

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)

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+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

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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

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

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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**

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Full name of responsible person

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Position

Student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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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