Augmenting efficacy of cognitive behavioral therapy with anti-disgust cognitive intervention on disgust propensity/ sensitivity, emotion acceptance, and OCD severity in patients with obsessive-compulsive disorder

Protocol summary

Study aim
Comparing the efficacy of psychological therapies on disgust propensity/ sensitivity, emotion acceptance, and OCD severity in patients with obsessive-compulsive disorder.

Design
A randomized clinical trial with a parallel group (cognitive behavioral therapy with or without anti-disgust cognitive intervention. The intervention and parallel groups each consist of 26 participants. Randomization was performed by a person who was blind to the objectives of the study.

Settings and conduct
After meeting the eligibility criteria, the enrolled participants will be randomly allocated to two intervention groups. In addition, each intervention will last 15 weekly sessions or three months. All participants will be assessed four times using research measures. Four assessment phases include 1) pre-treatment, 2) before the exposure and response prevention sessions, 3) posttreatment, and 4) three-month follow-up. Therapists, evaluators, and research assistants are different people.

Participants/Inclusion and exclusion criteria
Inclusion criteria: be at least 18 years old; equal to or more than 12 degrees education; diagnosed with contamination-based obsessive-compulsive disorder; have a fixed dose of the medication up to three months before the beginning of the study; completing informed consent.

Intervention groups

Main outcome variables
Disgust propensity/ sensitivity; Obsessive-compulsive disorder severity; Emotion acceptance.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20210914052475N1
Registration date: 2021-10-10, 1400/07/18
Registration timing: prospective

Last update: 2021-10-10, 1400/07/18
Update count: 0
Registration date
2021-10-10, 1400/07/18
Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-10-17, 1400/07/25
Expected recruitment end date
2021-12-16, 1400/09/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Augmenting efficacy of cognitive behavioral therapy with anti-disgust cognitive intervention on disgust propensity/sensitivity, emotion acceptance, and OCD severity in patients with obsessive-compulsive disorder

Public title
Augmenting cognitive behavioral therapy for obsessive-compulsive disorder with anti-disgust cognitive intervention

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
- Being at least 18 years old in the beginning of the study.
- Having an education grade equal to 12 or more.
- Diagnose with contamination-based obsessive-compulsive disorder as a primary diagnosis. Having a stable dose of medication from 3 months before the beginning of the study. Completing informed constant form.

Exclusion criteria:
- Diagnose with other comorbid psychiatric disorders or conditions except for major depressive disorder. Having a history of traumatic head injury or epilepsy.

Age
From 19 years old to 40 years old

Gender
Both

Phase
N/A

Groups that have been masked
- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed by a research assistant through the lottery method. First, the research assistant will give a code to each participant who met the eligibility criteria. The mentioned codes will be written on paper. Then, he will be poured all papers into an opaque container and intermittently allocated each participant to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The process of evaluation, randomization, and treatment for all participants will be conducted in two separate centers. In the first center, each participant will be evaluated by a research assistant who is blind to the study's objectives. He will assign each participant to one of two groups, as described in the randomization procedure. Then, each participant will refer to the second center to start the interventions. The second center is located at a one-kilometer distance from the first center. Therapists, researchers, evaluators, and data analysts will also present at the second center and will be utterly blind to the study objectives and which participant belonged to which group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Kharazmi University
Street address
Somayyeh building, Kharazmi University, South Moffateh st, Tehran
City
Tehran
Province
Tehran
Postal code
15719-14911

Approval date
2021-09-14, 1400/06/23

Ethics committee reference number
IR.KHU.REC.1400.027

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
Disgust propensity/ sensitivity

Timepoint
Pre-treatment, before exposure and response prevention sessions, post-treatment, three-month follow-up

Method of measurement
Disgust Propensity/ Sensitivity Scale (DPSS)
2

Description
Obsessive-compulsive disorder severity

Timepoint
Pre-treatment, before exposure and response prevention sessions, post-treatment, three-month follow-up

Method of measurement
Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

3

Description
Emotion acceptance

Timepoint
Pre-treatment, before exposure and response prevention sessions, post-treatment, three-month follow-up

Method of measurement
Non-judging & non-reactivity sub-scales of Five Facets Mindfulness Questionnaire

Secondary outcomes

1

Description
Acceptance rate of exposure and response prevention

Timepoint
Before exposure and response prevention sessions

Method of measurement
Percent of acceptance of exposure and response prevention

Intervention groups

1

Description
Intervention group: cognitive-behavioral therapy plus anti-disgust cognitive intervention, 15 weekly sessions, time of each session: 90 minutes, case conceptualization, disgust-related cognitive psychoeducation & intervention, exposure and response prevention, relapse prevention.

Category
Behavior

2

Description
Control group: cognitive-behavioral therapy, 15 weekly sessions, time of each session: 90 minutes, case conceptualization, exposure and response prevention, relapse prevention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Atiyeh clinic

Full name of responsible person
Davood Qasemzadeghan

Street address
Mehr cultural center, Khandayie blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research & technology assistance of Kharazmi University

Full name of responsible person
Dr Jamshid Shanbeh Zadeh

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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
Research & technology assistance of Kharazmi 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
Person responsible for scientific inquiries

Contact
Name of organization / entity
Kharazmi University
Full name of responsible person
Dr Behzad Salmani
Position
Ph.D. in Health Psychology
Latest degree
Ph.D.
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
Privacy of personal information
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable