

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### A mixed study of message framing in risky behaviors prevention education program and its evaluation in adolescent boy cyclists

#### Protocol summary

##### Study aim

Designing and Evaluating Message and Training Programs for Preventing Cyclists' Risky Behaviors

##### Design

Isfahan Secondary Secondary Schools were selected by random sampling from two schools (one as intervention group and the other as control group) and then through cyclists at school again using simple intervention and control group random sampling method. They will be selected The sample size was 86 persons in each of the intervention and control groups with a 20% probability of falling.

##### Settings and conduct

Two schools of Isfahan Secondary School will be selected based on random sampling method . The intervention group will receive the designed training program. The comparison group will not receive the message and the training program. In this study the data analyzer will also be blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Cycling2- Ability to express and share risky behavior experiences3 Adolescents age 15 to 19 years exclusion: Not willing to continue cooperation at any stage 2 lack of desire to participate in training sessions over a one meeting

##### Intervention groups

According to the qualitative study before the intervention, all the determinants of cycling risk behaviors at the individual level will be identified and then educational intervention for the intervention group in the form of training sessions, sending educational messages through social networks and delivery. Targeted training packages will be delivered. The message control and training groups will not be presented in the intervention group and the intervention variables will be measured by a Self-report questionnaire three times before, immediately and two months after the intervention. Finally, after the final evaluation of the group Controls will be trained

##### Main outcome variables

Reducing show off During Cycling 2 Using safety equipment during cycling

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191218045793N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **prospective**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

##### Registration date

2020-02-08, 1398/11/19

##### Registrant information

##### Name

Fatemeh Saber

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 4626 5985

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-08, 1399/01/20

##### Expected recruitment end date

2020-07-20, 1399/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A mixed study of message framing in risky behaviors prevention education program and its evaluation in adolescent boy cyclists

**Public title**  
The effect of educational intervention on cyclists' risky behaviors

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
cycling Having experience in risky behavior (performing show off and not using safety equipment) and being able to express and share them Male adolescents in the age group of 15 to 19 years  
**Exclusion criteria:**  
Not willing to cooperate at every stage of the research lack of desire to participate in training sessions over a one meeting

**Age**  
From **15 years** old to **19 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **172**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple Randomization - Randomization Unit - Individual - Randomization Tool: Random Number Table

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Study participants will be divided into case and control groups and each group will be unaware of what the other group received and to which group it is assigned. Also, in order to prevent bias in the data analysis, the data analyzer will be blinded to the type of study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
دانشگاه علوم پزشکی اصفهان  
**Street address**  
Azadi Square - Hezar Jerib Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
81746-73461

**Approval date**  
2019-09-25, 1398/07/03

**Ethics committee reference number**  
IR.MUI.RESEARCH.REC.1398.386

## Health conditions studied

1

**Description of health condition studied**  
Risky behaviors of cyclists

**ICD-10 code**  
**ICD-10 code description**

## Primary outcomes

1

**Description**  
reduce risky behavior (performing show off and not using safety equipment) of cycling and Improve attitude

**Timepoint**  
Before, immediately and two months after the intervention

**Method of measurement**  
En Self-report questionnaire from qualitative study

## Secondary outcomes

1

**Description**  
reducing cycling accidents

**Timepoint**  
Before, immediately and two months after the intervention

**Method of measurement**  
En Self-report questionnaire from qualitative study

## Intervention groups

1

**Description**  
According to the qualitative study prior to the intervention, all risk factors, including the reasons for performing show off cycling, and the reasons for not using safety equipment during cycling will be identified at the individual level, followed by the intervention for

the intervention group. The format of the training sessions, the sending of educational messages through social networks based on the key ideas extracted from the qualitative study, along with the provision of targeted training packages, will in fact help people become aware of the types of risky behaviors during cycling and its consequences. Then become knowledge of attitude and self-efficacy Will acquire the necessary and many other skills that will be systematically designed for safe behaviors.

**Category**

Prevention

**2****Description**

Control group: No control message and training sessions will be provided for the control group

**Category**

Other

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

آموزش و پرورش منطقه دو

**Full name of responsible person**

فرشته زمانی علویجه

**Street address**

Azadi Square - Hezar Jerib Street

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

**Street address**

Azadi Square - Hezar Jerib Street-Isfahan University Of Medical Sciences- bldg NO 4.research and technology

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**Province**

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research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Isfahan 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**

Fatemeh saber

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Fereshteh zamani-alivijeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Fatemeh saber

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Azadi Square - Hezar Jerib Street

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available