

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 2026

### The effect of evaluating the educational intervention based on the integrated model of stages of preparation for change (SOC) and the theory of planned behavior on traffic behaviors in 12-14 year-old female students

#### Protocol summary

##### Study aim

Determining the effect of the educational intervention based on the integrated model of stages of readiness for change and the theory of planned behavior on safe traffic behaviors in 12-14-year-old female students

##### Design

A clinical trial with a control group, with parallel groups, randomized using a table of random numbers, phase 1 on 76 patients

##### Settings and conduct

Conducting an intervention aimed at the impact of education on students' safe traffic behaviors Selection of schools from the first secondary girls' schools of Bouin Zahra as control and intervention groups using random allocation sampling method and selection of group members using random numbers table Conducting evaluation results in two stages before and one month after the intervention. Conducting the pre-test without name decker based on the code by the participants Conducting training classes by the researcher in 4 training sessions for the test group with a duration of 20 to 50 minutes. Setting the contents of the educational program based on the structures of the theory of planned behavior Conducting a post-test one month after the intervention. Routine training of the control group and evaluation one month later with a post-test

##### Participants/Inclusion and exclusion criteria

Entry requirements: female students 12-14 years old  
Conditions of non-entry: unwillingness to continue voluntary participation

##### Intervention groups

Educational intervention including 3 stages of planning, implementation and evaluation. Holding 4 training sessions for the intervention group. Evaluation results in two stages before the intervention and one month after the intervention using a questionnaire. Routine training

of the control group and evaluation one month later

##### Main outcome variables

Average awareness, attitude, intention, behavior

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221222056895N1**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

##### Registration date

2023-06-08, 1402/03/18

##### Registrant information

##### Name

Maryam Darziramandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3453 3629

##### Email address

m.darziramandi@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-20, 1402/03/30

##### Expected recruitment end date

2023-07-21, 1402/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of evaluating the educational intervention based on the integrated model of stages of preparation for change (SOC) and the theory of planned behavior on traffic behaviors in 12-14 year-old female students

**Public title**

The effect of educational intervention of planned behavior on traffic behaviors in female students

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

The willingness and satisfaction of students and their parents to participate in the study Being in the first 3 stages of preparation for change (according to the answers given to the algorithm of the stages of change) Studying in 2022-2023, female students in the age range of 12-14 years Possession of smart mobile phones by students or their parents to send educational posts or virtual education

**Exclusion criteria:**

Unwillingness to continue volunteering Suffering from physical and mental disorders and diseases that somehow prevent proper participation in the study (confirmed report by a doctor) Absence of more than 2 sessions in the training class

**Age**From **12 years** old to **14 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **76****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random sampling method, one of the schools will be selected as the control group and the other school will be selected as the intervention group. Then a list of 12-14 year old students of each school will be prepared and after complying with the entry and exit criteria using the table of numbers. The members of the control and intervention groups will be randomly selected.

**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**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Qazvin University of Medical Sciences, Blvd Shahid Bahonar

**City**

Qazvin

**Province**

Qazvin

**Postal code**

5981134197

**Approval date**

2023-03-18, 1401/12/27

**Ethics committee reference number**

IR.QUMS.REC.1401.369

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

Safe traffic behavior in 12-14-year-old female students of Buin Zahra city

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

Consciousness

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**2****Description**

Attitude

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**3****Description**

Perceived behavioral control

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**4****Description**

Behavioral intention

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**5****Description**

Stages of behavior change

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**6****Description**

Safe traffic behavior

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**7****Description**

Abstract norm

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

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

Age

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**2****Description**

Grade

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**3****Description**

Parents' occupation

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**4****Description**

Parents' education

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**5****Description**

The economic situation

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**6****Description**

A history of accidents leading to injuries in the family, relatives and friends

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**7****Description**

A history of accidents leading to death in the family, relatives and friends

**Timepoint**

Before the intervention, one month after the intervention

**Method of measurement**

Questionnaire

**Intervention groups****1****Description**

Intervention group: Face-to-face training 4 sessions of 45 minutes in 4 weeks with questions and answers along with slides and video playback, the educational content is compiled based on the theory of planned behavior. The educational program will include subjects to increase awareness, attitude, intention, behavior and perceived behavioral control and abstract norms.

**Category**

Behavior

**2****Description**

Control group: no action

**Category**

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The Revolution Flowers School

##### Full name of responsible person

Dr. Hadi Morshidi

##### Street address

Buin Zahra Education Department, Blvd Azadegan

##### City

Buin Zahra

##### Province

Qazvin

##### Postal code

3451667479

##### Phone

+98 28 3422 9315

##### Email

medu4636@rayana.ir

### 2

#### Recruitment center

##### Name of recruitment center

The Revolution Message School

##### Full name of responsible person

Dr. Hadi Morshidi

##### Street address

Buin Zahra Education Department, Blvd Azadegan

##### City

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##### Province

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##### Postal code

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##### Phone

+98 28 3422 9315

##### Email

medu4636@rayana.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Dr. Hadi Morshidi

##### Street address

Qazvin University of Medical Sciencest, Shahid  
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##### Province

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##### Phone

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##### Email

sph@qums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

##### Full name of responsible person

Maryam Darzi Ramandi

##### Position

Masters student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Health Promotion

##### Street address

No. 16, Blvd Sardar Soleimani, corner of Imam  
Hossein Square

##### City

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##### Province

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3458113594

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028234533629

##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Dr. Hadi Morshidi

##### Position

Doctorate in health education

##### Latest degree

Ph.D.

**Other areas of specialty/work**

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

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Hadi Morshidi

**Position**

Specialized doctorate in health education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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**Email**

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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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable