

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

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Amol

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Mazandaran

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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.

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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PhD student

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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