

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial investigating the effect of yoga on cognitive functions in women with HIV

Protocol summary

Study aim

Evaluation of the effect of yoga on cognitive functions in women with HIV

Design

In this single-blind clinical trial, 44 HIV patients will be assigned into parallel groups using the random blocks method.

Settings and conduct

The study population consists of HIV-infected women undergoing treatment at Behavioral Disease Counseling Center, Hamadan, Iran. In this single-blind study, the person responsible for data collection is blind to the type of treatment in participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Not participating in similar fitness activities. Exclusion criteria: Inability to perform respiratory, physical, and relaxation exercises; moderate to severe hepatic disorder; cardiovascular diseases; drug abuse; not doing regular exercise.

Intervention groups

The control group will not receive special training in addition to the routine treatment. The intervention group will receive yoga exercises, along with the treatment, consisting of two 1-hour sessions per week under the supervision of yoga teachers, one 1-hour session at home, and 15-minute relaxation exercises at the end of each session for 8 weeks.

Main outcome variables

Evaluation and comparison of cognitive functions between intervention and control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191216045756N1**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **prospective**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

Shahla Adelkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3837 1164

Email address

adelkhanis@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-09-18, 1399/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial investigating the effect of yoga on cognitive functions in women with HIV

Public title

Effect of yoga on cognitive functions in HIV patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Not participating in similar fitness activities

Exclusion criteria:
Inability to perform respiratory, physical, and relaxation exercises
Moderate to severe hepatic disorder
Cardiovascular diseases
Drug abuse
Not doing regular exercise

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects will be randomly assigned into two groups of 22 patients with blocks of 2 and 4 using the randomization method. A noninvolved researcher will determine the random allocation sequencing in sample selection using a the SAS software. Sequentially numbered sealed opaque envelopes will be used to conceal the sequencing. Accordingly, the participants will be given codes and assigned into the intervention and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study population consists of HIV-infected women undergoing treatment at Behavioral Disease Counseling Center, Hamadan, Iran. In this single-blind study, the person responsible for data collection is blind to the type of treatment in participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Vice Chancellor for Research, Hamedan University of Medical Sciences, Shahid Fahmideh Street

City

Hamedan

Province

Hamadan

Postal code
6517838678

Approval date
2019-12-12, 1398/09/21

Ethics committee reference number
IR.UMSHA.REC.1398.758

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

B20.0

ICD-10 code description

HIV disease resulting in mycobacterial infection

Primary outcomes

1

Description

Cognitive functions

Timepoint

Before and after the intervention

Method of measurement

Based on quantitative electroencephalography (QEEG)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive yoga exercises, along with the treatment, consisting of two 1-hour sessions per week under the supervision of yoga teachers, one 1-hour session at home, and 15-minute relaxation exercises at the end of each session for 8 weeks.

Category

Other

2

Description

Control group: The control group will not receive special training in addition to the routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Behavioral Counseling Center

Full name of responsible person
Shahla Adelkhani
Street address
Beginning at Takhti Street, Martyrs Health Center
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Hamadan
Postal code
6517838654
Phone
+98 81 3252 1411
Fax
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Hamedan_health@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Vice Chancellor for Research, Hamedan University of Medical Sciences, Shahid Fahmideh Street
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6517838678
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webda@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Islamic Azad University

Full name of responsible person
Shahla Adelkhani
Position
Student
Latest degree
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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and
secondary effects to be shared.

**When the data will become available and for how
long**

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in
science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science
center and university.

From where data/document is obtainable

Shahla Adelkhani provides the analysis code to the
applicants via email: adelkhanis@yahoo.com

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

Applicants can respond to the email of the respondent
and receive a response within a week.

Comments