

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the impact of educational messages based on an Extended Parallel Process Model on preventive behaviors of the infectious respiratory diseases, with emphasis on COVID-19 among elementary school girls: A four-group randomized trial

#### Protocol summary

##### Study aim

Comparing the impact of educational messages based on an Extended Parallel Process Model on preventive behaviors of the infectious respiratory diseases, with emphasis on COVID-19

##### Design

Clinical trial with control group and three intervention groups, one-way blind, randomized, on 300 students. Random number table was used for randomization.

##### Settings and conduct

a quasi-experimental educational intervention study designed and conducted in 1400 by simple random sampling method to investigate the effect of messages based on a parallel process model developed in fifth grade elementary school girls in Borkhar (a four-group intervention study). Will be.

##### Participants/Inclusion and exclusion criteria

Fifth grade students living in Borkhar city, have satisfaction for the company, having a smartphone and attending a virtual program (shad or WhatsApp) Unwillingness to continue the company, leaving the city, not completing the questionnaire in the pre-test or post-test, losing access to messages and questionnaires

##### Intervention groups

Group 1: Posters containing perceived intensity and sensitivity messages (perceived threat), Group 2: Posters containing perceived effectiveness messages, Group 3: Posters containing perceived threat and effectiveness messages based on EPPM and related to the topic of Covid Preventive Behaviors will be sent. Group 4 (Control Group): No intervention

##### Main outcome variables

Perceived Susceptibility and Severity, Self-efficacy, Response efficiency, Fear, Fear control, Danger control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210623051681N1**

Registration date: **2021-07-26, 1400/05/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-26, 1400/05/04**

Update count: **0**

##### Registration date

2021-07-26, 1400/05/04

##### Registrant information

##### Name

Soheila SHarifi Habibabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

2021-09-23, 1400/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparing the impact of educational messages based on an Extended Parallel Process Model on preventive behaviors of the infectious respiratory diseases, with emphasis on COVID-19 among elementary school girls: A four-group randomized trial

### Public title

Comparing the impact of educational messages based on an Extended Parallel Process Model on preventive behaviors of the infectious respiratory diseases, with emphasis on COVID-19

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Fifth grade elementary school girls living in Borkhar city  
Having the consent to participate in the study  
Having a smartphone and attending a virtual application (SHad or Whats App)

#### Exclusion criteria:

Student's unwillingness to continue participating in the study  
Leaving the city for any reason  
Failure to complete the questionnaire in the pre-test or post-test  
Loss of access to messages and questionnaires for any reason related to the smartphone and leaving the virtual application (SHad or Whats App)

### Age

From **11 years** old to **12 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **300**

### Randomization (investigator's opinion)

Randomized

### Randomization description

First, a list of names of all girls' schools in Borkhar city, including the number of fifth grade elementary students, is prepared and given to each of the schools. The city will be given a two-digit code (01,02, 03, ..., 38). Then we select 16 codes randomly using a simple random number table, then again sampled using a random number table of 16 schools, into different study groups (three intervention groups and one control group) Will be allocated.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The data analyzer is not aware of the allocation of individuals in study groups (intervention and control) which was done randomly. This random method has led to a one-way blinding of the study.

### Placebo

Not used

### Assignment

Factorial

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jerib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-06-09, 1400/03/19

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.127

## Health conditions studied

### 1

#### Description of health condition studied

Infectious Respiratory Diseases, with emphasis on Covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Respiratory Infectious Diseases Prevention Behaviors, with Emphasis on Covid-19

#### Timepoint

One week after the intervention

#### Method of measurement

A researcher-made questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first group of intervention: by referring to the schools in question and talking to the principal of each school, they are asked to cooperate, then the parents of the children are called and the plan is explained to them and if they want to cooperate, they are asked to use Their contact number in WhatsApp or Shad should form a group and be divided into 4 study groups according to the randomly selected samples and, if necessary, attend the school in accordance with the health protocols. This study will be invited to participate in the study. Research subjects will be justified on how to do it, the confidentiality of information and also the purpose of the study, and all of them will enter the study if they wish and after expressing their consent. Before conducting the educational intervention in order to perform (Pre-test), the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully. Online questionnaires will be completed within 7 days. Educational posters will be selected from educational posters approved by the Ministry of Health and will be divided into three test groups based on the content of the poster. Will be sent with the intervention group. In the first intervention group: after the pre-test, 3 posters containing messages of perceived severity and sensitivity (perceived threat) based on EPPM and related to the topic of preventive behaviors Quid will be sent. After the educational intervention for post-test, the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully.

