Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The Effectiveness of Inference-based Therapy Combined with Pharmacotherapy with Selective Serotonin Reuptake Inhibitors Compared to Selective Serotonin Reuptake Inhibitors Monotherapy in Treating Patients with Obsessive-Compulsive Disorder with Good Insight

Protocol summary

Study aim

The present study aims to compare the effectiveness of "inference-based therapy in combination with pharmacotherapy with selective serotonin reuptake inhibitors " to "selective serotonin reuptake inhibitors monotherapy" in the treatment of patients with obsessive-compulsive disorder with good insight.

Design

A clinical trial, with parallel groups, purposive sampling, phase 2 on 40 patients. Simple randomization was done.

Settings and conduct

The trial was conducted at Ebnesina Hospital in Shiraz. Participants were treated in two treatment groups. SSRIs were started at the lowest dose within the FDA-approved dose range and gradually increased, and three drugs were used: fluoxetine (ABIDI), sertraline (ABIDI), and fluvoxamine (Tehrandaru). IBT was also applied based on the IBT protocol during 24 45-minute sessions. The focus of this therapy is on eliminating obsessive doubt by overcoming the inferential confusion process. For this purpose, patients begin to change their obsessive narratives to non-obsessive narratives through therapeutic techniques during treatment. Inference-based therapy consists of 3 basic stages: education, intervention, and stabilization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. A primary diagnosis of OCD with good insight 2. Minimum level of education: High school diploma 3. Age between 18 to 50.4. Absence of suicidal risk/ current suicidal ideation. Exclusion criteria: 1. current Substance abuse 2. comorbid personality disorders, psychotic disorders, an organic mental disorder, a pervasive developmental disorder or mental retardation 3. evidence or diagnosis of bipolar disorder.

Intervention groups

There were 2 levels of intervention: 1. Pharmacotherapy with SSRI and inference-based therapy 2. pharmacotherapy with SSRI

Main outcome variables

The severity of the obsessions and compulsions

General information

Reason for update

Shortening the title of article in order to submit in journal

Acronym

IRCT registration information

IRCT registration number: **IRCT20231029059893N1**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2026-04-18, 1405/01/29**
Update count: **2**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Samaneh Karbakhsh ravari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date
2024-11-20, 1403/08/30
Actual recruitment start date
2023-12-02, 1402/09/11
Actual recruitment end date
2024-12-24, 1403/10/04
Trial completion date
2025-06-27, 1404/04/06

Scientific title
The Effectiveness of Inference-based Therapy Combined with Pharmacotherapy with Selective Serotonin Reuptake Inhibitors Compared to Selective Serotonin Reuptake Inhibitors Monotherapy in Treating Patients with Obsessive-Compulsive Disorder with Good Insight

Public title
Comparing the effect of "inference-based therapy and treatment with selective serotonin reuptake inhibitors" to "selective serotonin reuptake inhibitors" on obsessive-compulsive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A primary diagnosis of obsessive compulsive disorder with good insight Minimum level of education :High school diploma Age between 18 to 50 Absence of suicidal risk/ current suicidal ideation
Exclusion criteria:
current substance abuse comorbid personality disorders, psychotic disorders, an organic mental disorder, a pervasive developmental disorder or mental retardation evidence or diagnosis of bipolar disorder.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Education and Psychology -Shiraz University
Street address
Faculty of Education and Psychology, Shiraz University, Eram Square, Daneshjoo Blvd
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Shiraz
Province
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Postal code
71946-84334
Approval date
2023-04-18, 1402/01/29
Ethics committee reference number
IR.US.PSYEDU.REC.1402.022

Health conditions studied

1

Description of health condition studied
Obsessive Compulsive Disorder
ICD-10 code
F42.2
ICD-10 code description
Mixed obsessional thoughts and acts

Primary outcomes

1

Description
The patient's score on Yale-Brown Obsessive-Compulsive Scale
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Yale-Brown Obsessive-Compulsive Scale

Secondary outcomes

1

Description
The patient's score on the World Health Organization Quality of Life questionnaire - brief version
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
World Health Organization Quality of Life questionnaire - brief version

2

Description
The patient's score on Beck Depression Inventory
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Beck Depression Inventory

3

Description
The patient's score on Beck Anxiety Inventory
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Beck Anxiety Inventory

