

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of using a smartphone application (Yara) on anxiety, suicidal thoughts and sleep quality in patients with depression

Protocol summary

Study aim

This study aims to determine the effect of new developed YARA smartphone application on anxiety, sleep quality, and suicidal thoughts in patients with major depressive disorder.

Design

Clinical trial with control group, with parallel groups, randomized, on 64 patients. Card drawing was used for randomization.

Settings and conduct

This study will be conducted on 64 depressed patients referred to the psychiatric clinic of Urmia and Khoy hospitals. The samples will be selected by the convenience sampling and will be randomly assigned into two control and intervention groups. The intervention will be carried out through the use of a smartphone application (Yara) for three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study; being able to use a smartphone, install the application, and work with it; being diagnosed with major depressive disorder according to DSM-5 criteria; being literate; not being in the acute phase of major depressive disorder.

Intervention groups

Intervention group: patients in this group, in addition to receiving routine care, the Yara application was installed on the smartphones of the patients in the intervention group, and the researcher provided necessary instructions on how to use it during a justification session in the hospital conference room. Patients were taught about managing anxiety, sleep and suicidal thoughts. Control group: Patients in this group received routine care. Routine care includes being visited by a psychiatrist and being educated by a trained nurse.

Main outcome variables

Anxiety; Sleep quality; Suicidal thoughts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131112015390N7**

Registration date: **2024-01-04, 1402/10/14**

Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**

Update count: **0**

Registration date

2024-01-04, 1402/10/14

Registrant information

Name

Naser Parizad

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1348 7649

Email address

parizad.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using a smartphone application (Yara) on anxiety, suicidal thoughts and sleep quality in patients with depression

Public title

The effect of using a smartphone application (Yara) on anxiety, suicidal thoughts and sleep quality in depressed patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study
Having smartphone
Diagnosis of depression by DSM-5 criteria
Being literate

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted by a simple random method via drawing a card inside a sealed envelope. In this way, thirty-two (A) cards and thirty-two (B) cards were placed inside the opaque and sealed envelope. For concealment, based on the research sample size, 64 envelopes are prepared with aluminum foil, and each randomly created sequence is recorded on a card. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelopes is sealed and placed in a box. Patients who were eligible to participate in the study randomly selected one of the sealed envelopes. Patients who chose card A were in the control group, and those who chose card B were in the intervention group.

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 Urmia University of Medical Sciences

Street address

Emergency alley, Resalat Boulevard, Urmia University of Medical Sciences, Urmia.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-05-26, 1400/03/05

Ethics committee reference number

IR.UMSU.REC.1400.057

Health conditions studied

1

Description of health condition studied

Major depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The mean anxiety score using the Spielberger State-Trait Anxiety Inventory (STAI),

Timepoint

Measuring anxiety at the beginning of the study (before the study started) and after the study was completed.

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI);

2

Description

The mean sleep quality score using the Petersburg Sleep Quality Questionnaire

Timepoint

Measuring sleep quality at the beginning of the study (before the study started) and after the study was completed

Method of measurement

Pittsburgh Sleep Quality Index (PSQI);

3

Description

The mean score of suicidal thoughts using the Beck Suicidal Thoughts Questionnaire

Timepoint

Measuring suicidal thoughts at the beginning of the study (before the study started) and after the study was completed

Method of measurement

Beck Scale for Suicidal Ideation (BSSI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will use the researcher-made application (Yara) for three months. The Yara application will be designed and built by a computer software engineer in collaboration with the research team to help depressed patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry Clinic of Razi Hospital in Urmia

Full name of responsible person

Zeynab Soltani

Street address

First building on the right, Jabraben Hayan St., Shahid Dr. Qalipur St., Ibn Sina St, 11 km Saro Road, School of Nursing and Midwifery, West Azarbaijan, Urmia

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5756115335

Phone

+98 44 3223 4897

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soltani.zeinab.93@gmail.com

2

Recruitment center

Name of recruitment center

Psychiatry Clinic of Madani Hospital in Khoy

Full name of responsible person

Zeynab Soltani

Street address

Valiasr Square, Shahid Madani Hospital, Khoy city, West Azerbaijan.

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soltani.zeinab.93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

Emergency alley, Resalat Boulevard, Urmia University of Medical Sciences, Urmia.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

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

Oroumia University of Medical Sciences

Full name of responsible person

Zeynab Soltani

Position

Mater's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Naser Parizad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Zeynab Soltani

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work

Nursery

Street address

First building on the right, Jabraben Hayan St., Shahid Dr. Qalipur St., Ibn Sina St, 11 km Saro Road, School of Nursing and Midwifery, West Azarbaijan, Urmia.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data

When the data will become available and for how long

6 months after publication

To whom data/document is available

For all researchers in other organizations

Under which criteria data/document could be used

Any type of analysis is allowed.

From where data/document is obtainable

To the email of the person responsible for the study

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

It must be requested in writing and via email.

Comments