

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Compilation and evaluation of the self-regulation program of Internet use on the general health of adolescents

Protocol summary

Study aim

Determining the effect of educational intervention based on self-regulation on Internet addiction and general health aspects of adolescents

Design

The clinical trial has a matched and randomized control group. In phase 2, it will be done on 120 people. The samples will be selected in the form of simple random sampling from one of the six areas of education. In this way, from one of the six educational districts of Isfahan City, one girl's school and one boy's school as the control group will be taken.

Settings and conduct

The intervention will be conducted in girls' and boys' secondary schools in Isfahan City in the form of group training sessions. In this study, 8 training sessions were considered during 2 months to carry out the intervention. The training that will be given includes the healthy use of the Internet, the effects of Internet addiction in social life, the introduction of appropriate methods to encourage the healthy use of the Internet, methods of dealing with Internet addiction, and creating awareness to set goals and achieve a behavior change.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Voluntariness and conscious participation, High school student, Having a smartphone, No mental problems. Exclusion criteria: Not willing to participate in research, not being a high school student, not having a smartcell phone, suffering from mental problems.

Intervention groups

In this study, 8 training sessions were considered for 2 months to carry out the intervention. during which the necessary training will be given to the intervention group. Then the effects of the intervention will be examined in the form of pre-test and post-test on both groups.

Main outcome variables

Goal setting, self-efficacy, outcome expectancies,

outcome value, self-control, self-observation, self-reaction, general health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240120060737N1**

Registration date: **2024-02-05, 1402/11/16**

Registration timing: **prospective**

Last update: **2024-02-05, 1402/11/16**

Update count: **0**

Registration date

2024-02-05, 1402/11/16

Registrant information

Name

Fatemeh Fayazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3551 4363

Email address

fatemehfayazi@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-23, 1402/12/04

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compilation and evaluation of the self-regulation program of Internet use on the general health of adolescents

Public title

Compilation and evaluation of the self-regulation program of Internet use on the general health of adolescents

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Voluntariness and conscious participation High school student Having a smart phone No mental problems

Exclusion criteria:

Unwillingness to continue cooperation at any stage of the research

AgeFrom **11 years** old to **15 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **782****Randomization (investigator's opinion)**

Randomized

Randomization description

The samples will be selected by simple random sampling from one of the six education regions. In this way, in a simple random manner, from one of the six educational districts of Isfahan City, one girl's school as the intervention group and one girl's school as its control group, also one boy's school as the intervention group and one boy's school as the control group. The control group will be considered.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Modelling

Secondary Ids

empty

Ethics committees1**Ethics committee**

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174643461

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.MUI.DHMT.REC.1402.022

Health conditions studied1**Description of health condition studied**

Internet addiction

ICD-10 code**ICD-10 code description****Primary outcomes**1**Description**

Internet addiction

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Internet addiction questionnaire

Secondary outcomes1**Description**

General health

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

General health questionnaire

Intervention groups1**Description**

Intervention group: It will include boys and girls of the high school level, who will receive an educational intervention including the correct use of the Internet in eight sessions for 2 months. And then the effects of the intervention will be evaluated.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

High school

Full name of responsible person

Zohre Fathian dastgerdi

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

8174643461

Phone

+98 913 305 1315

Email

z_fathian@hlth.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

8174643461

Phone

+98 31 8183 3668

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zohre Fathian dastgerdi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

8174643461

Phone

+98 31 3792 3247

Email

z_fathian@hlth.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zohre Fathian dastgerdi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

8174643461

Phone

+98 31 3792 3247

Email

z_fathian@hlth.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Fayazi

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

8174643461

Phone

+98 61 3551 4363

Fax

+98 916 988 4010

Email

fatemehfayazi@hlth.mui.ac.ir

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

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All information and reports obtained will be published in the form of articles and will be available to everyone.

When the data will become available and for how long

After completing the research

To whom data/document is available

For the general public

Under which criteria data/document could be used

For scientific use and to improve the level of knowledge in this field

From where data/document is obtainable

To receive any data or documents, you can get the information you need by communicating with the project manager and colleagues at the address of Isfahan University of Medical Sciences, Faculty of Health, or by email or other messaging networks.

What processes are involved for a request to access data/document

Calling and e-mail communication with the person in charge of the research z_fathian@hlth.mui.ac.ir
fatemeh.fayazi200@gmail.com Mobile: 09169884010

Comments