#### **Category**

Behavior

## **2**

#### **Description**

The second group of intervention: by referring to the schools in question and talking to the principal of each school, they are asked to cooperate, then the parents of the children are contacted by phone and the plan is explained to them and asked if they want to cooperate using Their contact number should be grouped in WhatsApp or Shad and should be divided into 4 study groups according to the randomly selected samples and, if necessary, attend the school in accordance with health protocols. Students should be selected based on the inclusion criteria and qualified This study will be invited to participate in the study. Research subjects will be justified on how to do it, the confidentiality of information and also the purpose of the study, and all of them will enter the study if they wish and after expressing their consent. Before performing the educational intervention in order to perform (Pre-test), the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully. Online questionnaires will be completed within 7 days. Educational posters will be selected from educational posters approved by the Ministry of Health and based on the content of the poster will be divided into three test groups and during the intervention (one week) three

appropriate posters for each test group. Will be sent with the intervention group. In the second group of the intervention: After the pre-test, 3 posters will be sent containing the perceived efficiency messages based on EPPM and related to the topic of Covid prevention behaviors. After the educational intervention for post-test, the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully.

#### **Category**

Behavior

## **3**

#### **Description**

Intervention group 3: By referring to the schools in question and talking to the principal of each school, they are asked to cooperate, then the parents of the children are contacted by phone and the plan is explained to them and asked if they want to cooperate using Their contact number in WhatsApp or Shad should form a group and be selected in 4 groups according to the randomly selected samples and, if necessary, attend the school in accordance with health protocols. Students are selected based on the inclusion criteria and are eligible. This study will be invited to participate in the study. Research subjects will be justified on how to do it, the confidentiality of information and also the purpose of the study, and all of them will enter the study if they wish and after expressing their consent. Before conducting the educational intervention in order to perform (Pre-test), the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully. Online questionnaires will be completed within 7 days. Educational posters will be selected from educational posters approved by the Ministry of Health and will be divided into three test groups based on the content of the poster. Will be sent with the intervention group. In the third intervention group: After the pre-test, 3 posters containing threatening messages and perceived effectiveness based on EPPM and related to the topic of prevention behaviors will be sent. After the educational intervention for post-test, the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully.

#### **Category**

Behavior

## **4**

#### **Description**

Fourth intervention group (control): by referring to the schools in question and talking to the principal of each school, they are asked to cooperate, then the children's parents are called and the plan is explained to them and they are asked if they want to cooperate. Using their WhatsApp or Shad contact number, form a group and study in 4 groups according to the randomly selected samples and, if necessary, attend the school in

accordance with health protocols. Students are selected based on the inclusion criteria and Eligible students of this study will be invited to participate in the study. Research subjects will be justified on how to do it, the confidentiality of information and also the purpose of the study, and all of them will enter the study if they wish and after expressing their consent. Before conducting the educational intervention in order to perform (Pre-test), the link of the online questionnaire will be placed among the selected students of the test and control groups, then they will be asked to answer the questionnaire carefully. Online questionnaires will be completed within 7 days. Educational posters will be selected from educational posters approved by the Ministry of Health and will be divided into three test groups based on the content of the poster. Will be sent with the intervention group. In the fourth group of intervention: the group that is considered as the control group will not be subjected to any educational intervention and one week after the intervention, simultaneously with the first, second and third groups of the post-test in this The group will do the same.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Borkhar city schools

**Full name of responsible person**

Mohammad Reza Masoumi

**Street address**

Education of Borkhar city, Taleghani Blvd

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**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**

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**

Soheila SHarifi habibabadi

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for scientific**

## **inquiries**

### **Contact**

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## **Person responsible for updating data**

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## **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**

Not applicable

**Data Dictionary**

Not applicable