

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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

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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