

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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**

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**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

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**Province**

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5451773979

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**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**

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**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**

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East Azarbaijan

**Postal code**

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**Phone**

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**Email**

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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