

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effectiveness of neurofeedback on rumination and cognitive avoidance of people with obsessive-compulsive disorder

#### Protocol summary

##### Study aim

Determining the effectiveness of neurofeedback on rumination and cognitive avoidance in people with obsessive-compulsive disorder

##### Design

A controlled, parallel-group, single-blind, randomized, phase 2 trial of 30 patients. The rand function of Excel software was used for randomization

##### Settings and conduct

After obtaining the necessary permits and referring to Rahmon's counseling and psychological services center in Amol, the people who meet the entry criteria and are willing to participate in the research will be identified, then the Yale Brown Practical Obsession Questionnaire will be distributed among the people, 30 people who scored at least 16 from Yale Brown's Practical Obsession Questionnaire (1986) were selected as a sample and will be randomly assigned to an experimental group and a control group. The neurofeedback system will be used for the intervention of the experimental group. The participants in this study will be studied individually and for about two months through the neurofeedback device in rahnemon clinic. This research uses the Iranian BIOLINE 12-channel device, which can be implemented with the help of a computer system and related software

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. The selected people will be willing and interested in participating in the study. 2. Have obtained a minimum score of 16 from Yale Brown Practical Obsession Questionnaire 3. Be able to share their information and experiences. Exclusion Criteria: 1. Having a history of physical disorder that involves mental struggle

##### Intervention groups

15 people will be assigned to the experimental group (related to neurofeedback exercises), 15 people will be assigned to the experimental group (control)

##### Main outcome variables

Neurofeedback is the independent variable of the

present study. The first dependent variable is rumination and the second dependent variable is cognitive avoidance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230526058295N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

##### Registration date

2023-09-02, 1402/06/11

##### Registrant information

##### Name

Elahe Azizi

##### Name of organization / entity

Ayatollah amoli azade university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 933 490 8016

##### Email address

e.azizi1998@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-06, 1402/06/15

##### Expected recruitment end date

2023-09-16, 1402/06/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of neurofeedback on rumination and cognitive avoidance of people with obsessive-compulsive disorder

**Public title**

Investigating the effectiveness of neurofeedback on rumination and cognitive avoidance of people with obsessive-compulsive disorder

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

The selected people are willing and interested in participating in the study They Have obtained a minimum score of 16 from the 1986 Yale-Brown Obsession compulsion Questionnaire

**Exclusion criteria:****Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

People who met the entry criteria and were willing to participate in the research are identified. Then, Yale-Brown Practical Obsessive Compulsive Questionnaire was distributed among the people, 30 people who scored at least 16 from the Yale Brown Practical Obsessive Compulsive Questionnaire (1986) were selected as samples. 15 cards are prepared in the name of the experimental group and 15 cards in the name of the control group. After the cards are dealt, the participants will be asked to take one card each and place themselves in their group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

komite akhlagh Azad university of babol

**Street address**

3 km of Ghaemshahr road, Babol

**City**

Babol

**Province**

Mazandaran

**Postal code**

4615888774

**Approval date**

2023-07-03, 1402/04/12

**Ethics committee reference number**

IR.IAU.BABOL.REC.1402.016

**Health conditions studied****1****Description of health condition studied**

People with obsessive compulsive disorder

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Reducing post-test rumination and cognitive avoidance

**Timepoint**

Before the start of the intervention and two months after the start of the intervention

**Method of measurement**

Nolen, Hoeksma and Maro (1993) rumination questionnaire and Sexton and Dagas (2004) cognitive avoidance questionnaire in the pre-test and post-test stages.

**Secondary outcomes****1****Description**

Reducing the symptoms of obsessive-compulsive disorder

**Timepoint**

Two months after the start of the intervention

**Method of measurement**

Yale Brown Questionnaire (1986), Nolen, Hoeksma and Maro's Rumination Questionnaire (1993) and Sexton and Dagas Cognitive Avoidance Questionnaire (2004)

**Intervention groups**

## 1

### Description

Intervention group: Intervention group: 15 people will be assigned to the experimental group (related to neurofeedback exercises), 15 people will be assigned to the control group. The experimental group receives neurofeedback training during 18 regular sessions over a period of 6 weeks and three sessions per week.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Rahnemon clinic

#### Full name of responsible person

Elahe azizi

#### Street address

Darya 27/1 Alley, taleb amoli Ave

#### City

Amol

#### Province

Mazandaran

#### Postal code

4615888774

#### Phone

+98 933 490 8016

#### Email

e.zizi1998@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rahnemon clinic

#### Full name of responsible person

Elahe azizi

#### Street address

Darya 27/1, Taleb amoli Ave

#### City

Amol

#### Province

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#### Email

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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

Rahnemon clinic

### Proportion provided by this source

100

### Public or private sector

Private

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Persons

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Rahnemon clinic

#### Full name of responsible person

Elahe azizi

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Psychology

#### Street address

Isar 5 Alley, Janbazan Ave

#### City

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Elahe azizi

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Psychology

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Elahe Azizi

**Position**

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**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

The data will be available to all

**Under which criteria data/document could be used**

The use of documents for research and reference is allowed

**From where data/document is obtainable**

Applicants can apply through email to receive Email: e.azizi1998@gmail.com

**What processes are involved for a request to access data/document**

Applicants can apply via email to receive within a few weeks

**Comments**