

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of a social cognitive theory based educational intervention on mobile use behavior and its determinants among female high school students; an educational cluster randomized controlled trial

Protocol summary

Study aim

Investigating the effect of a social cognitive theory based educational intervention on mobile use behavior and its determinants among female high school students

Design

A clinical trial with parallel groups (intervention and control) with a sample size of 110 people in each group, which are randomly selected in a cluster. After determining the second secondary schools, 2 schools are randomly selected and an experimental or control group is assigned to each school in a simple random manner.

Settings and conduct

The research environment in this study is public high schools for girls in Ewaz

Participants/Inclusion and exclusion criteria

The female student is studying in the second secondary level unwillingness to participation; Parents' disagreement of her participation

Intervention groups

After the pre-test, training sessions for the intervention group will be held during 6 training sessions for 2 months, and they will receive the necessary training, one month after the end of the training intervention for each training group, the post-test will be completed. The same questionnaires will be done before the intervention. The control group will not receive any intervention. However, after the intervention and the collection of post-test results, all educational documents and taught content will be available to the members of the control group

Main outcome variables

Knowledge scores, outcome expectations scores, self-efficacy scores, self-control scores, behavioral intention scores, behavior scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110423006261N20**

Registration date: **2023-02-15, 1401/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-15, 1401/11/26**

Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-24, 1401/07/02

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a social cognitive theory based

educational intervention on mobile use behavior and its determinants among female high school students; an educational cluster randomized controlled trial	
Public title	Investigating the effect of a social cognitive theory based educational intervention on mobile use behavior
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	The student participating in the plan must have a smartphone for more than one year and have proper access to it. The student is studying in the second secondary level
Exclusion criteria:	The student's unwillingness to participate in the study Unwillingness of the student's family to participate in the study
Age	From 15 years old to 18 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 220
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, a simple randomization method is used, intervention and control group allocation is done using a lottery method, and the number of 2 schools, which are the clusters, are selected from among 8 girls' secondary schools in the city of Ewaz. The names of all 8 schools are written on a piece of paper and we randomly pick one. The school that was chosen first will be the control group and the second school will be the intervention group. Again, a lottery is drawn between individuals or couples in each school. From each school, 110 students whose student numbers are odd or even are selected for the control or intervention group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	In order to prevent information leakage, random allocation is doing in level of schools not students.
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Shiraz University of Medical Sciences
Street address	Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue
City	Shiraz
Province	Fars
Postal code	7134814336
Approval date	2022-10-03, 1401/07/11
Ethics committee reference number	IR.SUMS.SCHEANUT.REC.1401.094

Health conditions studied

<u>1</u>	
Description of health condition studied	mobile use behavior
ICD-10 code	
ICD-10 code description	

Primary outcomes

<u>1</u>	
Description	behavior
Timepoint	Before the intervention and 4 weeks after intervention
Method of measurement	Standardized pre-made questionnaire

<u>2</u>	
Description	Knowledge
Timepoint	Before the intervention and 4 weeks after intervention
Method of measurement	Standardized pre-made questionnaire

<u>3</u>	
Description	Intention
Timepoint	Before the intervention and 4 weeks after intervention
Method of measurement	Standardized pre-made questionnaire

Secondary outcomes

1

Description

outcome expectations

Timepoint

Before the intervention and 4 weeks after intervention

Method of measurement

Standardized pre-made questionnaire

2

Description

Efficacy

Timepoint

Before the intervention and 4 weeks after intervention

Method of measurement

Standardized pre-made questionnaire

3

Description

Self-control

Timepoint

Before the intervention and 4 weeks after intervention

Method of measurement

Standardized pre-made questionnaire

Intervention groups

1

Description

Intervention group: 110 students of the 10th, 11th and 12th grades of public high schools for girls are selected according to the sampling process, after the pre-test using a pre-made questionnaire, the educational intervention is implemented in the form of at least 6 educational sessions of 30-45 minutes. to be The educational title includes general information about the virtual space and mobile phones, the advantages and disadvantages of mobile phones, ways to overcome excessive use of mobile phones, ways to evaluate yourself about the duration of using mobile phones, choosing the right media and how to sit correctly and work with Mobile and tablet. These topics are based on reliable and related sources. Overall strategy include interactive methods such as interactive lectures, small group techniques, group discussion, questions and answers and home based assignments and self-teaching materials for pamphlets and booklets that runs by the researcher. Also if it is possible to expand and deepen learning in cyberspace, a group is created for text and video and audio messages. In addition, the duration and number of training sessions may increase based on the capacity, the willingness, the conditions of the participants in the class and other factors. Six weeks after the completion of the training, a post-test will be held.

Category

Behavior

2

Description

Control group: students in control group will experience no intervention but only routine school curricula.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Girl High Schools

Full name of responsible person

Kosar Zarebi

Street address

Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

14336 71348

Phone

+98 71 5233 1895

Email

k.zarebi75@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR Syed Basir Hashemi

Street address

Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3725 1001

Email

kaveh@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

Mohammad Hossein Kaveh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3725 1001

Email

kaveh@sums.ac.ir

Postal code

7134814336

Phone

+98 71 3725 1001

Email

kaveh@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Kosar Zarebi

Position

Master Student of Health Education and Health Promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 5233 1895

Email

k.zarebi75@yahoo.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

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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Kaveh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran.

City

Shiraz

Province

Fars