

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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)

##### Phone

+98 51 3869 1438

##### Email address

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

##### City

MASHHAD

##### Province

Razavi Khorasan

##### Postal code

0938131877

##### Phone

+98 51 3766 6805

##### Email

Farnaz.zanjani@yahoo.com

### Sponsors / Funding sources

#### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Saeed Eslami

##### Street address

University of Medical Sciences, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

0938131877

##### Phone

+98 51 3700 2317

##### Email

amiri.psy@gmail.com

#### 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

##### Street address

Ebnesina Hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

0938131877

##### Phone

+98 51 3700 2317

##### Email

amiri.psy@gmail.com

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Elham Taheri

##### Position

Assistant Professor

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Ebnesima Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

0938131877

**Phone**

+98 51 3700 2317

**Email**

elhamtaheri85@gmail.com

Mashhad University

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188986586

**Phone**

+98 51 3869 1438

**Email**

farnaz.zanjani@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Farnaz Abharzanjani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

**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