

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of mindfulness based stress reduction (MBSR) on CD4+ T Lymphocyte Count and Medical and Psychological Symptoms of HIV/AIDS infected patients referring to counseling center for behavioral diseases in Imam Khomeini Hospital, 2008

Protocol summary

Summary

This study evaluated the immediate and longer-term effectiveness of the mindfulness-based stress reduction (MBSR) program on CD4+ T Lymphocyte Count and medical and psychological symptoms among HIV+ patients in Tehran, Iran. Using a randomized controlled trial, data were obtained from HIV+ patients not yet receiving antiretroviral therapy who participated in either an 8-week MBSR (n=85) or a brief education and support condition (ESC) (n=86) at the Imam Khomeini Hospital. Assessments included CD4 count, Symptom Checklist-90-Revised (SCL-90R), and Medical Symptom Checklist (MSCL) at baseline, immediate post-test, and 3, 6, 9 and 12-month follow-up periods.

General information

Acronym

MBSR2

IRCT registration information

IRCT registration number: **IRCT201106084076N2**

Registration date: **2011-11-27, 1390/09/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-27, 1390/09/06

Registrant information

Name

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Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-06-09, 1387/03/20

Expected recruitment end date

2011-06-10, 1390/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness based stress reduction (MBSR) on CD4+ T Lymphocyte Count and Medical and Psychological Symptoms of HIV/AIDS infected patients referring to counseling center for behavioral diseases in Imam Khomeini Hospital, 2008

Public title

The effect of mindfulness based stress reduction on HIV patients

Purpose

Treatment

Inclusion/Exclusion criteria

HIV positive patients were eligible to participate in the study if they had these conditions: HIV+ confirmed by Western Blot, CD4 >200, Age >18, and Age ≤55, patients

were excluded if they had: current substance addiction, current psychosis, history of post-traumatic stress disorder, or if they had CD4 count under 200, or were clinically symptomatic (e.g., herpes zoster, oral candidiasis, shingles, significant weight loss)

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **245**

Randomization (investigator's opinion)

Randomized

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**

Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Ghods St

City

Tehran

Postal code

1148567

Approval date

2007-09-23, 1386/07/01

Ethics committee reference number

6503-55-04-86

Health conditions studied**1****Description of health condition studied**

HIV infected people

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes**1****Description**

CD4 lymphocyte count

Timepoint

Participants did CD4 count at pretest, immediate posttest, and 3, 6, 9 and 12 month post-intervention follow-up periods

Method of measurement

CD4 count was determined by flow cytometry

Secondary outcomes**1****Description**

Medical Symptom Checklist (MSCL) which is a 115-item self-report measure of physical symptomatology that quantifies the number of common medical symptoms occurring in the previous month, and Symptom Checklist-90-Revised (SCL-90R) includes a 90-item self-report of mental health measured on a 5-point rating scale to assess a broad range of psychological problems and symptoms of psychopathology

Timepoint

Participants completed the self-report questionnaires at pretest, immediate posttest, and 3, 6, 9 and 12 month post-intervention follow-up periods

Method of measurement

MSCL and SCL-90R Questionnaires

Intervention groups**1****Description**

Participants in the MBSR condition attended eight weekly group-based MBSR classes. MBSR is implemented in a class setting, in which sitting meditation, gentle mindful hatha yoga, a body scan meditation, and other approaches to cultivate mindfulness in everyday living are introduced. A psychologist who was formally trained in the MBSR program at the University of Massachusetts Center delivered the classes. In brief, session 1 and 2 consisted of a mindfulness body scan practice. Session 3 and 4 consisted of awareness of body postures via light Hatha yoga practices. Sessions 5 through 7 consisted of sitting mindfulness meditation. Session 8 consisted of a retreat lasting 6-7 hours, which incorporated all the practices learned in sessions 1 through 7. During the final session, a general discussion took place regarding encountering stress and how to apply MBSR techniques in daily life. Participants in control group received their usual clinical attention. Control group was provided with educational information and pamphlets about living healthy with HIV/AIDS. Education content focused on the following topics: 1) routes of HIV transmission, 2) HIV prevention, 3) facts and expectations about HIV drug therapy, and 4) maintaining positive behavior and cognitions while living with HIV. A psychologist was also

available for the control group members during the intervention period to provide individual counselling.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Voluntary Counselling and Testing (VCT) centre of Imam Khomeini hospital

Full name of responsible person

Maryam Foroughi

Street address

Imam Khomeini hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran deputy of research/Shabnam Norouz zadeh

Street address

Keshavarz Blvd, Qods street

City

Tehran

Grant name

گزارت معاونت پژوهشی دانشگاه تهران

Grant code / Reference number

6503

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Full name of responsible person

Maryam Foroughi

Position

MD

Other areas of specialty/work

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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