

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study of effect of Citalopram and Para-cognition therapy on severity of depression in major depressive disorder

Protocol summary

Summary

The present study is a clinical trial with a pretest-posttest design. After random selection and assignment of samples to control and 2 intervention groups (intervention groups-I and intervention groups-II). Interventions: intervention groups-I: para-cognitive therapy performs on the first intervention group during ten 1-hour sessions (a new method of psychotherapy that is mostly concerned with the effect of depression on thinking process than its content), In this model, depression is associated with some kinds of Mal-adaptive thinking styles, known as Cognitive-Attention Syndrome. This syndrome is characterized by repetitive thought in the form of anxiety or rumination on a threat and Mal-adaptive coping behaviors. Intervention groups-II: 10-60 mg citalopram (a standard and widely used antidepressant from SSRI group of antidepressants) will be administered in a daily single dose, the drug will be started 10 mg/day and then will be increased weekly to optimum dose (20-60 mg/day). Control group: do not receive any interventions and they will be placed on waiting list. All the groups will be evaluated twice (pre-test, post-test). We invite volunteers to participate in the study from outpatients diagnosed with depression in treatment centers and clinics of Isfahan. Thereafter, the volunteers will be interviewed by psychologists and psychiatrists based on the symptoms proposed by Diagnostic and Statistical Manual of Mental Disorders (DAM-IV-TR) to reach a definitive diagnosis of major depression disorder. The eligible patients randomly divide into three groups of citalopram (n=15), para-cognitive intervention (n=15), and control (n=15). A demographic form, which included items on age, gender, educational level, and occupation, will be used to gather demographic information. The following three questionnaires will be employed in this study, as well. Beck depression inventory-II, para-cognition questionnaire-30, Cognitive emotion regulation questionnaire.

General information

Acronym

Depression and Para-cognition therapy

IRCT registration information

IRCT registration number: **IRCT201602012266N5**

Registration date: **2016-04-11, 1395/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-11, 1395/01/23

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of effect of Citalopram and Para-cognition therapy on severity of depression in major depressive disorder

Public title

Effect of para-cognition therapy on depression

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18-60 years; mild-moderate depression; no psychotic symptoms; no history of mania and hypo-mania; no other axis-I Disorders; completing of consent form Exclusion criteria: Desire to exit from study; increasing the severity of depression and needing to complementary treatments; including to any other treatment modality during study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

simple (alternate) randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jerib St., Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

394225

Health conditions studied

1

Description of health condition studied

Major Depression

ICD-10 code

f32

ICD-10 code description

Primary outcomes

1

Description

severity of depression

Timepoint

before and after of intervention

Method of measurement

Qwstionair

Secondary outcomes

1

Description

Cognitive emotion regulation

Timepoint

before and after the intervention

Method of measurement

Questionair

Intervention groups

1

Description

intervention groups-I: para-cognitive therapy performs on the first intervention group during ten 1-hour sessions (a new method of psychotherapy that is mostly concerned with the effect of depression on thinking process than its content) ,

Category

Behavior

2

Description

Intervention groups-II: 10-60 mg citalopram (a standard and widely used antidepressant from SSRI group of antidepressants) will be administer in a daily single dose, the drug will be started 10 mg/day and then will be increased weekly to optimum dose (20-60 mg/day(

Category

Treatment - Drugs

3

Description

Control group: do not receive any interventions and they will be place on waiting list.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

khoshid hospital

Full name of responsible person

Gholam Reza Kheirabadi

Street address

behavioral Sciences Research Center, Isfahan
University of Medical Sciences, Isfahan, Iran

City

isfshsn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Nematbakhsh

Street address

Vice chancellor for research of Isfahan University of
Medical Sciences

City

Isfahan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Gholam Reza kheirabadi

Position

Associate Professor of psychiatry

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty