

# 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/mm<sup>3</sup> 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

Minoos 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/mm<sup>3</sup> 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.  
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+98 21 6658 1583  
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**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  
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Tehran  
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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  
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## Person responsible for scientific inquiries

#### Contact

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Maede sadat Etesami  
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Researcher  
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## Person responsible for updating data

#### Contact

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**Postal code**

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**Phone**

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**Email**

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**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