4

Description
The patient's score on Inferential Confusion Questionnaire, Extended Version
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Inferential Confusion Questionnaire, Extended Version

Intervention groups

1

Description
First intervention group: Pharmacotherapy with selective serotonin reuptake inhibitors and inference-based therapy Inference-based therapy is a cognitive therapy that takes place in 24 sessions of 45 minutes over 6 months. The focus of this therapy is on resolving obsessive doubt by overcoming the process of inferential confusion. To this end, during treatment, patients begin to change their obsessive narratives to non-obsessive narratives through therapeutic techniques. Inference-based therapy consists of 3 basic steps: Education, Interventions & Consolidation. The Education phase consists of 4 steps: 1. Educating that most of OCD symptoms are caused by doubt 2. Focusing on reasoning before doubt (inferential confusion) and showing clients that doubt or obsession does not arise without a prelude 3. Exploring how obsessive doubt derives its power and value from a compelling narrative that logically leads to doubt 4. Addressing the selectivity nature of obsessions in OCD by introducing the construct of feared self. The intervention phase consists of: 1. Demonstrating the client that there is no direct here-and-now evidence that would support the OCD doubt & therefore, the OCD story is produced entirely subjectively 2. Demonstrating the client that since obsessive doubt arises purely from within the person and not an external source, it is %100 irrelevant to here and now 3. Assisting the client recognize the exact moment when they have left the world of senses and entered the realm of imagination 4. Describing how obsessive doubt is always false -due to its opposition to reality And finally, the Consolidation phase:1. Encouraging the client to narrate a non-obsessive story 2.Introducing the client to many OCD tricks that make it seem as if the obsessive doubt is connected to reality. 3.Highlighting the selective nature of obsessive doubt besides the vulnerable self-theme that exists in doubt 4. Moving towards a life without OCD, developing a method to enable maintenance of gains and prevention of relapse. Pharmacotherapy was performed with three drugs, fluoxetine(ABIDI), sertraline(ABIDI), and fluvoxamine(Tehrandarou), which are FDA-approved for the treatment of OCD in terms of effectiveness and side effects. To minimize the side effects of the drugs, such as gastrointestinal side effects, dizziness, and other symptoms, treatment with SSRIs was started at a very low dose and over time, depending on the patient's tolerance to the drug side effects, the dose of the drugs was increased by the psychiatrist every 4-7 days until the target dose was achieved. A specific dose has been considered for each of the 4 drugs used: Recommended dose of sertraline: 50 to 200 mg per day Recommended dose of fluoxetine: 20 to 60 mg per day Recommended dose of fluvoxamine: 100 to 300 mg per day All drugs were used once a day, except for fluvoxamine, which was used twice a day due to its short half-life.
Category
Treatment - Other

2

Description
Second intervention group: Pharmacotherapy with selective serotonin reuptake inhibitors Pharmacotherapy was performed with three drugs, fluoxetine(ABIDI), sertraline(ABIDI), and fluvoxamine(Tehrandarou), which are FDA-approved for the treatment of OCD in terms of effectiveness and side effects. To minimize the side effects of the drugs, such as gastrointestinal side effects, dizziness, and other symptoms, treatment with SSRIs was started at a very low dose and over time, depending on the patient's tolerance to the drug side effects, the dose of the drugs was increased by the psychiatrist every 4-7 days until the target dose was achieved. A specific dose has been considered for each of the 4 drugs used: Recommended dose of sertraline: 50 to 200 mg per day Recommended dose of fluoxetine: 20 to 60 mg per day Recommended dose of fluvoxamine: 100 to 300 mg per day All drugs were used once a day, except for fluvoxamine, which was used twice a day due to its short half-life.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center

Ebne Sina Hospital

Full name of responsible person
Samaneh Karbakhsh Ravari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shiraz university

Proportion provided by this source
50

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

2

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamid Mohammadi

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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
Shiraz University of Medical Sciences

Proportion provided by this source
50

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
Shiraz University

Full name of responsible person
Samaneh Karbakhsh Ravari

Position
PhD student

Latest degree
Master

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
Despite attempts to anonymize data, there may be a risk of re-identification participants, which is unethical and violates the researcher's commitment to participants. There is also a concern that the original data may be valuable for the researcher's own future research.

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