Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Impact of Four Months Resistance Training and Recreational Sport Activities on CD4 Level, Body Composition and Psychological Health among HIV Infected Men in Tehran Positive Club

Protocol summary

Summary

The main goal of this project is to study effects of four months resistance training and recreational sport activities on CD4 level, quality of life, quality of sleep, anxiety and depression, clinical symptoms and body composition among HIV infected men. These group will be compare with the group of HIV infected men in control group without any physical activities during 4 months. Participants consist of 45 HIV positive men (with inclusion criteria include: being between 18 to 45 years old; don't be on highly active antiretroviral therapy or do not take any antiretroviral treatment at least in last six months; do not be actively addicted to any drug; be cooperative in this study and follow ups; do not have physical exercises in last six months) and will be exclude from the study if they take psychological drugs in order to treatment of anxiety and depression; has unstable condition regarding HIV infection status; has exacerbation in health condition during the study in a way that he could not do physical exercises. HIV positive men will be divided in three groups randomly which are mentioned below; men who will do resistance training for 4 months (15 participants); men who will do recreational sport activities for 4 months (15 participants); men who will do no physical activities for 4 months (15 participants).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604034076N18**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Minoo 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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Four Months Resistance Training and Recreational Sport Activities on CD4 Level, Body Composition and Psychological Health among HIV Infected Men in Tehran Positive Club

Public title

The Impact of Resistance Training and Recreational Sport

Activities on CD4 Level, Body composition and Psychological Health among HIV Infected Men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Be between 18 to 45 years old; don't be on highly active antiretroviral therapy or do not take any antiretroviral treatment at least in last six months; do not be actively addicted to any drug; be cooperative in this study and follow ups; do not have physical exercises in last six months. Exclusion criteria: Takes psychological drugs; has unstable condition regarding HIV infection status; has exacerbation in health condition during the study in a way that he could not do physical exercises

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Central building of TUMS, Ghods St, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.TUMS.REC.1395.2348

Health conditions studied

1

Description of health condition studied

HIV/AIDS

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases

Primary outcomes

1

Description

CD4 level

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Laboratory tests

Secondary outcomes

1

Description

Sleep quality

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Sleep Quality questionnaire (PSQI)

2

Description

Anxiety and depression

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Anxiety and Depression questionnaire (HAD)

3

Description

Body composition

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Body composition device

4

Description

Quality of life

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Quality of life questionnaire (SF-36)

5

Description

Clinical symptoms

Timepoint
Before intervention and 4 months after intervention
Method of measurement
Clinical symptoms checklist (MSCL & SCL90-R)

Intervention groups

1

Description
Intervention group: In this clinical trial, after getting consent of participants, we will conduct interviews based on questionnaires and following by that body composition of participants will be measured by body composition machine. These participants will be divided in three groups randomly. People in first group with resistance training, will do exercises with emphasis on big muscles three times a week for four months. The other group with recreational sport activities will do activities such as Ping-Pong, foosball and throwing darts three times a week based on their interests. At the end of four months, all the participants in three groups will be assessed body composition, CD4 level and Psychological Health.
Category
Other

2

Description
Control group: In this group no intervention will be made.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran positive club
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Resaerch Deputy of Tehran University of Medical Sciences
Full name of responsible person
Dr Younesian
Street address
Ghods Avn, Keshavarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Resaerch Deputy of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iranian Research Center for HIV/AIDS (IRCHA)
Full name of responsible person
Dr Minoo Mohraz
Position
Head of IRCHA
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iranian Research Center for HIV/AIDS
Full name of responsible person
Dr Minoo Mohraz
Position
Professor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Iranian Research Center for HIV/AIDS

Full name of responsible person

Farzaneh Vakil Ghahani

Position

Msc

Other areas of specialty/work

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Iranian Research Center for HIV/AIDS, Imam Khomeini Hospital, Keshavarz Blvd

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00

Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty