

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ladan Zarshenas

Position

Assistant Professor

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Person responsible for updating data

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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