Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
گرانت 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
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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