

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

razieh javaherirenani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1655

Email address

javaherirenani.r@iums.ac.ir

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

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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

۱۴۳۹۶۱۴۵۳۵

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

Razieh Javaheri Renani

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

Ertebat.tip@iums.ac.ir

Web page address

<https://tip.iums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2504

Fax

+98 21 8862 2703

Email

research-m@iums.ac.ir

Web page address

<https://vcr.iums.ac.ir/fa?sid=22>

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

Razieh Javaheri Renani

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

razieh.javaheri@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Razieh Javaheri Renani

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

razieh.javaheri@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Razieh Javaheri Renani

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

razieh.javaheri@yahoo.com

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