

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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#### Phone

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#### 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

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#### Province

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#### 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

process of the Steering Committee

**Comments**