# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

## The effectiveness of personalized computerized inhibitory training program (P-CIT) with Exposure and Response Prevention on the outcome of therapy in Patients with Contamination Obsessive-Compulsive Disorder

## Protocol summary

**Study aim**

evaluate the effect of a computer training program with exposure and response prevention(ERP) in reducing the symptoms of obsessive-compulsive disorder, depression, anxiety and increasing the quality of life and task control of people with OCD of the type of contamination / washing.

**Design**

Clinical trial, with control and experimental groups, parallel, single blind, randomized, on 30 patients. A randomization table is used for randomization

**Settings and conduct**

From patients with OCD subtype contamination/washing who referred to the clinic of the Faculty of Behavioral Sciences and Mental Health,Hazrat Rasoul Akram Hospital and Iran Psychiatric Hospital in 2021 ,30 people will be selected and will assign randomly to groups.The pre-tests are performed by an evaluation that is blinded by assigning the code to the groups. Then, before starting the ERP treatment, the experimental group receives P-CIT and and starts its daily implementation at home, and 1 week later they enter ERP treatment while continuing to run it. The control group enters ERP treatment without receiving a program. ERP treatment for both groups are performed in the clinic of the Faculty of Behavioral Sciences and Mental Health. At the end the post-test is taken and the data are analyzed by a blinded statistical analyst.

**Participants/Inclusion and exclusion criteria**

inclusion criterion:Initial diagnosis of obsessive-compulsive disorder exclusion criterion:Concurrent psychiatric disorders

**Intervention groups**

The intervention group includes patients with obsessive-compulsive disorder (OCD) of the type of contamination / washing who receive a combined intervention of a personalized computerized inhibitory training(PCIT) program with exposure and response prevention (ERP). The control group includes patients with OCD of the type of contamination / washing who receive a ERP.

**Main outcome variables**

Obsessions and compulsions

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211027052887N1**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**
Update count: **0**

**Registration date**

2021-10-31, 1400/08/09

**Registrant information**

**Name**

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**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-11-06, 1400/08/15

**Expected recruitment end date**

2021-12-21, 1400/09/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effectiveness of personalized computerized inhibitory training program (P-CIT) with Exposure and Response Prevention on the outcome of therapy in Patients with Contamination Obsessive-Compulsive Disorder

**Public title**
The effectiveness of personalized computerized inhibitory training program (P-CIT) with Exposure and Response Prevention on obsessive-compulsive disorder
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Initial diagnosis of obsessive-compulsive disorder (OCD) by a psychiatrist and then obtaining a score of 16 or higher on the Yale-Brown Obsessive-Compulsive Disorder Scale (YBOCS) Having insight so that the patient is aware of the problems and illness and also has a non-insane understanding of the cause and meaning of her illness. Familiarity with computers and email and how to work with them Age between 18 to 55 years' old and At least Diploma education
**Exclusion criteria:**
Receiving psychological and pharmacological treatments for 3 months before entering the study (in the case of patients treated with psychiatric drugs if the dose of the drug in them is stable 6 weeks before the study and remains at the same dose during the study from Study will not be deleted). Concurrent psychiatric disorders such as bipolar disorder and related disorders, schizophrenia spectrum disorders and other psychotic disorders, addictive disorders and substance-related disorders (In the case of other mental disorders, patients will not be excluded from the study if the symptoms of OCD are more severe and harmful than the symptoms of the accompanying mental disorder). Having vision problems that can not be treated with medical treatment or prescription glasses. Having hearing problems that can not be treated with medical treatment or hearing aids. Having serious thoughts of active suicide Organic brain disorder based on family and patient reports
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **30**

**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, the Restricted Randomization method of Balance Block Randomization will be used.The size of all the blocks was equal and in this study, we will have 4 blocks. Excel will be used for generation of random sequence .Allocation concealment is also used. Using Sequentially numbered, sealed, opaque envelopes, each random sequence created is recorded on a card. And the cards are placed in the envelopes of the letter, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Evaluator and statistical analysts are blind to the research process. Statistical analyst is blind to research so that data analysis can be done without bias
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences
**Street address**
Hemmat Highway between Chamran and Sheikh Fazlollah Iran University of Medical Sciences Headquarters Fifth Floor
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**Postal code**
۱۴۴۹۶۱۴۵۳۵
**Approval date**
2020-12-07, 1399/09/17
**Ethics committee reference number**
IR.IUMS.REC.1399.972

