

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The Effect of Nicotine on Cognitive functions and Positive Affection in individual with Mild Cognitive Impairment

#### Protocol summary

##### Study aim

The aim of this study was to determine the effectiveness of nicotine on working memory and positive emotion in patients with MCI (Mild Cognitive Impairment).

##### Design

Clinical trial with control group, with parallel group, double-blind, randomized, phase 2 on 30 patients. For randomization, SNOSE method (sealed envelope) and computer software for generating random numbers were used.

##### Settings and conduct

This study was performed in neurology clinics in Tabriz. Patients were selected by convenience sampling method. Then they were randomly divided into control and intervention groups. The intervention group was given chewing gum contain of nicotine and the control group was given non-nicotine gum. Participants, researchers and analyzers of the results, were unaware of the study groups type (blinded).

##### Participants/Inclusion and exclusion criteria

Participants included 30 male patients referred to clinics and medical centers in Tabriz city who were selected by convenience sampling method and randomly assigned to the control and intervention groups. Inclusion criteria included male patients, age between 20 and 60 years, having a definitive diagnosis of mild cognitive impairment, no heart and brain disease, no use of psychiatric drugs, no hypertension and no smoking. Exclusion criteria also included unwillingness to participate in the study or withdrawal from the study and the occurrence of side effects after nicotine use.

##### Intervention groups

The intervention group consisted of 15 male patients with mild cognitive impairment who received chewing gum containing 2/mg of nicotine. The control group also included 15 male patients with mild cognitive impairment who received non-nicotine gum.

##### Main outcome variables

Enhancement of working memory, increase of positive

affect

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190418043313N1**

Registration date: **2022-01-13, 1400/10/23**

Registration timing: **retrospective**

Last update: **2022-01-13, 1400/10/23**

Update count: **0**

##### Registration date

2022-01-13, 1400/10/23

##### Registrant information

##### Name

Esmail Khodadadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3198 2103

##### Email address

esmailkhodadadi11@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-02, 1398/02/12

##### Expected recruitment end date

2019-06-02, 1398/03/12

##### Actual recruitment start date

2019-05-02, 1398/02/12

##### Actual recruitment end date

2019-05-31, 1398/03/10

##### Trial completion date

2019-06-05, 1398/03/15

### Scientific title

The Effect of Nicotine on Cognitive functions and Positive Affection in individual with Mild Cognitive Impairment

### Public title

The effect of nicotine on cognitive function

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Male patients Age between 20 and 60 years Have a definitive diagnosis of mild cognitive impairment No risk of heart and brain disease No use of psychiatric drugs No risk of hypertension Not being a smoker

#### Exclusion criteria:

Having severe cognitive impairment Inability to communicate with researcher and answer the questionnaire

### Age

From **20 years** old to **60 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **30**

Actual sample size reached: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The samples were assigned to two groups of intervention and control, randomly and using random numbers by computer software to generate random numbers (Random sequence generation). Also, the SNOSE (Sequentially numbered, opaque, sealed envelope) method was used for concealment. The number of envelope numbers was prepared and a number was placed inside each of them. The sealed envelopes were then selected by an anonymous person, and after the envelopes were opened, the type of group of participants was determined.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is blinded for participants, principal investigator and co-researcher, data collectors, outcome assessor and data analyser. It should be noted that participants were explained about the purpose and intervention and informed consent was obtained from them, but to avoid bias, they were not informed about their group in study.

### Placebo

Used

### Assignment

Parallel

### Other design features

The design of this study, is before and after intervention with the control group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Islamic Azad University-Tabriz Branch

##### Street address

Islamic Azad University, Tabriz Branch, Basij Highway, Azad University Square.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157944533

#### Approval date

2019-01-01, 1397/10/11

#### Ethics committee reference number

IR.IAU.TABRIZ.REC.1397.032

## Health conditions studied

### 1

#### Description of health condition studied

Mild cognitive impairment

#### ICD-10 code

G31.84

#### ICD-10 code description

Mild cognitive impairment, so stated

## Primary outcomes

### 1

#### Description

Working memory score in Wechsler Memory Scale

#### Timepoint

Before and after 2 hours of intervention

#### Method of measurement

Wechsler Memory Scale

### 2

#### Description

Positive affect score in PANAS questionnaire

#### Timepoint

Before and after 2 hours of intervention

#### Method of measurement

Positive and Negative Affect Schedule (PANAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Each member of the intervention group was given a chewing gum made by Nikolife Company containing 2 mg of nicotine at a time and the participants chewed it for 2 hours.

#### Category

Treatment - Other

### 2

#### Description

Control group: Receiving of chewing gum without nicotine for 2 hours.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neurology Clinic of Imam Reza Hospital, Tabriz

##### Full name of responsible person

Esmail Khodadadi

##### Street address

Golgasht Street, front of the central organization of the Tabriz university of medical sciences, Tabriz, Iran

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3334 7059

##### Fax

##### Email

esmailkhodadadi11@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Esmail Khodadadi

##### Street address

Basij Highway, Azad University Square, Tabriz, Iran

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157944533

##### Phone

+98 41 3331 8681

##### Email

esmailkhodadadi11@gmail.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Islamic Azad University, Tabriz Branch

#### 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

Islamic Azad University

##### Full name of responsible person

Esmail Khodadadi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Public Health

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Basij Highway, Azad University Square, Tabriz, Iran

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## Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

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**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**

All potential data can be shared after identifying participants.

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

No change or manipulation of data

**From where data/document is obtainable**

Email address: esmailkhodadadi11@gmail.com Phone number: 00989143481951 Responsible Name: Esmail Khodadadi

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

Request to send data via email, commitment not to change or manipulate data, commitment to notify results, send data after 3 working days.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Esmail Khodadadi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Public Health

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