

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Designing, implementing, and evaluating of educational program based on a Multi-Theory Model regarding preventive behaviors of Covid-19 in students

Protocol summary

Study aim

Determining the effect of educational program based on the multi-theory model on preventive behaviors of Covid-19 (handwashing, vaccination, and wearing a mask) in Yazd students

Design

A clinical trial with a control group will be performed on 100 undergraduate students.

Settings and conduct

The study will be conducted in Yazd universities. First, the questionnaire of preventive behaviors will be translated and psychometrically based on a multi-theory model. The educational program will be implemented based on a multi-theory model for 50 students as an intervention group. Coursing will not be done. And students will be placed in the intervention and control group based on the last digit of the student number.

Participants/Inclusion and exclusion criteria

All undergraduate students studying at Yazd universities will be included in the study. Graduate students are not considered in the present study due to their higher knowledge and smaller population in the classrooms.

Intervention groups

In the intervention group, group discussion sessions are held to construct a participatory dialogue. An educational video is shown to construct behavioral trust. To structure the physical environment change, work on environmental facilities. A motivational speech will be given to construct the emotional transformation. A self-monitoring checklist will be used to change the exercise structure. And for the structure of changing the social environment, an educational program will be conducted for university officials to support students in carrying out preventive behaviors.

Main outcome variables

participatory dialogue Behavioral confidence Changing the physical environment Emotional transformation

Practice for change Changing social environment
Initiation of preventive behaviors from covid-19
Maintaining preventive behavior from covid-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211226053527N1**

Registration date: **2022-03-19, 1400/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-19, 1400/12/28**

Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

Mahdieh khaleghi moori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3721 5759

Email address

m.khaleghi@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-12, 1400/12/21

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementing, and evaluating of educational program based on a Multi-Theory Model regarding preventive behaviors of Covid-19 in students

Public title

Designing, implementing and evaluating of educational program based on a Multi-Theory Model regarding preventive behaviors of Covid-19 in students in Yazd city

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Studying at Yazd University having a smartphone internet access Having Whats App & Telegram applications undergraduate students

Exclusion criteria:**Age**From **18 years** old to **22 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Two-stage random cluster sampling method First, all universities in Yazd will be selected as study clusters, then individuals will be randomly selected from each cluster and based on the last digit of the student number will be transferred to the intervention and control groups. Students whose last digit of the student number is even will be in the intervention group and students whose last digit of the student number is an individual will be in the control group.

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**

Research Ethics Committees of School of Public Health - Shahid Sadoughi University of Medical Scienc

Street address

East Esteghlal Street

City

Yazd

Province

Yazd

Postal code

8917834585

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.SSU.SPH.REC.1400.179

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

covid19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

initiation of behavior

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

With an online questionnaire

2**Description**

maintain of behavior

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

With an online questionnaire

Secondary outcomes**1****Description**

participatory dialouge

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

2

Description

behavioral confidence

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

3

Description

change in physical environment

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

4

Description

emotional transformation

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

5

Description

practice for change

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

6

Description

change in social environment

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

With an online questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, an educational program based on a multi-theory model will be implemented for students. For the structure of participatory dialogue, group discussion sessions, for the structure of behavioral confidence in film screening, for the structure of physical environment change, adjustment of environmental access, for the structure of emotional transformation, motivational speech, for the

structure of practice to change self-monitoring checklist and for the structure of social environment. University officials will be executed.

Category

Behavior

2

Description

Control group: The educational program will not be implemented for the control group and only for the observance of ethical considerations, at the end of the study, an educational pamphlet will be distributed among the students of this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd universities

Full name of responsible person

Mahdieh Khaleghi Moori

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East Esteghlal Street

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Yazd

Province

Yazd

Postal code

8917834585

Phone

+98 922 801 6995

Email

mah.khaleghi.ph@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

dr Amir Hooshang Mehrparvar

Street address

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Yazd

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Postal code

8917834585

Phone

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Email

mah.khaleghi.ph@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Mahdieh Khaleghi Moori

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Email

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

Yazd University of Medical Sciences

Full name of responsible person

Mahdieh Khaleghi Moori

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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

Yazd University of Medical Sciences

Full name of responsible person

Mahdieh Khaleghi Moori

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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

Yes - There is 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

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the study will be visible in the published articles of the dissertation.

When the data will become available and for how long

November 2022

To whom data/document is available

Readers of dissertation articles

Under which criteria data/document could be used

The data in the articles can be used with the condition of referencing the article

From where data/document is obtainable

Refer to articles

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

Refer to articles

Comments

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