

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effectiveness of Cognitive Rehabilitation Therapy (CRT) on enhancement of executive functions (EF) in patients with HIV-infection (CH)

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of 24-session 3-month cognitive rehabilitation on cognitive functioning of HIV positive patients

Design

Current study is a clinical trial with parallel group design and 60 eligible persons will randomly assign to one of intervention (30)and control group(30)

Settings and conduct

location of conducting current project is Iranian research center for HIV/AIDS(IRCHA) situated in Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria:1-Diagnosed with HIV infection 2-18 < Age > 50 3-No history of CD4 count under 200 cells/mm³ 4-No History of hospitalization because of any kind of opportunistic infection 5-Not Co-infected with Hepatitis C 6-No current use of psychiatric medication 7-No drug/Alcohol use/abuse(Abstinent for at least 2 years) 8- History of any kind of head trauma/Injury 9-Consented for participation Exclusion criteria:1-Significant visual and auditory damage 2-Not diagnosed with severe anxiety or depression

Intervention groups

The participants in the intervention group for 3 months performing computerized cognitive training. participants of the control group will be asked to maintain their levels of physical activity during study period.

Main outcome variables

Cognitive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100601004076N22**

Registration date: **2018-09-09, 1397/06/18**

Registration timing: **retrospective**

Last update: **2018-09-09, 1397/06/18**

Update count: **0**

Registration date

2018-09-09, 1397/06/18

Registrant information

Name

Mino0 Mohraz

Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 7984

Email address

minoomohraz@ams.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Cognitive Rehabilitation Therapy (CRT) on enhancement of executive functions (EF) in patients with HIV-infection (CH)

Public title

Brain cognitive function rehabilitation in HIV-infected patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with HIV infection 18 < Age > 50 No history of CD4 count under 200 cells/mm³ No History of hospitalization because of any kind of opportunistic infection Not Co-infected with Hepatitis C No current use of psychiatric medication No drug/Alcohol use/abuse(Abstinent for at least 2 years) History of any kind of head trauma/Injury Consented for participation

Exclusion criteria:

Significant visual and auditory damage Not diagnosed with severe anxiety or depression

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible volunteers will randomly be assigned to intervention and control groups. randomization will be done by a randomization list that will be generated by computerized software program.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are not informed weather they are in control group or experimental group. They don't know if others are receiving rehabilitation or not.

Placebo

Not used

Assignment

Other

Other design features

Participants are considered as experimental group if they be able to participate in whole 24 rehabilitation sections for 3 months, the remains are determine as control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Tehran University of Medical Sciences

Street address

Central building of TUMS, Ghods St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

0123456789

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3323

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Cognitive function

Timepoint

pre and post study period and 3 months after end up the study

Method of measurement

computerized cognitive test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants will participate in 24 90-minute cognitive rehabilitation sections twice a week including 9 cognitive practices which get harder every section gradually to enhance the effectiveness of the practice on the one's cognition.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian research center for HIV/AIDS(IRCHA)

Full name of responsible person

Minoos Mohraz

Street address

Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1583
Email
ircha@tums.ac.ir
Web page address
http://ircha.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice-presidency for science and technology
Full name of responsible person
Zeinab Farhadi
Street address
33, 5th St., North Kargar St
City
Tehran
Province
Tehran
Postal code
1439634665
Phone
+98 21 8216 1127
Fax
Email
companies@insf.org
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice-presidency for science and technology
Proportion provided by this source
75
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Minoos Mohraz

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Iranian Research Center for HIV/AIDS (IRCHA), Imam Khomeini Hospital
City
Tehran
Province
Tehran
Postal code
1956865432
Phone
+98 21 6694 7984
Email
ircha@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maede sadat Etesami
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Iranian research center for HIV/AIDS, Imam Khomeini hospital
City
Tehran
Province
Tehran
Postal code
1123565479
Phone
+98 21 6658 1583
Email
msetesamy@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maede Sadat Etesami
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address

Iranian Research Center for HIV/AIDS, Imam Khomeini
Hospital

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 6694 7984

Email

msetesamy@gmail.com

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

No - There is not 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

Not applicable

Data Dictionary

Not applicable