

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A mixed Study for Message Framing in Risk-Driven Prevention Education Program and its Evaluation in School Service Drivers

Protocol summary

Improving driver behavior, preventing risky behavior, protecting students' health

Study aim

Design, Evaluate the Message, and Prevent Risky Drivers Behavioral Training Program

Design

The sample will be selected from among the drivers of Tehran city schools and randomly selected based on the area. -Calculate Sample Size: Based on previous studies, the sample size was estimated to be 82, with a confidence level of 95% and 80% test capability

Settings and conduct

Tehran city schools, Tehran elementary school drivers, randomly selected areas and 200 drivers will be randomly selected and divided into three groups and each group received the mentioned questionnaires completed after 6 Months will follow

Participants/Inclusion and exclusion criteria

1. Being a school service driver. 2. The desire to have an interview 3. Having experience in risky behavior and being able to express and share them Exclusion criteria 1- Not willing to continue collaborating at any stage of the research

Intervention groups

1. Educational intervention The educational intervention will be conducted within the framework of the theory of planned behavior in the intervention group. The educational intervention will include a training session based on the key ideas extracted from the qualitative study and TPB structures along with a targeted training package. The variables will be evaluated before and 3 months after the intervention (86). 2. Validate the message This part of the study will be a three-group intervention study involving a control group and two intervention groups that will examine the impact of message based on planned behavior theory and vision theory on risky behavior of drivers. Positive framed messages and the second intervention group will receive negative framed messages in a pamphlet format but no control message

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045789N1**

Registration date: **2019-12-31, 1398/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-31, 1398/10/10**

Update count: **0**

Registration date

2019-12-31, 1398/10/10

Registrant information

Name

Freshteh Zamani-Alavijeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3292

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-27, 1398/07/05

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A mixed Study for Message Framing in Risk-Driven Prevention Education Program and its Evaluation in School Service Drivers

Public title

A mixed Study for Message Framing in Risk-Driven Prevention Education Program and its Evaluation in School Service Drivers: Application of Planned Behavior Theory

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being a school service drive Wanting to do an interview
Having experience in risky behavior and being able to express and share them

Exclusion criteria:

Not willing to cooperate at any stage of the research

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization, Randomization Unit: Individual,
Randomization Tool: Random Number Table

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 Isfahan University of Medical Sciences

Street address

Bldg No. 4, Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2019-09-25, 1398/07/03

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.385

Health conditions studied

1

Description of health condition studied

Risky Drivers Behaviors

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce risky driving behavior

Timepoint

3months after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Changes in drivers' attitudes

Timepoint

3 months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: The educational intervention will be conducted within the framework of the theory of planned behavior in the intervention group. The training intervention will include a training session based on the key ideas extracted from the qualitative study and TPB constructs along with a targeted training package and a positive framework-oriented message.

Category

Prevention

2

Description

Intervention group: The educational intervention will be conducted within the framework of the theory of planned

behavior in the intervention group. The educational intervention will include a training session based on the key ideas extracted from the qualitative study and the TPB constructs along with a targeted training package and a negative framework-oriented message

Category

Prevention

3**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**

Education District 2 of Tehran

Full name of responsible person

Fresheteh Zamani-Alavijeh

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Hezar Jerib street, Isfahan University Of Medical Sciences, , Iran

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fe.zamani@hlth.mui.ac.ir

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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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

Fresheteh Zamani-Alavijeh

Position

Associate Professor,

Latest degree

Ph.D.

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

Fresheteh Zamani-Alavijeh

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
Shadi fathizadeh
Position
Student
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province

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