

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### A comparative Study on the effect of anxiety management training on two methods of Microlearning and a Gamification based website on anxiety control in 13-15 years old adolescent girls in Shiraz

#### Protocol summary

##### Study aim

Comparison of the effect of anxiety management training on two methods of Microlearning and a Gamification based website on anxiety control in 13-15 years old adolescent girls in Shiraz

##### Design

Clinical trial dedicated to intervention and control groups (totally design of 400 patients), based on community and training-counseling, with parallel groups, no blind groups, Randomized cluster

##### Settings and conduct

The effect of two methods of Microlearning & Gamification is used to reduce anxiety of adolescent girls. The place of execution is Shiraz girls' schools. The Spielberger questionnaire measures anxiety level of them & in case of mild to moderate anxiety, they enter into one of 3 groups: MicroLearning, Gamified training, control group. At the end, Spielberger Questionnaire will be completed again.

##### Participants/Inclusion and exclusion criteria

Inclusion criterias: 1-Girls aged 13 to 15 years old who study in schools of Shiraz 2-Obtain a score of 20 to 80 from the Spielberger anxiety inventory (mild to severe anxiety) 3-The desire to collaborate and participate in research and parents' satisfaction with how research is conducted 4-Ability to work with computers. Exit criterias: 1-Do not participate in one of the pre- or post-test sessions 2-History of mental disorders and use of sedation drugs 3-Experience the crisis, during the intervention or 40 days before

##### Intervention groups

1-anxiety management training group with method of Microlearning: View short video clips online and through a regular website that will take 4 weeks, and almost 2 videos will be on the website per week. 2-The group receives anxiety management training on the method of Gamification: Watching short clips through a Gamified

website that will take 4 weeks and almost 2 videos will be on the website per week. 3-Control group: A group that does not get online education

##### Main outcome variables

Control the anxiety of teenage girls

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181208041887N1**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **prospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

##### Registration date

2019-01-10, 1397/10/20

##### Registrant information

##### Name

Elham Saranjam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3831 0420

##### Email address

saranjam@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative Study on the effect of anxiety management training on two methods of Microlearning and a Gamification based website on anxiety control in 13-15 years old adolescent girls in Shiraz

**Public title**

A comparative study on the effect of anxiety management training on anxiety control in 13-15 years old adolescent girls

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

13-15 years old girl students in Shiraz Get score between 20 to 80 from the Spielberger's Anxiety Inventory (Mild to Severe anxiety) The desire to collaborate and participate in research and parents' satisfaction of How to do research Ability to work with computers

**Exclusion criteria:**

Do not participate in one of the pre or post-test sessions  
History of mental disorders or using sedations  
Experience the crisis, during the intervention or 40 days before

**Age**

From **13 years** old to **15 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **400**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, a randomly cluster will be selected from the four education districts of Shiraz, from which three state-run girls' schools will be selected by systematic random sampling and then from each school in a randomized, three class (of each Grade, one class) will be selected. After receiving informed consent, the Spielberger Anxiety Inventory is presented to them. Adolescents who have entered the study criteria and have received the above questionnaire for mild anxiety score are selected to enter the study. And these teenagers are randomly assigned to three groups of Microlearning, Gamification and Control.

**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 Shiraz University of Medical Science

**Street address**

Central Building of Shiraz University of Medical Science, Zand Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2018-12-22, 1397/10/01

**Ethics committee reference number**

IR.SUMS.REC.1397.897

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

**Primary outcomes****1****Description**

The effect of Microlearning on anxiety management of adolescent girls

**Timepoint**

Before the intervention, Immediately after and two weeks after the intervention

**Method of measurement**

Spielberger Anxiety Inventory (state and trait anxiety)

**2****Description**

The Effect of method of Gamification on Anxiety Management of Adolescent Girls

**Timepoint**

Before the intervention, Immediately after and two weeks after the intervention

**Method of measurement**

Spielberger Anxiety Inventory (state and trait anxiety)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first Intervention group: The recipient of anxiety management trainings on the method of Microlearning

#### Category

Behavior

### 2

#### Description

The second Intervention group: The recipient of anxiety management trainings on the method of Gamification based website

#### Category

Behavior

### 3

#### Description

Control group: No receiving anxiety management trainings

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Girls' schools of Shiraz

##### Full name of responsible person

Dr.Askar Najafi

##### Street address

General Education Department of Fars Province, East Moaddel St

##### City

Shiraz

##### Province

Fars

##### Postal code

71345-314

##### Phone

+98 71 3233 5953

##### Email

public\_ir@farsedu.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Ali Bahador

#### Street address

Research assistance, Shiraz University of Medical Science, Zand Blvd

#### City

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#### Phone

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#### Fax

+98 71 3235 9317

#### Email

info@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

Elham Saranjam

##### Position

Master student of Nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

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saranjam@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ladan Zarshenas

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences

**Full name of responsible person**

Elham Saranjam

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Province**

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**Postal code**

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**Phone**

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**Email**

Saranjam@sums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable