Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of mobile -based Logotherapy on depressive symptoms, suicidal ideation and hoplessness in patients with major depressive disorder reffered to clinics affiliated with Shiraz University of Medical Sciences,1400

Protocol summary

Study aim

Determining the effect of mobile-based sign therapy on depressive symptoms, suicidal ideation and despair of patients with major depression referred to clinics affiliated to Shiraz University of Medical Sciences, 1400

Design

A double-blind randomized clinical trial with a pretest-posttest and follow-up design with a control group. The research sample, considering 20% of the loss, will include 70 people who will be placed in one of the experimental or control groups by a simple random sampling method using randomization software.

Settings and conduct

This research is a double-blind clinical trial in clinics affiliated with Shiraz University. First, patients with major depression who meet the inclusion criteria will be referred to the research team by a psychiatrist patient. After completing the informed consent form, the questionnaires will be provided to the participants online. they will be placed in one of the experimental or control groups by a simple random method. The experimental group will receive logotherapy and the control group will receive drug therapy via mobile. Immediately and 3 months later, both groups will be tested again and the results will be analyzed

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a diagnosis of major depression based on the opinion of a psychiatrist according to DSM-V criteria

Intervention groups

.The experimental group will receive 8 semantic therapy training packages in 8 weeks by attending the virtual group via mobile and WhatsApp programs. The content of these training packages will be a collection of texts, sounds, images, and purposeful educational videos that will be available to people on a daily basis. The control group will remain on the waiting list until the end of the study and will receive only sertraline drug therapy training.

Main outcome variables

Symptoms of depression; Disappointment; Suicidal thoughts.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051664N1**
Registration date: **2021-07-24, 1400/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-24, 1400/05/02**
Update count: **0**

Registration date

2021-07-24, 1400/05/02

Registrant information

Name

Marzieh Shemiran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3824 2810

Email address

farzanehsh80@email.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mobile -based Logotherapy on depressive symptoms, suicidal ideation and hoplessness in patients with major depressive disorder reffered to clinics affiliated with Shiraz University of Medical Sciences,1400

Public title

Investigating the effect of mobile -based Logotherapy on depressive symptoms, suicidal ideation and hoplessness in patients with major depressive disorder

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of major depression based on the opinion of a psychiatrist according to DSM-V criteria Having a depression score of 8 or higher based on the short form of the Beck Depression Inventory Have a hoplessness score of 9 or higher based on the Beck Disappointment Questionnaire Having suicidal ideation based on Beck Suicide Thought Questionnaire screening questions Start treatment with the antidepressant drug sertraline based on a psychiatrist's prescription Internet accessible mobile phone

Exclusion criteria:

Reluctance to participate in the study Presence of psychotic symptoms in the patient Having other chronic mental disorders such as personality disorders, bipolar disorder or mental retardation in the patient Having chronic physical illnesses such as diabetes or MS Unforeseen physical or mental problems during the intervention Taking other antidepressants except sertraline by the patient The need to hospitalize the patient for any reason, including the high risk of suicide in the patient according to the psychiatrist Incompetence in completing the consent form (such as lack of knowledge of the time, place, person and the presence of psychotic symptoms)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method using randomization software (from software Random allocation). First, the list of participants is obtained, then each of them is assigned a score or number, and using simple randomization software and using a table of random numbers, participants are divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants, statistical analysts, and questionnaire reviewers will have no information about the status of individuals in the groups and the type of training provided in the groups. Participants in the groups have no knowledge of whether they are in the experimental or control group. Participants only know that they are receiving training but are not aware of the type of intervention they are receiving. Researchers, statistical analysts, and questionnaire reviewers are also unaware of the type of intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Karim Khan Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences and Health Services

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.SUMS.REC.1400.238

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2

Description of health condition studied

suicidal ideations

ICD-10 code

R45.851

ICD-10 code description

Suicidal ideations

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention, immediately after the intervention, 3 months later

Method of measurement

Beck Depression Inventory: BDI-11

2

Description

hoplessness

Timepoint

Before the intervention, immediately after the intervention, 3 months later

Method of measurement

Beck hopelessness scale(BHS)

3

Description

Suicidal thoughts

Timepoint

Before the intervention, immediately after the intervention, 3 months later

Method of measurement

Beck Scale for Suicide Ideation (BSSI)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The control group will remain on the waiting list until the end of the study and will receive only sertraline drug therapy training.

Category

Other

2

Description

Intervention group: Receive semantic therapy training. The purpose of semantic therapy in this study is to provide 8 semantic therapy training packages in 8 consecutive weeks for patients with major depression based on the treatment methods suggested by Frankel and his followers, taken from The book "Man in Search of Meaning" is presented. Participants will receive 8 semantic therapy training packages in 8 weeks by attending the virtual group via mobile and WhatsApp program. The content of these training packages will be a collection of texts, sounds, images and educational videos. Which will be available to people on a daily basis.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital Clinic

Full name of responsible person

Dr. Ebrahim Moghimi Sarani

Street address

next to 13 Aban Park ,Hafez St

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

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2

Recruitment center

Name of recruitment center

Hafez Hospital Clinic

Full name of responsible person

Dr. Arvin Hedayati

Street address

Chamran Street, beginning of Abivardi

City

Shiraz

Province

Fars

Postal code

7194634786

Phone

+98 71 3647 9531

Email

Hafez@sums.ac.ir

3

Recruitment center

Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Dr. Mani Ramsey
Street address
Namazi Square, next to Namazi Hospital
City
Shiraz
Province
Fars
Postal code
7134814734
Phone
+98 71 2127 0000
Email
motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mehrzad Lotfi
Street address
Karim Khan Zand Street, in front of Palestine Street
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Province
Fars
Postal code
7134814336
Phone
+98 71 3323 3236
Email
President_d@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Shemiran
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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No3.3rd floor.saeed bulding.16th Alley.20 meters from Imam Khomeini Street
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Marzieh Shemiran
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No3.3rd floor.saeed bulding.16th Alley.20 meters from Imam Khomeini Street
City
Shiraz
Province
Fars
Postal code
7178897901
Phone
+98 71 3824 2810
Email
farzanehsh80@email.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Shemiran
Position
Student
Latest degree
Bachelor
Other areas of specialty/work

Nursery

Street address

No3.3rd floor.saeed bulding.16th Alley.20 meters from Imam Khomeini Street

City

Shiraz

Province

Fars

Postal code

7178897901

Phone

+98 71 3824 2810

Email

farzanehsh80@email.com

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

Anonymous study data will be shared in correspondence with the project manager

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

A closer look at the data of patients with major depression

From where data/document is obtainable

Correspondence via email

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

After obtaining permission from the security unit and the university's vice chancellor for research, the data will be made available to the individual.

Comments