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 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). Control group: do not receive any interventions and they will be place on waiting list. All the groups will be evaluate 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

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Email address

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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
Quwstionair

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
khorshid hospital

Full name of responsible person
Gholam Reza Kheirabadi

Street address
behavioral Sciences Resaerch Center, Isfahan University of Medical Sciences, Isfahan, Iran

City
isfsshsn

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
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Other areas of specialty/work

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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