Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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
Street address
East Esteghlal Street
City
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
East Esteghlal Street
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Yazd
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Postal code
8917834585
Phone
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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
Street address
East Esteghlal Street
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Position
student
Latest degree
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Person responsible for updating data

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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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