

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Comparison of the Effectiveness of cognitive rehabilitation based Rehacoms cognitive software with exposure and response prevention (ERP) and drug intervention in improving neuropsychological deficits and clinical associates in patient with Obsessive Compulsive disorder.

Protocol summary

Study aim

The Effectiveness and Comparison of three interventions models in Patients with Obsessive Compulsive Disorder

Design

Experimental study with Multiple Baseline Design.

Settings and conduct

Among the patients referred to the psychiatry psychology clinic of Hazrat Rasool Akram Complex hospital, who are diagnosed with Obsessive Compulsive disorder by a psychiatrist, 6 patients selected based on the inclusion criteria and purposive sampling, and are randomly assigned to three treatment models.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Includes the diagnosis of Obsessive Compulsive disorder, age range to 17 to 48 years old, with 12 years schooling or above level, satisfaction and commitment, non simultaneous participation in other treatment programs. The exclusion criteria including the absence of more than two sessions, comorbidity of OCD with Psychotic or Bipolar disorder, suicidal ideation or attempt in the last 6 months, Substance abuse or Alcohol abuse.

Intervention groups

First intervention group: Includes drug intervention that is performed by a psychiatrist. Second intervention group: Includes behavioral therapy based on exposure and response prevention (ERP) method. (It is based on the Foa protocol and et al, 2001) which is codify and perform by researcher. Third intervention group: Two months after the completion of therapeutic interventions, the samples will be re-evaluated in order to follow the process of changes.

Main outcome variables

Including the scores of the Beck's depression scale II and anxiety questionnaire scores, and the second edition of the Yale - Brown Obsessive Compulsive Scale II score.

General information

Reason for update

Acronym

OCD

IRCT registration information

IRCT registration number: **IRCT20210504051176N1**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **retrospective**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

shamsoddine kahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3302

Email address

kahani.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-12, 1401/07/20

Expected recruitment end date

2022-11-14, 1401/08/23

Actual recruitment start date

2022-10-12, 1401/07/20

Actual recruitment end date

2022-11-14, 1401/08/23

Trial completion date

2023-04-12, 1402/01/23

Scientific title

The Comparison of the Effectiveness of cognitive rehabilitation based Rehacoms cognitive software with exposure and response prevention (ERP) and drug intervention in improving neuropsychological deficits and clinical associates in patient with Obsessive Compulsive disorder.

Public title

The Effectiveness and Comparison of three Intervention Models in Patients with Obsessive - Compulsive Disorder.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Obsessive Compulsive Disorder, age 17 to 48 years,12 years schooling and higher education level, and commitment to participate in research and not participating in other therapies at the same time.

Exclusion criteria:

It includes the absence of more than two sessions, comorbidity of OCD with psychotic or bipolar disorder, suicidal ideation or attempt in the last 6 months, substance abuse or Alcohol abuse.

Age

From **17 years** old to **48 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **6**

Actual sample size reached: **6**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

None of the patients knew which treatment groups they belonged to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University Shiraz Unit

Street address

Shiraz, km 5 of Sadra city, Shiraz Islamic Azad University campus

City

Shiraz

Province

Fars

Postal code

74731-71987

Approval date

2022-06-15, 1401/03/25

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1401.013

Health conditions studied**1****Description of health condition studied**

Obsessive Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes**1****Description**

Neuropsychological problems

Timepoint

Before the intervention, Treatment sessions, After the intervention, 2 months the end of the intervention (follow up)

Method of measurement

Neuropsychological tests such as Wisconsin Card, Stroop Test, etc

Secondary outcomes**1****Description**

Severity of Obsessive Compulsive Disorder

Timepoint

Before the intervention, Treatment sessions, After the intervention, 2 months after the end of the intervention(follow up)

Method of measurement

Yale Brown Obsessive Compulsive Scale

2**Description**

Severity of Depression

Timepoint

Before the intervention, Treatment sessions, After the intervention, 2 month after the end of the intervention(follow up)

Method of measurement

Beck depression Inventory

3**Description**

Severity of Anxiety

Timepoint

Before the intervention, Treatment sessions, After the intervention, 2 month after the end of the intervention(follow up)

Method of measurement

Beck Anxiety Inventory

Intervention groups**1****Description**

First intervention group: Includes drug intervention that is performed by a psychiatrist. Second intervention group: Includes behavioral therapy based on exposure and response prevention (ERP) method. (It is based on the Foa protocol and et al, 2001) which is codified and perform by the researcher. Third intervention group: Includes a cognitive rehabilitation intervention that is carried a rehabilitation co therapist. Two months after the completion of therapeutic interventions, the samples will be re-evaluated in order to follow the process of changes.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Rasool Akram Hospita

Full name of responsible person

Shamsoddin Kahani

Street address

Starkhan- Kh. Niyash St. Harat Rasool Akram Hospital

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2400

Email

Rasoolhospital@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr.Mohamadreza ghaedi

Street address

The 5 km of Sadra, city, Shiraz Islamic Azad University

City

Shiraz

Province

Fars

Postal code

7198774731

Phone

+98 71 3641 0041

Fax

+98 71 3641 0059

Email

info@iaushiraz.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Iran University of Medical Sciences

Full name of responsible person

Shamsoddin Kahani

Position

Clinical Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Starkhan-Kh. Niyash-St. Hazrat Rassol Akram Hospital

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2400

Email

Sh.kahani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shamsoddin kahani

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

The 5 km of Sadra,city, Shiraz Islamic Azad University

City

Shiraz

Province

Fars

Postal code

7198774731

Phone

+98 21 8887 3302

Email

Sh.kahani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shamsoddin kahani

Position

PhD student

Latest degree

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Other areas of specialty/work

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Street address

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Email

Sh.kahani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After removing the confidential information, the files related to demographic and interventional information can be provided to clinical psychologists

When the data will become available and for how long

After all articles are published

To whom data/document is available

Clinical Psychologists

Under which criteria data/document could be used

In order to collaborate scientifically, but they are not allowed to analyze and publish

From where data/document is obtainable

Refer to the researcher's email (Shamsoddin kahani)

What processes are involved for a request to access data/document

After the publication of the article and proof of acquaintance, send an email for the experimental design of a single subject. Approximate delivery time mwill be 2 to 3 months

Comments