Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Esmail Khodadadi
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Associate professor
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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