Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Evaluation of the effect of minor depression self-care software on the severity of depression among students of Mazandaran University of Medical Sciences

Protocol summary

Study aim
The effect of mobile self-care software, on the severity of minor depression in students of Mazandaran University of Medical Sciences (2021)

Design
A concealed, randomized clinical trial with an intervention group and a control group, in which 56 students are grouped by random numbers using the SAS software.

Settings and conduct
Research environment: Mazandaran University of Medical Sciences Patients will be randomly assigned to one of the two groups of mobile therapy and the control group based on random numbers. In the mobile-based treatment group, software containing treatment assignments will be provided to patients. No assignments are given in the control group. Participants will not be given information about the group they are in.

Participants/Inclusion and exclusion criteria
Students that studying at Mazandaran University of Medical Sciences; Students with access to smartphones; Students with minor depression (based on PHQ-9).
Exclusion criteria: Students who have suicidal thoughts.

Intervention groups
The intervention group includes students with minor depression who install a designed mobile system and use it for their treatment. The severity of depression in these people will be measured by this app on a weekly basis.
The control group includes students who have minor depression and will not receive any intervention. Like the intervention group, the severity of their depression will be measured weekly.

Main outcome variables
Degree of depression severity measured using PHQ-9 tool.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201031049206N1**
Registration date: **2021-01-13, 1399/10/24**
Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**
Update count: **0**

Registration date
2021-01-13, 1399/10/24

Registrant information

Name
Saeed Barzegari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8898 3037

Email address
barz_saeed@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-05-05, 1400/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of minor depression self-care software on the severity of depression among students of Mazandaran University of Medical Sciences

Public title
Design, implementation and evaluation of screening and self-care software for minor depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
En Be a student of Mazandaran University of Medical Sciences. According to PHQ-9 tool have minor depression.

Exclusion criteria:
Taking sedatives Dissatisfaction Underlying diseases such as hypothyroidism and ... History of self-harm History of suicide

Age
From **18 years** old to **26 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple individual randomization method with flipping coins will be used. Randomization tool: SAS statistical software. We will use the website to create a random sequence. We will use the central randomization method (email) for allocation concealment.

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 School of Health and Paramedical Sciences - Tehran University of Medical Science

Street address
No. 17, Fardanesh Alley, Ghods St., Enghelab St., Enghelab Sq., Tehran

City
Tehran

Province
Tehran

Postal code
44361-14177

Approval date
2019-06-19, 1398/03/29

Ethics committee reference number
IR.TUMS.SPH.REC.1398.085

Health conditions studied

1

Description of health condition studied
Mild depression

ICD-10 code
F32.8

ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Depression score in PHQ-9 questionnaire

Timepoint
Before the intervention, 7, 14, and 21 days after the start of the intervention

Method of measurement
PHQ-9 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Students install the software on their smartphone and complete the PHQ-9 questionnaire. If they have a mild depression, they are invited to use the software. Participants will follow the assignments provided in the software for 4 weeks (4 sessions, each session is two weeks). The proposed intervention includes a combination of basic cognitive-behavioral therapy and self-regulatory therapy. The tasks are the worksheets and concepts of these two treatments.In the first session, the user will be given tasks to improve self-awareness and tools for daily planning.Our goal in the second session is behavioral activation,Identify lost activities, and prevent idealism.In the third session, we increase the areas of activity and the number of activities of the behavioral activation worksheet and lead the user to choose promotion activities, we will identify users areas of life that have promotion or deterrence goals, we will identify the person's negative thoughts.In the final session, we will extend behavioral activation to

various areas of the user's life, we will replace negative thoughts with logical ones, and by determining the costs and benefits of perfectionist thoughts, we will prepare the user to reconsider and determine realistic thoughts, we will also determine the cost-effectiveness of this changes for each of their goals.At the end of each session, the severity of their depression will be measured by the PHQ-9 questionnaire.

Category

Behavior

2

Description

Control group: The rest of the students whose mild depression was confirmed by the questionnaire will be grouped in the control group.These students will not be subject to any intervention and we will receive their depression severity at the end of each week (4 weeks) via email.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Sciences

Full name of responsible person

Dean of Amol School of Nursing, Midwifery and Paramedical Sciences

Street address

Talib Amoli St., Fayyaz Bakhsh Alley

City

Amol

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 4422 1919

Email

ict@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

No. 17, Fardanesh Alley, Ghods St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

44361-14177

Phone

+98 21 8898 2905

Email

alliedmed@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Saeed Barzegari

Position

Student

Latest degree

Master

Other areas of specialty/work

Health Information Management

Street address

No. 27, Ostad Shahriyar Alley, First 12 Meter Alley

City

Ahar

Province

East Azarbaijan

Postal code

5451773979

Phone

+98 41 4423 7355

Email

barz_saeed@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeed Barzegari

Position

Student

Latest degree

Master

Other areas of specialty/work
Health Information Management
Street address
No. 27, Ostad Shahriyar Alley, First 12 Meter Alley
City
Ahar
Province
East Azarbaijan
Postal code
5451773979
Phone
+98 41 4423 7355
Email
barz_saeed@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Saeed Barzegari
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Health Information Management
Street address
No. 27, Ostad Shahriyar St., the first 12-meter alley
City
Ahar
Province
East Azarbaijan
Postal code
5451773979
Phone
+98 41 4423 7355
Email
barz_saeed@yahoo.com

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
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available