina Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9319797139
Approval date
2018-04-09, 1397/01/20
Ethics committee reference number
IR.MUMS.fm.REC.1396.489

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F93.2

ICD-10 code description

Social anxiety disorder of childhood

Primary outcomes

1

Description

Social Anxiety Scale with Spin Questionnaire

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Spin Social Anxiety Scale (2000)

2

Description

Depression Scale with Beck Questionnaire

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Beck Depression Inventory

3

Description

Fear of Negative Assessment with Wilson & Rappi's Consequences of Social Incidents (2005)

Timepoint

Pre-test, post-test, follow-up

Method of measurement

Wilson & Rappi's Consequences of Social Incidents (2005)

4

Description

Quality of Life Score with the World Health Organization Short Life Style Quality Scale (1989)

Timepoint

Pre-test - Post-test - Follow up
Method of measurement
World Health Organization Quality of Life Scale (1989)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the pre-test, only the experimental group under the supervision of the psychiatrist received the seven paroxetine packs each week, which were related to the therapist until the end of the study, and the control group was not subjected to any treatment intervention, and the dependent variables were examined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Adora Specialist Consulting and Psychotherapy Center, Mashhad

Full name of responsible person

Dr. Farnaz Abhar Zanjani

Street address

No. 111, between Janbaz Ave and Samaneh Ave; Ferdowsi Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Eslami

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mahdi Amiri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of ethical issues, data is confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available