

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Assessing the effect of environmental activity on depressive symptoms

Protocol summary

Study aim

Determining the effect of environmental activity on depressive symptoms

Design

•Randomized controlled trial with concurrent control and blinded outcome assessment. Computerized block randomization with concealed sequences. There are 40 members for each group and 80 as a whole. The participants enter the study after sample completion and will be followed up for one month after the end of the study.

Settings and conduct

Depression symptoms screening by 9-Item Patient health questionnaire (PHQ9) and Beck Depression inventory II (BDI-II) among people who refer to Valfajr Clinic; Patients with mild to moderate depressive symptoms participating in the study after obtaining informed consent; Randomized allocation to intervention and control groups (each group contains 40 patient); Receiving educational worksheet by both groups and participating in environmental activity by intervention group that consists of planting and maintenance of plants in Almahdi Park., Azadi Squar.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 and above, Mild to moderate depression, Desire to participate in the study. Exclusion criteria: Severe depression, Any physical or mental diseases that could limit the environmental activity, Antidepressant drugs consumption, No desire to participate in the study.

Intervention groups

Both intervention and control groups will receive educational worksheet as a treatment for depressive symptoms, but the intervention group will participate in environmental activity too. The intervention lasts for 6 weeks. We use Beck depression Inventory II (BDI-II) to assess the depression intensity and the effect of environmental activity on 0,3,6,10 weeks. We also use 12-Item short form health survey (SF12) for both intervention and control groups to evaluate their quality

of life.(the alternative aim of the study)

Main outcome variables

Depression severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181206041871N1**

Registration date: **2019-10-12, 1398/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-12, 1398/07/20**

Update count: **0**

Registration date

2019-10-12, 1398/07/20

Registrant information

Name

France Minagar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3444 1082

Email address

minagar.f@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of environmental activity on depressive symptoms

Public title

Assessing the effect of environmental activity on depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate depression aged 18 and above The desire to participate in the study

Exclusion criteria:

severe depression Antidepressant drugs consumption Any physical or mental diseases that could limit the environmental activity. No desire to participate in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization will be implemented using Microsoft Excel software. Quadruple blocks of random numbers with allocation to the groups are created. Based on that, the concealment sequences will be clarified. Only the creator of this file will know about it. Each random number will be written on an envelope in the same order that they have been created. Also, the name of the allocated group to that number (intervention or control) will be written on a piece of paper, and will be put in that envelope and sealed. All 4 envelopes are packed in one package and will be given to the person responsible for the delivery of them. In this way, 4 envelopes in a package will be given to 4 participants to choose from. Obviously, the person is unaware of the contents of the envelopes and the relevant groups. After delivering them to the participants and opening them, it will become clear which group the person will go to.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad tower, Hemmat freeway, Tehran.

City

Tehran

Province

Tehran

Postal code

14496-14535

Approval date

2018-10-27, 1397/08/05

Ethics committee reference number

IR.IUMS.REC.1397.549

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F33.8

ICD-10 code description

Other recurrent depressive disorders

Primary outcomes

1

Description

Depression scores on Beck depression inventory II (BDI-II) scale

Timepoint

Assessing depression severity by Beck Depression Inventory (BDI-II) before intervention, 3 weeks after starting the intervention, at the end of intervention (6th week) and 1 month after the ending of the intervention.(0,3,6,10)

Method of measurement

Second version of 21- Item Beck Depression Inventory (BDI-II)

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before the intervention, at the end of intervention (6th week) and 1 month after the ending of the intervention.(0,6,10)

Method of measurement

Intervention groups

1

Description

"The intervention group" will receive educational worksheet and also participate in environmental activity in a garden belonged to Flower and Herbal Clinic located in Almahdi Park in Azadi Square. The duration of environmental activity is twice weekly for one and a half hours for 6 weeks and consists of vegetable and flower growing. Educational worksheet includes behavioral activation, daily activity schedule, breathing training instruction, and relaxation instruction. They are then monitored at 0, 3, 6 and 10 weeks using the "Beck Depression Inventory" (BDI-II) and "12-Item short form health survey for quality of life (SF12)" questionnaires.

Category

Treatment - Other

2

Description

Control group: The Control group will receive educational work sheet that consists of behavioral activation, daily activity schedule, breathing training instruction, and relaxation instruction. They are then monitored at 0, 3, 6 and 10 weeks using the "Beck Depression Inventory" (BDI-II) and "The 12-Item Short Form Health Survey (SF-12)" questionnaires.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valfajr Clinic

Full name of responsible person

France Minagar

Street address

West Tehran Health Center, West Dastgheib Ave., Ostad Moin BLV., Azadi St.

City

Tehran

Province

Tehran

Postal code

1349845951

Phone

+98 21 6602 3042

Fax

+98 21 6600 1931

Email

admins@iums.ac.ir

Web page address

http://whc.iums.ac.ir

1

Sponsor

Name of organization / entity

Preventive Medicine and Public Health Center

Full name of responsible person

Dr. Marzieh Nojoomi

Street address

Preventive Medicine and Public Health Center, Iran University of Medical Sciences, Next to Milad tower, Hemmat Freeway.

City

Tehran

Province

Tehran

Postal code

14496-14535

Phone

+98 21 8670 3350

Email

pmph@iums.ac.ir

Web page address

http://pmph.iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Preventive Medicine and Public Health Center

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

Iran University of Medical Sciences

Full name of responsible person

France Minagar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

No. 49, East 4th Ave., Gohardasht

City

Karaj

Province

Alborz
Postal code
3146987676
Phone
+98 26 3444 1082
Fax
Email
minagar.f@tak.iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
France Minagar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
No. 49, East 4th Ave., Gohardasht
City
Karaj
Province
Alborz
Postal code
3146987676
Phone
+98 26 3444 1082
Fax
Email
minagar.f@tak.iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
France Minagar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
No. 49, East 4th Ave., Gohardasht
City
Karaj
Province

Alborz
Postal code
3146987676
Phone
+98 26 3444 1082
Fax
Email
minagar.f@tak.iums.ac.ir

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

Yes - There is 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

Title and more details about the data/document

Data will not be available due to ethical issues. Only results will be published.

When the data will become available and for how long

Data will not be available due to ethical issues. Only results will be published.

To whom data/document is available

Data will be available only to researchers. The report will be submitted to the sponsor. The result will be published in an article in a journal that accepts it.

Under which criteria data/document could be used

Data is available only to researchers. Document is available at the discretion of the sponsor and the journal chief editor. (The journal which the article will be published in.)

From where data/document is obtainable

France Minagar, MD. francemina@yahoo.com

What processes are involved for a request to access data/document

Data will not be available.

Comments

This study is conducted according to the rules of Iran University of Medical Sciences and Ethics Committee.