

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The Effectiveness of Interpersonal Psychotherapy on Reducing Depression Signs and Increasing Quality of Life in Depressed Women

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Determining the effectiveness of interpersonal psychotherapy on the components of depression in depressed women and the components of quality of life in depressed women.

Last update: **2021-07-16, 1400/04/25**

Update count: **0**

#### Registration date

2021-07-16, 1400/04/25

#### Design

Randomised(using random number table) Clinical trial with control group on 30 depressed female patients

#### Registrant information

##### Name

Niloofar Rafiei Alhosaini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3444 1894

##### Email address

niloorafie74@gmail.com

#### Settings and conduct

samples will be randomly divided into experimental and control groups. The control group participate in pre-test and post-test, but the intervention group will participate in 12 interpersonal psychotherapy sessions held in Dr. Zahra Khoramipour's clinic and medical office, and in the end of psychotherapy sessions they will take the post-test. In addition, after completing the research, in order to respect the rights of individuals in the control group, interpersonal psychotherapy sessions will be perform for them.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a female gender-Having depression symptoms based on Beck scale Exclusion criteria:Not willing to participate in the intervention-It is not possible to access them-Lack of significant depressive symptoms based on the Beck scale

#### Expected recruitment start date

2021-07-16, 1400/04/25

#### Expected recruitment end date

2021-07-21, 1400/04/30

#### Intervention groups

The intervention group receives interpersonal psychotherapy. The control group does not receive any treatment.

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Depression Signs-Quality of Life

#### Trial completion date

empty

#### General information

#### Scientific title

The Effectiveness of Interpersonal Psychotherapy on Reducing Depression Signs and Increasing Quality of Life in Depressed Women

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210706051804N1**

Registration date: **2021-07-16, 1400/04/25**

#### Public title

Effect of Interpersonal Psychotherapy in Depressed Women

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a female gender Having informed consent to participate in the study and sign the consent form Collaboration with the researcher Attending all intervention sessions Having depression symptoms based on Beck scale

### Exclusion criteria:

to be absent in 2 sessions of training intervention Not willing to participate in the intervention It is not possible to access them Lack of significant depressive symptoms based on the Beck scale Refusal to sign the consent and disagree on the treatment protocol

## Age

From **20 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Ordering individuals in to control and intervention group using Randomisation (individual type), with random number table

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

### 1

#### Registry name

سامانه ملی اخلاق در پژوهش های زیست پزشکی

#### Secondary trial Id

IR.IAU.KHSH.REC.1400.018

#### Registration date

2021-07-03, 1400/04/12

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Ethics System in Biomedical Research- Islamic Azad University - Khomeini Shahr Branch (Rese

##### Street address

Robat St., after Ostad Shahriyar, 48th Alley

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8139887376

#### Approval date

2021-07-03, 1400/04/12

#### Ethics committee reference number

IR.IAU.KHSH.REC.1400.018

## Health conditions studied

### 1

#### Description of health condition studied

MDD

#### ICD-10 code

F33

#### ICD-10 code description

Major depressive disorder, recurrent

## Primary outcomes

### 1

#### Description

Depression Signs

#### Timepoint

Before treatment and immediately after treatment sessions

#### Method of measurement

Beck Depression Inventory

### 2

#### Description

Quality of Life

#### Timepoint

Before treatment and immediately after treatment sessions

#### Method of measurement

WHOQOL-BREF

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The reference of this protocol is: Comprehensive guide to interpersonal psychotherapy(Weissman, Markowitz& Klerman, 2008), The guide to interpersonal psychotherapy(Weissman, Markowitz & Klerman,2018),Interpersonal psychotherapy 2E a clinician's guide(Stuart & Robertson,2012),Clinical handbook of psychological disorders: A step-by-step treatment manual(Barlow2014). Acute IPT treatment for

major depression comprises initial, middle, and termination phases. And each session last 50 to 60 min (Barlow, 2014): The Initial Phase (Sessions 1-3) Tasks of the initial sessions of IPT for major depression include eliciting the patient's chief complaint; reviewing her symptoms and establishing a diagnosis; determining the interpersonal context for the current depressive episode; forming a therapeutic alliance; and setting the frame of the treatment, The Middle Phase (Sessions 4-9) Having made the treatment contract and chosen an interpersonal problem area as the focus of treatment, the therapist can proceed to the middle phase of sessions, in which the goal is to work on resolving the focal problem area. Each session begins with the question, "How have you been feeling since we last met?" This question elicits an interval history of mood, events, and interpersonal interactions that transpired between sessions. It also keeps the patient focused on current mood and situation. The patient is likely to respond by describing mood ("I felt really down") or an event ("My husband and I had a huge fight"). After further inquiry, the therapist links the patient's mood to a recent event, Oran event to her mood ("No wonder you felt depressed after the fight you had with your husband!"). The Termination Phase (Sessions 10-12) In the final sessions, the therapist reviews the patient's progress in symptom improvement, as well as the extent to which the patient has resolved the focal problem area. By reviewing why the patient is better, through the actions she has taken to resolve the interpersonal focus, the therapist reinforces the patient's growing self-esteem by pointing out that the patient's action have led to her gains. The therapist congratulates the patient on her progress and hard work, and expresses optimism that the patient can maintain that progress independent of the therapist.:

#### **Category**

Treatment - Other

#### **2**

#### **Description**

Control group: The control group participate in pre-test and post-test, but in order to respect the rights of individuals in the control group, interpersonal psychotherapy sessions will be perform for them.

#### **Category**

Other

### **Recruitment centers**

#### **1**

#### **Recruitment center**

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

Private office of Dr. Zahra Khoramipoor

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

Dr. Zahra Khoramipoor

##### **Street address**

Robat St

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8139895757

##### **Phone**

+98 31 3436 0412

##### **Email**

drkhoramipoor1@gmail.com

### **Sponsors / Funding sources**

#### **1**

#### **Sponsor**

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

Islamic Azad University

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

Niloofar Rafiei Alhosaini

##### **Street address**

Khomeini Shahr, Manzarria, end of Daneshjoo Boulevard, Islamic Azad University, Khomeini Shahr Branch

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

119/84175

##### **Phone**

+98 31 3366 0011

##### **Email**

site@iaukhsh.ac.ir

##### **Web page address**

<http://iaukhsh.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Islamic Azad 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**

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

Islamic Azad University

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

Niloofar Rafiei Alhosaini

##### **Position**

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Robat St., after Ostad Shahriyar, 48th Alley

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8139887376

**Phone**

+98 31 3444 1894

**Email**

niloorafie74@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Niloorafie Rafiei Alhosaini

**Position**

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Robat St., after Ostad Shahriyar Alley, 48th Alley

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8139887376

**Phone**

+98 31 3444 1894

**Email**

niloorafie74@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Niloorafie Rafiei Alhosaini

**Position**

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Robat St., after Ostad Shahriyar , 48th Alley

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8139887376

**Phone**

+98 31 3444 1894

**Email**

niloorafie74@gmail.com

**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