# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## An Investigation into the Effects of mobile based Logotherapy on Mood Symptoms and Suicidal Ideation in Patients with Major Depressive Disorder Undergoing Ketamine Therapy

### Protocol summary

**Study aim**
The Effect of Mobile-Based Meaning-Centered Therapy on Mood Symptoms and Suicidal Ideation in Patients with Major Depressive Disorder Undergoing Ketamine Therapy at ebnesina Hospital in 2026

**Design**
Clinical trial with a control group, a single-blind, randomized on 50patients

**Settings and conduct**
Conducted at Ebnesina Hospital, this study examines the impact of mobile-based meaning-centered therapy on suicidal ideation and depression in MDD patients. The intervention is delivered via WhatsApp, and control group participants will receive the materials post-study.

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria: Age 18–60; DSM-5 diagnosis of MDD; prescribed ketamine therapy; absence of comorbid psychiatric or chronic physical illnesses ; no history of epilepsy; and normal intelligence and literacy. Exclusion Criteria: Withdrawal of consent; new psychiatric diagnosis during the study; non-compliance with protocols; requirement for hospitalization (including high suicide risk); initiation of other antidepressants; or impairment in orientation.

**Intervention groups**
Following informed consent, participants will complete online depression and suicidal ideation questionnaires and be assigned to either the intervention or control group via simple randomization. The intervention group will receive twelve meaning-centered therapy packages via WhatsApp over four weeks, delivered three times weekly between 9:00 and 10:00 a.m.

**Main outcome variables**
The aim of this study is to evaluate the effect of meaning-centered therap on individuals with Major Depressive Disorder (MDD), with assessments conducted through the administration of standardized questionnaires.

### General information

**Reason for update**

**Acronym**
logotherapy

**IRCT registration information**
IRCT registration number: **IRCT20260505069272N2**
Registration date: **2026-06-05, 1405/03/15**
Registration timing: **prospective**

Last update: **2026-06-05, 1405/03/15**
Update count: **0**

**Registration date**
2026-06-05, 1405/03/15

**Registrant information**

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-06-10, 1405/03/20

**Expected recruitment end date**
2026-10-22, 1405/07/30

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

An Investigation into the Effects of mobile based Logotherapy on Mood Symptoms and Suicidal Ideation in Patients with Major Depressive Disorder Undergoing Ketamine Therapy

**Public title**

Logotherapy on Suicidal Ideation in Patients with Major Depressive Disorder Undergoing Ketamine Therapy

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having major depressive disorder based on the psychiatrist’s opinion in accordance with DSM-V criteria Need to initiate ketamine administration under the psychiatrist’s order

**Exclusion criteria:**

Lack of insight into psychological illness Comorbidity of other psychological disorders with major depressive disorder

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random sequence generation was performed by an independent statistician using block randomization with block sizes of 4 and 6, stratified by sex, in SPSS software. To ensure allocation concealment, the generated sequence was placed in opaque, sealed, and sequentially numbered envelopes to prevent any prediction of group assignments in advance. Enrollment and screening of eligible participants were carried out by Researcher 1. After completion of the enrollment process and obtaining informed consent, the next envelope in sequence was opened, and the allocation group was determined by Researcher 2, after which participants were assigned to their respective groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

To ensure blinding, the individual responsible for randomization is not aware of the codes assigned to the participants, and the randomization is carried out using a computer program. At the end of the study, the person entering the data from the completed questionnaires into SPSS, as well as the statistical analyst, are unaware of which participant completed the information and whether they belong to the intervention or control group

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

**Street address**

Karim Khan Zand Boulevard - Central Building of Shiraz University of Medical Sciences - Research and Technology Deputy Unit

**City**

shiraz

**Province**

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**Postal code**

7193613119

**Approval date**

2026-05-24, 1405/03/03

**Ethics committee reference number**

IR.SUMS.NUMIMG.REC.1405.016

## Health conditions studied

### 1

**Description of health condition studied**

Major depressive disorder-Anxiety-Suicide Ideation-Ketamine therapy-Logotherapy

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

depression (by completing the Patient Health Questionnaire)

**Timepoint**

Before the start of the study, one hour after the first ketamine injection, 14 days after the last injection, and three months after the intervention will be performed.

**Method of measurement**

the Patient Health Questionnaire

## Secondary outcomes

### 1

**Description**

Assessment of the impact of suicidal thoughts (measured by completing the Cognitive Suicide Scale questionnaire)

**Timepoint**

Before the start of the study, one hour after the first ketamine injection, 14 days after the last injection, and three months after the intervention will be performed.

