Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of cognitive behavioral therapy using virtual reality-based exposure and response prevention (VR - ERP) and cognitive behavioral therapy in adults with obsessive-compulsive disorder-contamination/washing

Protocol summary

Study aim
Designing and developing of virtual reality exposure treatment and response prevention for patients with obsessive-compulsive disorder type of contamination / washing

Design
Clinical trial, with control and experimental groups, parallel, one-sided blind, randomized, on 36 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 in 1400, According to the inclusion and exclusion criteria, 36 people will be selected and will assign randomly to control and experimental groups. . Cognitive-behavioral therapy will be performed in the clinic of the Faculty of Behavioral Sciences and Mental Health. cognitive behavioral therapy using virtual reality-based exposure and response prevention will be performed at the growth center of the Faculty of Behavioral Sciences and Mental Health.

Participants/Inclusion and exclusion criteria
inclusion criterion Adults with obsessive-compulsive disorder of the type of contamination / washing with mild, moderate and severe severity inclusion criterion Diagnostic criteria of obsessive-compulsive disorder of non-contamination / washing type

Intervention groups
In control and experimental groups, cognitive-behavioral therapy developed by Robert Leahy and Stephen Holland will be used in 12 sessions. In control group in vivo and imaginal exposure and in experimental group virtual reality exposure will be used. Before stating first session, all participants will complete BDI, BAI, OBQ-44 and YBOCS as pre-test. After the treatment is completed, they will fill the above questionnaires as post-test. After 3 months, they will fill the questionnaires as follow-up.

Main outcome variables
Obsessions and compulsions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210214050353N1**
Registration date: **2021-10-16, 1400/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-16, 1400/07/24**
Update count: **0**

Registration date
2021-10-16, 1400/07/24

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-04, 1400/07/12

Expected recruitment end date
2021-10-22, 1400/07/30

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

Scientific title
Comparison of the effectiveness of cognitive behavioral therapy using virtual reality-based exposure and response prevention (VR - ERP) and cognitive behavioral therapy in adults with obsessive-compulsive disorder-contamination/washing

Public title
Comparison of the effectiveness of cognitive behavioral therapy using virtual reality-based exposure and response prevention (VR - ERP) and cognitive behavioral therapy in OCD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults with obsessive-compulsive disorder of the type of contamination / washing with mild, moderate and severe severity based on DSM-5 At least Diploma education Age between 18 to 50 years' old
Exclusion criteria:
Patients with psychiatric disorders including psychotic disorders, substance use disorder and bipolar disorder Patients with neurological, neurological disease and no history of seizures Patients with severe personality disorders including paranoid, schizoid, schizotypal, borderline, antisocial, narcissistic personality disorder Diagnostic criteria of obsessive-compulsive disorder of non-contamination / washing type including ordering, symmetry, checking
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Restricted Randomization method of block randomization will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process, so that the number of samples assigned to each of the study groups become equal and in this study, we will have 4 blocks. Excel software was used to generate a random sequence. Allocation concealment is also used, which is the method used to execute a random sequence on study participants. In such a way that the assigned group is not known before the individual is assigned. 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
Iran University of Medical Sciences, fifth floor
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-09-28, 1400/07/06
Ethics committee reference number
IR.IUMS.REC.1400.595

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, 3 months after the intervention
Method of measurement
Yale-brown obsessive compulsive scale

Secondary outcomes

1

Description
the symptoms of depression
Timepoint
before the intervention, last session, 3 months after intervention
Method of measurement
Beck Depression Inventory

2

Description
the symptoms of anxiety
Timepoint
before the intervention, last session, 3 months after intervention
Method of measurement
Beck Anxiety Inventory

3

Description
Obsessive beliefs
Timepoint
before the intervention, last session, 3 months after intervention
Method of measurement
Obsessive Beliefs Questionnaire-44

4

Description
Disability
Timepoint
before the intervention, last session, 3 months after intervention
Method of measurement
World Health Organization Disability Assessment Scale-2

Intervention groups

1

Description
Intervention group: cognitive behavioral therapy using virtual reality-based exposure and response prevention (VR-ERP) therapy : At first, Participants will complete the questionnaires as a pre-test including: Yale-brown obsessive compulsive scale, Beck Depression Inventory, Beck Anxiety Inventory, Obsessive beliefs questionnaire-44, World Health Organization Disability Assessment Scale-2. Then, they enter the training phase to get used to moving in the virtual environment. In this stage, they encounter a natural environment in the living room and do a number of tasks such as check the room for a few minutes, turn on the TV, Move objects inside the shelves. Then, Then, they enter the experimental phase. This step includes 12 sessions. Individual treatment sessions are held weekly. Each session includes a discussion about the previous week's homework and an obsessive-compulsive self-assessment, cognitive reconstruction of maladaptive thoughts in 20 minutes and virtual reality exposure and response prevention in 25 to 45 minutes. Then next week's assignment, which includes reviewing educational materials, self-examination will be specified. The first two sessions focus on case conceptualization and the introduction of a treatment plan. Session 12 will be devoted to relapse prevention. Participants will then complete the questionnaires as a post-test. In follow-up phase, participants will complete the research questionnaires after 3 months.
Category
Treatment - Other

2

Description
Control group: Cognitive behavioral therapy: At first, Participants will complete the questionnaires as a pre-test including: Yale-brown obsessive compulsive scale, Beck Depression Inventory, Beck Anxiety Inventory, Obsessive beliefs questionnaire-44, World Health Organization Disability Assessment Scale-2. Then, they receive 12 sessions of cognitive-behavioral therapy. Individual treatment sessions are held weekly. Each session includes a discussion about the previous week's homework and an obsessive-compulsive self-assessment, cognitive reconstruction of maladaptive thoughts in 20 minutes and in-vivo or imaginal exposure and response prevention in 25 to 45 minutes. Then next week's assignment, which includes reviewing educational materials, self-examination will be specified. The first two sessions focus on case conceptualization and the introduction of a treatment plan. Session 12 will be devoted to relapse prevention. Participants will then complete the questionnaires as a post-test. In follow-up phase, participants will complete the research questionnaires after 3 months.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center

Tehran institute of psychiatry

Full name of responsible person
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Sponsors / Funding sources

1

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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

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Razieh Javaheri Renani

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Student

Latest degree
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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