Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 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. Niyaish St. Harat Rasool Akram Hospital
City
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1445613131
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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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Province
Fars
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7198774731
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+98 71 3641 0041
Fax
+98 71 3641 0059
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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
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Person responsible for scientific inquiries

Contact

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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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Person responsible for updating data

Contact

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Shamsoddin kahani

Position
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Latest degree
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Other areas of specialty/work
Psychology

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Phone
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Email
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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