**Method of measurement**

Suicide Cognition Scale questionnaire

## Intervention groups

### 1

**Description**

Intervention group: For the sampling in this study, patients with major depressive disorder who meet the inclusion criteria and are using injectable ketamine will be referred to the research team by a specialist in neurology and psychiatry. After completing the informed consent form, the depression and suicidal ideation questionnaires will be provided to the participants online. Then, the participants will be allocated into either the intervention or control group by simple randomization using randomization software.Then, the individuals in the intervention group, by joining the virtual group through mobile phone and in the WhatsApp application, will receive eight meaning-centered therapy educational packages over a period of four weeks. The content of these educational packages will include a set of targeted educational texts, audio files, images, and videos, which will be provided to the participants three days per week between 9 and 10 a.m. The protocol of the virtual meaning-centered therapy training sessions will be developed by the researchers, and the content of these sessions will be based on Victor Frankl's meaning-centered therapy theory and similar studies.The weekly educational packages will include the following, in order:In the first week, educational packages 1, 2, and 3 will be presented. In this package, multimedia content regarding the goals and plans of the group, familiarization with Frankl's life, the causes of depression and hopelessness based on the meaning-centered therapy approach, and familiarization with self-awareness skills will be provided to the participants. With the aim of finding meaning in life, the participants will be asked to describe their experiences of suffering and loss in past life and how they overcame previous hardships in their lives, and in a group exercise in order to increase self-awareness, they will record their strengths and weaknesses, fulfilled and unfulfilled desires and tendencies, hopes and expectations, and answer these questions: Who am I? Who do I want to be? What things do I like and what things do I dislike?In the second week, educational packages 4, 5, and 6 will be presented. In this package, with the aim of searching for meaning in life, content regarding the ways of attaining meaning, finding meaning through experiential values, the three values from Dr. Frankl's viewpoint, and the stages of determining life values will be provided to the participants. With the aim of making individuals aware of their life values, the participants will be asked to organize their life goals and values. In the group exercise, the participants will be asked to imagine themselves in the place of a person whom they would like to be like. Content regarding nature and the meaning of life, love and the meaning of life, self-love, and gratitude will be provided to the participants. The participants will be asked to perform the exercises of love and gratitude and also to prepare a list of the things they have that are worthy of gratitude.In the third week, educational packages 7, 8, and 9 will be presented. In this package, with the aim of finding meaning through doing work, content regarding creativity and enjoying life as well as hope, moral virtues, the concept of suffering, and the limitations of life will be provided to the participants. The participants will be asked to perform a useful task or a valuable activity for themselves or others during this week and share it with others. Also, in order to overcome limiting thoughts, the participants will be asked to answer this question: "If God answered your wish, what wishes would you have?"In the fourth week, educational packages 10, 11, and 12 will be presented. In this package, with the aim of finding meaning through attitudinal values and understanding meaning through conscience, content on existential limitations, content related to the concepts of death and loneliness, and finding the meaning of life in various dimensions will be presented. The concepts of freedom and choice, responsibility and effort, aggressive and discouraging behaviors will be explained, and also, with the aim of controlling negative thoughts and feelings, positive thinking techniques will be taught. The participants will be asked to use these techniques in necessary situations and share the results with others.The control group will remain on the waiting list until the end of the study and will only receive educational content, including video and educational texts about ketamine pharmacotherapy, three days per week between 9 and 10 a.m.At the end of the study, the provided trainings will also be made available to the control group, and their احتمالی questions will be answered.It should be noted that the patients will be visited by the specialist in neurology and psychiatry according to routine practice, and in case exclusion criteria are observed, such as the need for hospitalization due to a high risk of suicide or the need to use other antidepressant drugs, the patient will be excluded from the study.At baseline and after the completion of the interventions, the questionnaires will be completed online by the participants.

**Category**

Rehabilitation

### 2

**Description**

Control group: The control group will undergo their treatment stages. Before the start of the study, one hour after the initial ketamine therapy, 14 days after the end of ketamine therapy, and 3 months after the end of ketamine therapy after the completion of meaning-centered training and relevant questionnaires are completed. During the total study time, all participants will be in contact with the researcher in WhatsApp and

through direct calls and their questions will be answered. In order to observe ethical points in research, educational contents are provided to the control group after the completion of the study. In case of observing clear suicidal thought problems at any time of performing the research or at the end at the time of determining results, participants will be removed from the research and referred to a psychologist.

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Ebnesina Psychiatric Hospital, Shiraz
**Full name of responsible person**
Fahimeh Sadat Hosseini
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## Sponsors / Funding sources

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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**
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**
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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**
The educational content for the intervention group consists of twelve separate modules from Frankl's logotherapy program, which are provided to the patient. At the end of the study, the written content of these training materials will be published in the related article. In accordance with ethical research principles, and after de-identifying all personal information, the completed questionnaire documents, obtained results, and statistical analyses will be made available to the participants. The data will be published without names. All potentially shareable data will be accessible once participant information has been fully de-identified
**When the data will become available and for how long**
The access period begins after the completion of the research and the publication of the relevant article
**To whom data/document is available**
Access is permitted for all applicants
**Under which criteria data/document could be used**
With citation of the source, data can be used without making modifications.
**From where data/document is obtainable**
After publication of the results, volunteers may request access to further documents via the email of the responsible person, Ms. Dr. Maryam Shaygan (m2620.shaygan@gmail.com), and through Hazrat Fatemeh School of Nursing.
**What processes are involved for a request to access data/document**
In case of demand for access to the documents of this research, send your request to the responsible person's email. The documents will be provided to the volunteers at the earliest opportunity, in compliance with research ethics principles.
**Comments**