

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Study the effectiveness of omega 3 fatty acid as adjuvant treatment on depression, aggression and poor impuls control in hospitalized patients of borderline personality disorder

#### Protocol summary

##### Study aim

Study the effectiveness of omega 3 fatty acid on depression, aggression and poor impuls control in patients of borderline personality disorder hospitalized in Razi psychiatric hospital.

##### Design

Clinical trial, control and intervention group, factorial, two blinded, accidental, phase 3 on 46 patient. The software will use for randomization.

##### Settings and conduct

All patients with borderline personality disorder are hospitalized in Razi Psychiatric hospital who have the criteria for entering the study will be divided into two intervention and control groups by web software, and for both group of patients DBT psychotherapy will be performed and they will receive olanzapine ranging from 5 to 15 mg . The intervention group will also be given a 2 gram omega 3 capsule daily for 6 weeks. All patients will be filed at the beginning of study and end of week 12 Hamilton depression questionnaires, bass and perry aggression and barat impulsiveness and the person who will review the participants in terms of the criteria of entering the study and the person who will attend the group will be different.

##### Participants/Inclusion and exclusion criteria

Definitive diagnosis of borderline personality disorder based on DSM V, Age range between 18 till 60 years old, Disorder leads to referral for treatment and hospitalization, IQ is higher than 70, Patient and patients price have conscious consent to participate in the study. Having metabolic disorder, having extra pyramidal symptoms

##### Intervention groups

Control group includes patients with borderline personality disorder who will be treated with olanzapine and psychotherapy. Intervention group includes patients with borderline personality disorder who will be treated

with olanzapine, omega 3 and psychotherapy.

##### Main outcome variables

depression, aggression, poor impulse control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210531051453N1**

Registration date: **2021-07-30, 1400/05/08**

Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**

Update count: **0**

##### Registration date

2021-07-30, 1400/05/08

##### Registrant information

##### Name

Ensieh Sadri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4405 7355

##### Email address

sadri.ensieh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-01, 1400/05/10

##### Expected recruitment end date

2022-03-11, 1400/12/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study the effectiveness of omega 3 fatty acid as adjuvant treatment on depression, aggression and poor impuls control in hospitalized patients of borderline personality disorder

**Public title**

Effect of omega 3 fatty acid in borderline personality disorder

**Purpose**

Treatment

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

Definitive diagnosis of borderline personality disorder based on DSM V Age range between 18 till 60 years old Disorder leads to referral for treatment and hospitalization IQ is higher than 70 Patient and patients price have conscious consent to participate in the study

**Exclusion criteria:**

Having psychological disorders except substance abuse disorder Having diabetes, metabolic disorders, serious medical or neurological diseases Having extrapyramidal symptoms such as hands tremor, mouth watering, neck dystonia, rigidity and akathisia Pregnancy and breastfeeding

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **23**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to fix some possible tours in this study, simple coincidence will be observed. In this study, to randomly allocate people to two groups, first using software under the web <https://www.Randomization.com> a random sequence of number will be created. Also cases such as the person who will create sequence, the person who will check the participants in terms of entry and exit criteria and enroll them in the study, and the person who will assign the participants to the groups are separated from each other.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The design of this study will take place in terms of

blindness. This type of design is so that the people studied are not aware of the type of study and the evaluation is not aware of the intervention in every patient. The purpose of this type of design is to prevent the appearance of the observers net. This tour means that the results observed from the plane are affected by the attitude and behavior of the patient or doctor. So the design of this study will be done in a way to minimize possible nets and results closer to reality.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of university of social welfare and rehabilitation sciences

**Street address**

No 17, South Ebrahimi Ave, East Ferdos Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1481958465

**Approval date**

2020-01-14, 1398/10/24

**Ethics committee reference number**

IR.USWR.REC.1398.208

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

Borderline personality disorder

**ICD-10 code**

F60.3

**ICD-10 code description**

Borderline personality disorder

**Primary outcomes****1****Description**

Depression

**Timepoint**

At the beginning of study and 12 weeks after study

**Method of measurement**

Depression based on Hamilton scale

## 2

### **Description**

impulse control

### **Timepoint**

At the beginning of study and 12 weeks after study

### **Method of measurement**

impulse control based on Barratt scale

## 3

### **Description**

aggression

### **Timepoint**

At the beginning of study and 12 weeks after study

### **Method of measurement**

Aggression based on Bus and Perry scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

"Intervention group": Olanzapine is an atypical antipsychotic drug with C17H20N4S chemical formulation and tino benzodiazepine derivatives with half life of 21 to 54 hours and has liver metabolism that can inhibit the attraction of serotonin and dopamine at the end of presynapsis nervous system that can reduce aggression and to get better mood. This drug will be used with the dose of 5 to 15 mg per day according to the patient's response for 6 weeks and the drug used by Abidi pharmaceutical company, Omega 3 drug is a long chain fatty acid means an 18 carbonic chain with 3 double transplanted on 9, 12 and 15' s carbons. That according to the hypothesis of reducing Omega 3 fatty acids in the membrane of neurons of borderline personality disorder, this drug will be used with the dose of 2 grams a day for 6 week and the drug used by Actover pharmaceutical company. Currently, the only approved treatment for borderline personality disorder is psychotherapy and this treatment is now the most effective treatment for this disorder. Therapists use behavioral therapy to control patient's momentum and anger explosions and to reduce their sensitivity to criticism and expulsion, and through social skills training, the patient is helped to see the impact of their actions on other than their inter individual behavior. Improve Dialectical Behavioral Therapy (DBT), which is the most common type of psychotherapy used in this patient is especially used in patient who have attempted suicide or self esteem and give better control of momentum in patients for 4 weeks and every week for one hour in the psychotherapeutic clinic in Razi Psychiatric hospital will be performed by final year Psychiatric resident.

#### **Category**

Treatment - Drugs

## 2

### **Description**

"Control group:" Olanzapine is an atypical antipsychotic drug that can reduce aggression and to get better mood by impact on serotonin and dopamine. This drug will be used with the dose of 5 to 15 mg per day according to the patient's response for 6 weeks and the drug used by Abidi pharmaceutical company, According that the only approved treatment for borderline personality disorder is psychotherapy, Dialectical Behavioral Therapy (DBT), the most common type of psychotherapy will be used in these patients for 4 weeks and every week for one hour in the psychotherapeutic clinic in Razi Psychiatric hospital will be performed by final year Psychiatric resident.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Razi psychiatric hospital

##### **Full name of responsible person**

Ensieh Sadri

##### **Street address**

Taghiabad Blvd, Rey Town

##### **City**

Reycity

##### **Province**

Tehran

##### **Postal code**

1866958891

##### **Phone**

+98 21 3340 1220

##### **Email**

Razi.pr@uswr.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

University of social welfare and rehabilitation sciences

##### **Full name of responsible person**

Dr Mohammad Reza Khodaei

##### **Street address**

Koodakyar Ave, Vekenjak Blvd, Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985713871

##### **Phone**

+98 21 2218 0083

##### **Email**

Pr@uswr.ac.ir

#### **Grant name**

**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?

Yes

**Title of funding source**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Ensieh Sadri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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Sadri.ensieh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Ensieh Sadri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Ensieh Sadri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available