## 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**
Severity of signs and symptoms in patients with obsessive-compulsive disorder
**Timepoint**
before the intervention, last session, 2 months after the intervention
**Method of measurement**
Yale-brown obsessive compulsive scale

## Secondary outcomes

**1**

**Description**
Quality of Life
**Timepoint**
before the intervention, last session, 2months after intervention
**Method of measurement**
World Health Organization's Quality of Life Questionnaire (WHOQOL-BREF)

**2**

**Description**
task control
**Timepoint**
before the intervention, last session, 2months after intervention
**Method of measurement**
Stroop

**3**

**Description**
Anxiety, depression, stress
**Timepoint**
before the intervention, last session, 2months after intervention
**Method of measurement**
Depression Anxiety and Stress Scales

## Intervention groups

**1**

**Description**
Intervention group: personalized computerized inhibitory training program (P-CIT) with exposure and response prevention (ERP): First, participants complete the research questionnaires as a pre-test, then 1 week before the start of ERP sessions, in order to personalize the training program. In individual sessions, the computer inhibitor will first view and confirm the obsessive-compulsive images used in the program, which have been approved by experts and individuals with obsessive-compulsive disorder and localized, and after the necessary explanations and practical training, The P-CIT program, along with OpenSesame 3.0 software (using Pytho 2.7.6), will be available for installation and running at home and will run for seven days, three times a day (each time). 15 minutes) will do. After seven days at the clinic, they will begin a course of 17 sessions of ERP treatment while continuing to perform P-CIT. In this way, 2 treatment sessions are held for each person every week.. They run the program 3 times a day at home during the research and intervention, and will deliver the result of each run in the form of an Excel file to the therapist in the next session. It should be noted that the images will be updated at each stage of treatment based on the patient's current most annoying symptoms and will be approved by each person in the experimental group before implementation.At the end of the ERP sessions and again in the follow-up phase, after 2 months, participants will complete the research questionnaires again.
**Category**
Treatment - Other

**2**

**Description**
Control group:exposure and response prevention(ERP): Participants first complete the research questionnaires as a pre-test. The control group also entered the treatment of 17 sessions of exposure and prevention of response according to the guideline of exposure therapy and prevention of response (ritual) for obsessive-compulsive disorder without any computer program. They will be held in such a way that 2 treatment sessions are held for each person every week. ERP Sessions: Session 1: The therapist begins to gather information about the patient's obsession and his or her medical history. The rationale and description of the treatment will also be stated for the patient and the issue of self-review will be raised. Confrontation topics will be prepared. Sessions 3 to 7: Confrontation and prevention of rituals will be practiced in each session, which will gradually increase their difficulty until the eighth session. Depending on the patient's symptoms, prescriptions for visual encounters will be provided. Session 8: The patient will face the highest item in his or her hierarchy. Session 9-16: Repetition or variation of previous encounters and other introductions. Anxiety-inducing stimuli will be incorporated into the hierarchy. (If possible, one or two visits to the patient's home are recommended to observe and guide his or her encounters.) Final Session: Assessing the patient's therapeutic progress and preparing him or her to return to normal behavior will discuss strategies to prevent relapse. Finally, four to six follow-up telephone calls will be made on a weekly basis to assist the patient in the transition from the active

phase of treatment. At the end of the ERP sessions and again in the follow-up phase, after 2 months, participants will complete the research questionnaires again.

**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Tehran Psychiatric Institute, Iran Psychiatric Hospital, Hazrat Rasoul Akram Hospital

**Full name of responsible person**
fatemeh jafarian dehkordi

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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**Full name of responsible person**
Hossein Keyvani

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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**
Iran 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**
Iran University of Medical Sciences

**Full name of responsible person**
fatemeh jafarian dehkordi

**Position**
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**
There is no more information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable