

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of emotional schemas therapy augmented exposure and response prevention, drug therapy and exposure and response prevention treatment on obsessive-compulsive, anxiety and depression symptoms, obsessional beliefs and quality of life in people with obsessive - compulsive disorder

Protocol summary

Study aim

-Compilation, validation and initial impact of the STERP protocol. - Determining the difference in the effectiveness of treatment of STERP in obsessive compulsive disorder

Design

The present study has been developed in two stages: protocol development, validation, and clinical testing. In the first stage, after integrating the two protocols and evaluating by experts, for the purpose of validating the protocols, the protocol will be implemented using a case study on 3 patients with Obsessive-compulsive disorder (OCD). In the next step, after coordinating with the centers, patients are referred based on a psychiatrist's diagnosis and a research associate, evaluates patients with SCID-5-CV and SCID-5-PD. Finally, according to the inclusion criteria, 45 patients with Obsessive-compulsive disorder (OCD) are selected through targeted sampling. then, 15 patients are randomly assigned to Emotional Schemas Therapy augmented exposure and response prevention, and 15 patients of prevention and response prevention, and 15 receive only drug treatment.

Settings and conduct

This study will be carried out at Psychiatric Institute and Imam Hossein Hospital in Tehran. The main therapist and patients do not know how to allocate to treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of obsessive-compulsive disorder(OCD); being at the age of 18 to 50 years.
Exclusion criteria: suicidal thoughts; psychotic disorder based on SCID-5-CV; substance abuse and dependence; severe personality disorders based on SCID-5-PD

Intervention groups

Intervention group 1: Emotional Schemas Therapy augmented exposure and response prevention.
Intervention group 2: exposure and response prevention treatment. Control group: drug therapy.

Main outcome variables

Anxiety - Obsessive beliefs - Quality of life - Obsessive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141108019855N7**
Registration date: **2019-01-28, 1397/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Samira Masumian

Name of organization / entity

Tehran Psychiatry Institute

Country

Iran (Islamic Republic of)

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+98 21 3349 6990

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Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2018-06-22, 1397/04/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of emotional schemas therapy augmented exposure and response prevention, drug therapy and exposure and response prevention treatment on obsessive-compulsive, anxiety and depression symptoms, obsessional beliefs and quality of life in people with obsessive - compulsive disorder

Public title

The effect of emotional Schemas Therapy augmented exposure and response prevention on obsessive - compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Diagnostic Criteria for Obsessive-Compulsive Disorder Having at least a cycle education level Having a minimum age of 18 and a maximum of 50 years

Exclusion criteria:

Suicidal thoughts Psychotic disorder based on SCID-5-CV Substance use and abuse and dependence on any substance severe personality disorders

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients enter the treatment groups based on the lottery

Blinding (investigator's opinion)

Double blinded

Blinding description

In addition to the original researcher, the evaluator is also blind.

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

Next to Milad Tower, Hemat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۹۶-۱۴۵۳۵

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.IUMS.REC.1397.175

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**

Obsessive symptoms

Timepoint

Before, immediately after and two months after treatment

Method of measurement

Yale-Brown Obsessive-Compulsive Scale-Second Edition

2**Description**

Anxiety

Timepoint

Before, after and two months after treatment

Method of measurement

Four Systems Anxiety Questionnaire (FSAQ):

3**Description**

Obsessive beliefs

Timepoint

Before, after and two months after treatment

Method of measurement

Obsessive-Verbal Questionnaire

4

Description

Quality of Life

Timepoint

Before, after and two months after treatment

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Emotional Schemas Therapy augmented exposure and response prevention: In the initial stage (sessions 1-3), establishing a therapeutic relationship, measuring and evaluating emotional schemas, formulating the case, providing treatment logic and therapeutic goals, teaching on obsessive-compulsive disorder, and presenting a model of anthropology and explaining the treatment of emotional schema Preliminary explanation and presentation of the logic of confrontation and prevention of a brief response, attention to the patient's adaptive and non-adaptive emotions, and the presentation of the task of emotional functioning are emphasized. In the changing phase (sessions 4-10), addressing the patient's painful excitement and patient emotional schemas, and designing behavioral experiments to challenge them, presenting the task, describing emotions and challenges with troublesome emotional schemas (accepting emotions, validating emotions) Is considered. Also, confrontational meetings begin by identifying anxiety and hierarchy. In the final phase (sessions 10-14), focusing on transferring new skills and achievements to the living environment and preventing recurrence is carried out, and the final summing up of the lessons is assessed and reassessed.

Category

Treatment - Other

2

Description

Intervention group 2: exposure and response prevention; The focus of these meetings is on: Reviewing the patient's reactions to the previous treatment session, Assessing the task of the previous session, logic of treatment and self-review forms, Collecting detailed information from obsessive-compulsive symptoms, Providing a hierarchy of all anxious situations, Performing confrontation with initial cases in a hierarchy

(starting to confront situations with moderate anxiety), Providing treatment plan, Providing final summaries and feedback.

Category

Treatment - Other

3

Description

Control group: drug therapy: the patients in the control group received SSRIs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein Hospital

Full name of responsible person

Samira Masumian

Street address

Mansouri Alley, Nayesh Street, Sattarkhan Street

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2

Recruitment center

Name of recruitment center

Institute of Psychiatry

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Samira Masumian

Position

PhD candidate in clinical psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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Person responsible for updating data

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Position

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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

No more information

Study Protocol

Yes - There is 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
Title and more details about the data/document
Only information about the outcome
When the data will become available and for how

long
2019
To whom data/document is available
Therapists and Clinical Specialists
Under which criteria data/document could be used
Treatment
From where data/document is obtainable
Tehran Psychiatric Institute
What processes are involved for a request to access data/document
By email or by face-to-face
Comments