

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The efficiency of emotion regulation on Gross model on Illogical Believes on Patient at risk of suicide: Clinical trial with control group

#### Protocol summary

Emotion regulation, Gross model, Irrational beliefs, Suicide risk

#### Study aim

Investigating the The efficiency of emotion regulation on Gross model on Illogical Believes on Patient at risk of suicide

#### Design

Clinical trial with control group, with parallel groups, single-blind, randomized, was used on 30 patients. Each participant is given a unique code. People who have an even code are classified in the control group (15 people) and people who have an odd code in the test group (15 people). The tester has no role in dividing them.

#### Settings and conduct

The participants were 30 patients who had a high score on the suicidal ideation scale based on the screening done at Ibn Sina Hospital in Shiraz, and Gross and John's emotional regulation questionnaire, Beck's suicidal ideation scale, and Jones' 40-question irrational beliefs. , Beck's frustration scale and Beckham et al.'s cognitive triangulation, before the intervention, after the intervention and one month after the intervention, will be completed by both groups and will be analyzed with SPSS software. To check the efficiency of the Gross model in emotion regulation, group therapy sessions were designed for the experimental group. The control group receives education related to public health and has no knowledge of the intervention of the experimental group.

#### Participants/Inclusion and exclusion criteria

The main conditions for entering the study before randomization: 1) Have a high score on the suicide scale. 2) Have a stable mood: The main conditions of not entering the study before randomization: Patients who are not interested in participating in the plan.

#### Intervention groups

The experimental group is the group for whom group therapy sessions are conducted using the Gross model method. The control group is the group that receives education related to public health.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131130015589N4**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

##### Registration date

2023-07-01, 1402/04/10

##### Registrant information

##### Name

Arash Mani

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 3070

##### Email address

mania@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-04, 1402/04/13

##### Expected recruitment end date

2023-07-14, 1402/04/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The efficiency of emotion regulation on Gross model on Illogical Believes on Patient at risk of suicide: Clinical trial with control group

**Public title**  
The efficiency of emotion regulation on Gross model on Illogical Believes on Patient at risk of suicide

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Have a high score on the suicide scale. Have a stable mood.  
**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: 30

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The current research will be conducted as a single-blind clinical trial, and the sample members will be 30 patients who, based on screening, had a high score on the suicidal ideation scale upon entering Ibn Sina Hospital in Shiraz. Each participant is given a unique code. People who have an even code are classified in the control group (15 people) and people who have an odd code are classified in the experimental group (15 people).

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Islamic Azad University, Shiraz Branch

## Street address

Islamic Azad University Pardis, km 5 Sadra City road, Shiraz

## City

Shiraz

## Province

Fars

## Postal code

71993

## Approval date

2023-06-19, 1402/03/29

## Ethics committee reference number

IR.IAU.SHIRAZ.REC.1402.026

## Health conditions studied

### 1

#### Description of health condition studied

Emotion regulation

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Gross model

#### ICD-10 code

#### ICD-10 code description

### 3

#### Description of health condition studied

Illogical Believes

#### ICD-10 code

#### ICD-10 code description

### 4

#### Description of health condition studied

Risk of suicide

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Up-regulation (proper regulation) or down-regulation of positive or negative emotions. Also emotional re-evaluation and emotional suppression of the studied subjects

#### Timepoint

Before the intervention, After the intervention and one month after the intervention

#### Method of measurement

Emotional Regulation Questionnaire (EPQ) Gross and John (2003)

## 2

### **Description**

Irrational beliefs of the studied people such as: helplessness against change, expecting approval from others, avoiding problems and emotional irresponsibility.

### **Timepoint**

Before the intervention, After the intervention and one month after the intervention

### **Method of measurement**

Standard questionnaire of irrational beliefs Jones (1969) version 40 questions

## 3

### **Description**

The severity of suicidal thoughts in the studied subjects

### **Timepoint**

Before the intervention, After the intervention and one month after the intervention

### **Method of measurement**

Beck Suicidal Ideation Scale (BSS)

## 4

### **Description**

Measuring the intensity of negative attitude, pessimism and hopelessness towards the future

### **Timepoint**

Before the intervention, After the intervention and one month after the intervention

### **Method of measurement**

Beck Hopelessness Scale (BHS)

## 5

### **Description**

Evaluation of three cognitive dimensions of attitude in the studied subjects based on attitude towards self, attitude towards the world, attitude towards the future

### **Timepoint**

Before the intervention, After the intervention and one month after the intervention

### **Method of measurement**

Beckham et al. Cognitive Triad Inventory (CTI)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 15 of the patients who, based on the screening, had a high score on the scale of suicidal thoughts upon entering the Ibn Sina Hospital in Shiraz, and were assigned an individual code in the classification, are included in this group (the examiner has no role in their classification). First, an explanatory meeting is held for sample people. Then, for this group, eight group therapy sessions of Grass's emotion

regulation model with specific topics will be provided for two hours and within a month. For each session, a task is determined that is close to the topic. The topics of the sessions include: 1) introduction, 2) selection of the situation, 3) selection of the situation, 4) modification of the situation, 5) expansion of attention, 6) cognitive evaluation, 7) response adjustment and 8) application evaluation.

#### **Category**

Other

## 2

#### **Description**

Control group: 15 patients who, based on the screening, had a high score on the suicidal ideation scale upon entering the Ibn Sina Hospital in Shiraz, and received an even code in the division, are included in this group (the examiner has no role in their division). This group receives education related to public health.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ibn Sina Psychiatry Training Hospital, Shiraz

##### **Full name of responsible person**

Maryam Amiry

##### **Street address**

Next to Bostan 13 Aban, Hafez St.

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7199896376

##### **Phone**

+98 917 301 4295

##### **Fax**

##### **Email**

mania@sums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Arash Mani Kazeron

##### **Street address**

Hafez Medical Education Hospital, Chamran Blvd., Shiraz

##### **City**

Shiraz

##### **Province**

Fars

**Postal code**  
7199896376

**Phone**  
+98 917 301 4295

**Email**  
mania@sums.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No

**Title of funding source**  
Islamic Azad University, Shiraz branch

**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**  
Islamic Azad University

**Full name of responsible person**  
Arash Mani Kazeron

**Position**  
Associate Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Neuroscience

**Street address**  
Hafez Medical Education Hospital, Chamran Blvd., Shiraz

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7199896376

**Phone**  
+98 71 3627 9319

**Email**  
mania@sums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Arash Mani Kazeron

**Position**  
Associate Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Neuroscience

**Street address**  
Hafez Educational Hospital, Shahid Chamran Boulevard, Shiraz

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7199896376

**Phone**  
+98 71 3627 9319

**Fax**  
+98 71 3627 9319

**Email**  
mania@sums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Maryam Amiry

**Position**  
Researcher

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Psychology

**Street address**  
Amiri House, third door from the right, NO. 5, Javamanardi Alley, NO. 7, Molana Street, Phase 1, Sadra New City, Shiraz, Fars

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7199896376

**Phone**  
+98 71 4260 0078

**Email**  
DonyAmiry91@gmail.com

## 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**  
Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available