Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

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.

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

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

Main outcome variables
Depression Signs-Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210706051804N1**
Registration date: **2021-07-16, 1400/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-16, 1400/04/25**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-16, 1400/04/25

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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
Isfehan
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 last50 to 60min(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 shave 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

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8139895757

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

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119/84175

Phone

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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
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Person responsible for scientific inquiries

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Position
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Latest degree
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Person responsible for updating data

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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