Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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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2

Recruitment center
Name of recruitment center
Psychiatry Clinic of Madani Hospital in Khoy
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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