

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Comparison of the effects of positive psychotherapy in two ways, face-to-face and virtual reality, on the meaning of life, self-criticism and suicidal thoughts in hospitalized adolescents with suicidal thoughts.

#### Protocol summary

##### Study aim

Comparison of the effect of positive psychotherapy using virtual reality on the meaning of life, self-criticism and suicidal thoughts in adolescent patients with suicidal thoughts.

##### Design

A clinical trial with two-way blind parallel groups, where 111 patients will be placed in three intervention 1, intervention 2 and control groups by cluster randomization method. In this study, random allocation of departments in the hospital will be done by someone outside the study using randomization software

##### Settings and conduct

Patients with suicidal thoughts are admitted to neuropsychiatric hospitals in Shiraz. They are randomly placed into one of three groups: intervention group 1 receives virtual reality treatment, intervention group 2 receives in-person treatment, and the control group receives usual hospital treatments. Participants complete questionnaires before and after the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study Preparedness and favorable psychological conditions of the patient to participate in the intervention Having suicidal thoughts based on the information in the patient's file Exclusion criteria: Refusal to continue participating in the study (during the study) Occurrence of unexpected physical or mental problems during study Inability to actively participate in the treatment process (for reasons such as slowness of thinking, slowness of speech, etc.)

##### Intervention groups

All patients with the entry criteria assigned to the two intervention groups will receive 4 sessions of positive psychotherapy through virtual reality and face-to-face, and the control group will receive the usual hospital treatment.

#### Main outcome variables

Suicidal ideation, meaning of life, self-criticism

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201001048893N9**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

##### Registration date

2023-10-07, 1402/07/15

##### Registrant information

##### Name

Maryam Shaygan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3626 7345

##### Email address

m2620.shaygan@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-19, 1402/08/28

##### Expected recruitment end date

2024-09-21, 1403/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Comparison of the effects of positive psychotherapy in two ways, face-to-face and virtual reality, on the meaning of life, self-criticism and suicidal thoughts in hospitalized adolescents with suicidal thoughts.

**Public title**  
The Investigating the effect of positive psychotherapy in both face-to-face and virtual reality methods on the meaning of life, self-criticism and suicidal thoughts in hospitalized adolescents with suicidal thoughts.

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Willingness to participate in the study Preparation and favorable psychological conditions of the patient to participate in the intervention (for example: absence of psychotic symptoms and aggression) Having suicidal thoughts based on the information in the patient file and diagnostic interview screening questions (CIDI) by a senior psychiatric nursing student.  
**Exclusion criteria:**  
Opting out of continuing to participate in the study (during the study) Occurrence of unexpected physical or mental problems during study Inability to actively participate in the treatment process (for reasons such as slowness of thinking, slowness of speech, etc.)

**Age**  
From **12 years** old to **24 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **111**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, cluster controlled randomization method is used, where hospital departments (instead of individuals) will be considered as the randomization unit. In this study, random assignment of departments in the hospital will be done by someone outside the study using randomization software. In other words, the numbers of the sections will be entered into the randomization software, and this software will place the sections in one of the intervention or control groups completely randomly and by coding. The reason for choosing the cluster randomization method is to prevent and protect against data contamination that can occur in the randomization of people.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**  
In this study, in order to blind and prevent possible bias, interpretation of questionnaires and data entry and analysis will be done by someone outside the study. Also, the 28 clinical caregiver does not know how to assign people and the type of training of people. In order to prevent data contamination in this study, hospital departments will be randomized instead of individuals, and in fact, department numbers will be entered into the randomization software, and this software will be completely random and by coding the departments into one of two groups. control or intervention.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics Committee in the Research of Nursing and Midwifery, Management and Medical Information-Shiraz

**Street address**  
School of Nursing and Midwifery, Nemazee Square, Zand St., Shiraz, Iran

**City**  
SHIRAZ

**Province**  
Fars

**Postal code**  
71936-13119

**Approval date**  
2023-07-15, 1402/04/24

**Ethics committee reference number**  
IR.SUMS.NUMIMG.REC.1402.066

**Health conditions studied**

**1**

**Description of health condition studied**  
Suicidal ideation

**ICD-10 code**  
R45.851

**ICD-10 code description**  
Suicidal ideations

**Primary outcomes**

**1**

**Description**

Meaning in life

**Timepoint**

Before and immediately after the intervention

**Method of measurement**

Purpose in life questioner

## Secondary outcomes

### 1

**Description**

Self-criticism

**Timepoint**

Before and immediately after the intervention

**Method of measurement**

Self-Criticism-Reassurance Scale

### 2

**Description**

Suicidal ideation

**Timepoint**

Before and immediately after the intervention

**Method of measurement**

Suicide cognitions questionnaire

## Intervention groups

### 1

**Description**

Intervention group 1: receiving four sessions of positive psychotherapy through virtual reality including teaching positive psychotherapy modules such as forgiveness, kindness and gratitude. These trainings for the intervention group will be done by virtual reality glasses and software designed specifically for these glasses. By using these glasses, the patient will be placed in a 3D and virtual environment and will also hear the voice of the psychotherapist who communicates with him through the headset. The mentioned content will be broadcast to the patient four times a day and the patient will complete the questionnaires before and after the intervention.

**Category**

Other

### 2

**Description**

Intervention group: Receiving four sessions of positive psychotherapy including modules of kindness, gratitude and forgiveness in person and face to face. The patient will receive the mentioned trainings by the project partner, senior psychiatric nursing student, in person and in four sessions every other day. These patients will also complete the questionnaires before and after the end of the intervention.

**Category**

Other

### 3

**Description**

Control group: They will receive the usual hospital treatments for 4 sessions, every other day.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Ebne Sina Hospital

**Full name of responsible person**

Sepideh Alipour

**Street address**

8th Street, Hafez street, Shiraz

**City**

Shiraz

**Province**

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**Postal code**

14336 - 71348

**Phone**

+98 71 3228 9604

**Email**

sinahosp@sums.ac.ir

### 2

**Recruitment center**

**Name of recruitment center**

Hafez hospital

**Full name of responsible person**

Sepideh Alipour

**Street address**

Hafez educational and therapeutic center, Abiverdi beginning, Chamran street, Shiraz

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**Phone**

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**Email**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Roksana JanGHorban

**Street address**

Vice Chancellor for Research and Technology, Zand

St. Central Building of Shiraz University of Medical Sciences, 7th floor,

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3212 2430

**Email**

vcrdep@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**

Dr Maryam Shaygan

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

psychology

**Street address**

Community-based Psychiatric Care Research Center, 2nd Floor, Fatemeh PBUH School of Nursing and Midwifery, Building 3, Namazi Teaching Hospital, Namazi Square, Shiraz, Iran

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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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**

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 academic and scientific institutions

**Under which criteria data/document could be used**

Systematic reviews and meta-analyses

**From where data/document is obtainable**

Contact via email: m2620.shaygan@gmail.com

**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**