

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

An approach towards reducing road traffic injuries and improving public health through big-data telematics: a randomized trial

Protocol summary

Study aim

Effect of Telematics in reducing road traffic injuries

Design

This study is an intelligent trial which will be conducted by equipping 2000 vehicle with telematics (a device which collect and transfer data from engine and driving style to a data warehouse).

Settings and conduct

Vehicles will be randomly assigned to control vs. intervention. Data regarding any driving patterns and traffic accidents will be collected from both arms (intervention and control) for 18 months and to estimate the efficacy of device on several outcomes. The devices will also provide descriptive data on air pollution and roads conditions as well as specific markers of high-risk driving patterns, such as speed, sudden acceleration, deceleration, changing direction etc. These markers will be used as the main study outcomes to measure the efficacy of the intervention. Only in the intervention arm, the device will send two types of feedback to drivers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years old, having driving certificate, owning the vehicle or being the driver of the vehicle, having informed consent, having mobile for receiving SMS. Exclusion criteria: addiction, having criminal record

Intervention groups

Our Telematics provided GPS-based travel data and accelerometer-based crash information and sensory data for the purpose of this research. All data comes will be stored in systems database which makes it possible to load the data conveniently into our designed analytical software packages without noticeable pre processing. . the intervention group will receive SMS feed back and control group do not receive any SMS .

Main outcome variables

parameters such as high risk driving pattern ,...to measure efficacy of intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040391N1**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Nazila Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-26, 1396/09/05

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

2017-11-26, 1396/09/05

Actual recruitment end date

2018-01-19, 1396/10/29

Trial completion date

2018-01-19, 1396/10/29

Scientific title

An approach towards reducing road traffic injuries and improving public health through big-data telematics: a randomized trial

Public title

Effect of Telematics in reducing road traffic injuries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age over 18 years old having driving certificate owing the vehicle or being the driver of the vehicle having inform consent having mobile for receiving SMS

Exclusion criteria:

addiction having criminal record

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **2000**

Actual sample size reached: **2000**

Randomization (investigator's opinion)

Randomized

Randomization description

clusters were randomly allocated to intervention and control group by simple randomization method .

Blinding (investigator's opinion)

Single blinded

Blinding description

the participants do not know about who will receive SMS

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

No. 21, Beasat Str. West Fatemi Str

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR. NIMAD. REC.1394.016

Health conditions studied

1

Description of health condition studied

Examination for driving licence

ICD-10 code

Z02.4

ICD-10 code description

Encounter for examination for driving license

Primary outcomes

1

Description

Driver's driving behavior

Timepoint

Every week for 18 months

Method of measurement

from our servers from the data that Telematix sent

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: SMS from TELEMATIX

Category

Prevention

2

Description

Control group: Do not receive SMS from TELEMATIX

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Non_Communicable Diseases Research center

Full name of responsible person

Ayyoob Jafari

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Second floor, No. 10, Jalal Al-e-Ahmad Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

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Grant name

National Institute for Medical Research Development

Grant code / Reference number

940567

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

No

Title of funding source

National Institute for Medical Research Development

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

Tehran University of Medical Sciences

Full name of responsible person

Nazila Rezaei

Position

Associate Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

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Position

Associate Professor

Latest degree

Specialist

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Epidemiology

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Person responsible for updating data

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Full name of responsible person

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available