

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Development and Evaluation of Serious Games for Diagnosis and Cognitive Improvement of Patients with Mild Cognitive Impairment(MCI)

Protocol summary

Study aim

To develop a serious game for assessment and improvement of cognitive status of patients with mild cognitive impairment(MCI).

Design

A before-after study without control group on 30 MCI patients , without blinding, to compare the MMSE and ACE-R score, before and after playing the game

Settings and conduct

According to the number of patients referred to Brain and Cognition Clinic in Iran University of Medical Sciences, 30 patients who are at the MCI stage will be selected using convenience and purposive sampling methods. Selecting patients, holding a briefing session, and implementing MMSE/ACE-R are accomplished by a neurologist in Brain and Cognition Clinic in Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

A neurologist should confirm the initial diagnosis of mild cognitive impairment in patients. Participant should have almost the same medical test result. Participants should not have disabilities in the upper limbs. A neurologist should confirm participants have no other mental health problems. Participants should be willing to participate in the study and complete the informed consent form.

Intervention groups

The participants are asked to play parts of the game as prescribed by a neurologist, three days a week, at least 45 min each time, for three months at home since the appointed date. Results of each game run are considered as a point and recorded along with the duration of the study. At the end of three months, Mini-Mental State Exam (MMSE) and Addenbrooke's Cognitive Examination-Revised (ACE-R) will be retaken from the participants by the same neurologist at the same location.

Main outcome variables

Mini-Mental State Exam (MMSE) score before and three months after playing games; Addenbrooke's Cognitive Examination-Revised (ACE-R) score before and three

months after playing games

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211020052824N1**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Abbas Sheikhtaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and Evaluation of Serious Games for Diagnosis and Cognitive Improvement of Patients with Mild Cognitive Impairment(MCI)

Public title

Serious games for patients with mild cognitive impairment (MCI)

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

A neurologist should confirm the initial diagnosis of MCI in patients. Participants should have almost the same medical test results. They should be willing to participate in the study and complete the informed consent form.

Exclusion criteria:

Participants have disabilities in the upper limbs. participants have other mental health problems according to the neurologist.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway, Tehran, Iran

City

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Province

Tehran

Postal code

14665354

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1397.1364

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

Mini-Mental State Examination (MMSE) test score

Timepoint

At beginning of study and after three months

Method of measurement

This outcome will be measured using standard Mini-Mental State Examination (MMSE) test. MMSE is the most common test applied to assess cognitive impairment. MMSE has been translated into Persian and validated for Iranians. Implementing MMSE will be accomplished by a neurologist in Brain and Cognition Clinic in Iran University of Medical Sciences at the beginning of the study. At the end of three months, MMSE will be retaken from the participants by the same neurologist at the same location.

2

Description

Addenbrooke's Cognitive Examination (ACE_R) test score

Timepoint

At beginning of study and after three months

Method of measurement

This outcome will be measured using Addenbrooke's Cognitive Examination-Revised version tools. This test examines memory, language, and visual-spatial skills more broadly than MMSE and includes verbal fluency components. ACE-R has been translated into Persian and validated for Iranians. Implementing ACE-R will be accomplished by a neurologist in Brain and Cognition Clinic in Iran University of Medical Sciences at the beginning of the study. At the end of three months, ACE-R will be retaken from the participants by the same neurologist at the same location.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants will be asked to play parts of the game as prescribed by a neurologist, three days a week, at least 45 min each time, for three months at home since the appointed date. Results of each game will be considered as a point and recorded along with the duration of the study. The proposed game will be designed for Attention and orientation, Memory, Language, and Visuospatial aspects based on the cognitive aspects of ACE-R and MMSE tests. This game will be an Android-based game which will be developed by the researchers after conducting a systematic review on the available games. The proposed game contains some little games, and each of these games will be related with a cognitive aspect of these two tests.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and cognitive clinic in Iran University of Medical Sciences

Full name of responsible person

Mostafa Almasi-Dooghaee

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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?

Yes

Title of funding source

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Abbas Sheikhtaheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

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Farveh Sabermahani

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Master

Other areas of specialty/work

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The result of the systematic review regarding the game scenarios and their effectiveness. Design consideration and the degree of correlation between the proposed game's score and the results of clinical tests. The effect of the suggested game on the participants' cognitive abilities.

When the data will become available and for how long

From beginning of 2022

To whom data/document is available

Researchers who intended to the field of this study

Under which criteria data/document could be used

In selection or design serious game for patients with mild cognitive impairment

From where data/document is obtainable

Abbas Sheikhtaheri

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

Contact with sheikhtaheri.a@iums.ac.ir

Comments