

# 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

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Tehran

**Province**

Tehran

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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

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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

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## 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

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## 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**

Master

**Other areas of specialty/work**

Psychology

**Street address**

The 5 km of Sadra city, Shiraz Islamic Azad University7

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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**