

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effect of real time feedback (real time alert beep and SMS on a daily basis), gain reward and lose reward for controlling speed level in commercial drivers in order to reduce traffic injuries in Iran; a field randomized trial

Protocol summary

Study aim

Assess how real-time feedback, rewards, and penalties and speed cameras affect speeding among commercial drivers in Iran

Design

data will be collected for 24 months: 1-month Run-In, 3 months baseline, 9 months of intervention, and 6 months post-intervention. 5 months of analysis and report. Driver age and sex will be ascertained from drivers via phone interviews at the time of recruitment. Trip weather conditions will be obtained by polling the Weather Underground Application Program Interface (API) at the end of each trip.

Settings and conduct

This trial aims to investigate the effect of feedback (alarm system and daily SMS), reward system, and deprivation of rewards to control speed in the city in drivers of public vehicles.

Participants/Inclusion and exclusion criteria

All commercial drivers with a cell phone. Drivers will be randomly assigned to study arms stratified according to vehicle type.

Intervention groups

CONTROLS: Drivers will be unobtrusively monitored using telematics devices. **GROUP A:** Drivers will receive real-time alerts and daily text messages. **GROUP B:** Drivers will receive real-time alerts, daily text messages, and rewards that would increase to a maximum of 100000 Tomans per month based on their daily performance. **GROUP C:** Drivers will receive real-time alerts, daily text messages, and will be offered 100000 Tomans at the beginning of each month if they maintain a perfect driving record but will see the rewards diminish with poor performance.

Main outcome variables

The primary outcome is the distance traveled per trip at

speeds more than 10% above the speed limit as a proportion of total travel on high-speed roads.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037572N1**

Registration date: **2020-08-03, 1399/05/13**

Registration timing: **prospective**

Last update: **2020-08-03, 1399/05/13**

Update count: **0**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Negar Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

n.rezaei81@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of real time feedback (real time alert beep and SMS on a daily basis), gain reward and lose reward for controlling speed level in commercial drivers in order to reduce traffic injuries in Iran; a field randomized trial

Public title
Evaluating the effect of real time feedback (real time alert beep and SMS on a daily basis), gain reward and lose reward for controlling speed level in commercial drivers in order to reduce traffic injuries in Iran; a field randomized trial

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All commercial drivers
Exclusion criteria:
Not having cell phone

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized

Randomization description
Drivers will be randomly assigned to study arms stratified according to vehicle type. We have the list of names of all available drivers and vehicle types. Stratified randomization is achieved by generating a separate block for vehicle type, and subjects are assigned to the appropriate block. After all, subjects have been identified and assigned into blocks, computerized simple randomization is performed within each block to assign subjects to one of the groups.

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

National Institute for Medical Research Development

Street address

#21 , Besat St., Fatemi St.

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.NIMAD.REC.1399.032

Health conditions studied

1

Description of health condition studied

Injury

ICD-10 code

T14.9

ICD-10 code description

Unspecified injury

Primary outcomes

1

Description

distance traveled per trip at speeds more than 10% above speed limit as a proportion of total travel on high-speed roads (speed limits > 90 km/h).

Timepoint

In time of speed increase by Telematics and GPS

Method of measurement

Telematics

Secondary outcomes

1

Description

proportion of distance traveled at more than 20% above speed limit on high-speed roads

Timepoint

In time of speed increase

Method of measurement

Telematics devices

2

Description

number of harsh acceleration/braking events

Timepoint

when harsh acceleration/braking

Method of measurement

Telematics devices

3

Description

harsh turns

Timepoint

when harsh turns

Method of measurement

Telematics devices

4

Description

crash/near-crash events

Timepoint

whenever crash/near-crash events happens

Method of measurement

Telematics devices

Intervention groups

1

Description

Intervention group: GROUP A (INFORMATION ONLY): Drivers will receive real-time alerts and daily text messages. The alerts will be loud audio beeps by the telematics device when speed exceeds 10% of posted limit. Text messages will provide a summary indicator of time spent speeding in the last day and comparisons with performance of other drivers. Drivers will be able to text back to receive locations of speed violations in the last day.

Category

Behavior

2

Description

Intervention group: GROUP B (GAIN OF REWARD): Drivers will receive real-time alerts, daily text messages, and rewards that would increase to a maximum of 100000 Tomans per month based on their daily performance

Category

Behavior

3

Description

Intervention group: GROUP C (LOSS OF REWARD): Drivers will receive real-time alerts, daily text messages, and will be offered 100000 Tomans at the beginning of each month if they maintain a perfect driving record but will see the rewards diminish with poor performance.

Category

Behavior

4

Description

Control group(NO INTERVENTION): Drivers will be unobtrusively monitored using telematics devices

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Non Communicable Diseases Research Center

Full name of responsible person

Negar Rezaei

Street address

Jalal Al-e-Ahmad Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1911713735

Phone

+98 21 8863 1293

Email

rezaei@ncdrc.info

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

Dr Malekzadeh

Street address

#21,Besat St., Fatemi St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419693111

Phone

+98 21 6692 3561

Email

nimadiran@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Institute for Medical Research Development

Proportion provided by this source

100

Public or private sector

Private

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

Tehran University of Medical Sciences

Full name of responsible person

Negar Rezaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Second Floor, No.10, Jalal Al-e-Ahmad Highway,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1911713735

Phone

+98 21 8863 1293

Email

rezaei@ncdrc.info

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Negar Rezaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Second Floor, No.10, Jalal Al-e-Ahmad Highway,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1911713735

Phone

+98 21 8863 1293

Email

rezaei@ncdrc.info

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazila Rezaei

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Second Floor, No.10, Jalal Al-e-Ahmad Highway,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1911713735

Phone

+98 21 8863 1293

Email

n.rezaei@ncdrc.info

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

a part of data related to primary outcome

When the data will become available and for how long

The access period begins a few months after the publication of the results, depending on the opinion of the Steering Committee

To whom data/document is available

For researchers working in academic, scientific and non-academic institutions who are also engaged in the industry

Under which criteria data/document could be used

The use of documents is in any case subject to the permission of the Steering Committee

From where data/document is obtainable

Dr. Negar Rezaei

What processes are involved for a request to access data/document

It varies depending on the type of application and the

