

Role of yoga therapy against tuberculosis in people living with HIV infection

Submission date 19/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/06/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tuberculosis continues to be a major public health challenge in India and it is one of the most common opportunistic infection in people living with HIV (PLHIV). PLHIV has an 8 times higher risk of developing TB than persons without TB infection. The risk increases with the progression of HIV and the lowering of the CD4 T cell count. PLHIV resort to the use of traditional and complementary medicine (T & CM) to supplement antiretroviral treatment in order improve their health and quality of life. One such T & CM is yoga therapy to improve respiratory (breathing) functions. The aim of this study is to assess the effect of yoga therapy against TB in PLHIV.

Who can participate?

People living with HIV infection aged 18-65 years who are taking antiretroviral treatment and who have received or completed isoniazid prophylactic therapy, and who are physically fit to perform yoga therapy.

What does the study involve?

Participants are randomly allocated to the intervention group or the control group. The intervention group receive yoga therapy and the control group receive usual care and support. The yoga therapy intervention includes asana, pranayama and yoga nidra in a structured way delivered by a trained qualified yoga instructor.

What are the possible benefits and risks of participating?

Participants in the intervention group may benefit from an improvement in CD4 T cell count and viral load and possible prevention of tuberculosis. There are no risks involved.

Where is the study run from?

Public Health Foundation of India (India)

When is the study starting and how long is it expected to run for?

December 2019 to March 2023

Who is funding the study?

Department of Science and Technology, Government of India (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
LN0899

Study information

Scientific Title
Role of yoga therapy against tuberculosis in people living with HIV infection: a randomized controlled trial

Acronym
Yoga TB project

Study objectives
Is yoga therapy effective against primary prevention of tuberculosis in people living with HIV infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 09/01/2020, Institutional Ethics Committee, Smt NHL Municipal Medical College (Ahmedabad Ellisbridge, Ahmedabad 380006 Gujarat, India; +91 (0)79 26576275; nhlic2019@gmail.com), ref: YHIV/AC/DST/12/2019
2. Approved 05/03/2021, Institutional Ethics Committee (Public Health Foundation of India Delhi NCR, Plot No. 47, Sector 44, Institutional Area, Gurgaon – 122002, India; +91 (0)124-4781400; contact@phfi.org), ref: TRC-IEC 451/20

Study design

Double-arm randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of tuberculosis in people living with HIV infection

Interventions

Eligible People Living with HIV (PLHIV) are allocated to the interventional group and the control group by a simple random allocation. This is done by an independent statistician with the help of a computer-generated random number table. The random allocation sequence is concealed from the independent statistician enrolling the participants. Masking is not possible due to a strong PLHIV network and patient staying in the same locality or job place. The outcome assessor will be blind for assessing the study outcome.

Intervention group: PLHIV in the intervention group are provided with a yoga therapy intervention. This consists of a joint loosening exercise (5 min), asana (yogic postures, 10 min), pranayama (yogic breathing exercise, 10 min) and yoga nidra (guided meditational sleep, 15 min). A 40-minute session is given to the PLHIV once a month for 3 months, followed by high definition video, audio and booklet. Participants are asked to practice yoga therapy at home. The total duration of intervention is 3 months followed by first follow up at 6 months from enrolment and then six-monthly until 2 years. The yoga therapy intervention is given by a trained and qualified (graduate degree holder) yoga trainer.

Control group: PLHIV in the control group are not given yoga therapy intervention and are given the usual care and support.

Intervention Type

Behavioural

Primary outcome(s)

1. Occurrence of tuberculosis among PLHIV, diagnosed by Nucleic Acid Amplification test (NAAT), or sputum smear microscopy or chest X-ray when a PLHIV has a presumptive TB as evident by positive 4S symptom screening consisting of cough, fever, weight loss or night sweat, presence of any one irrespective of duration.
2. CD4 T cell count measured by flow cytometry methods at baseline, 6, 12, 18, and 24 months
3. Viral load measured using real time PCR at baseline, 6, 12, 18, and 24 months

Key secondary outcome(s)

1. Proportion of opportunistic infections other than tuberculosis, measured by taking clinical history at baseline, 6,12, 18 and 24 months
2. Treatment outcome of the diagnosed TB cases amongst PLHIV, measured by sputum smear microscopy at the end of the intensive phase of anti TB treatment and at the end of continuation phase of anti TB treatment

Completion date

16/03/2023

Eligibility

Key inclusion criteria

1. Age 18 - 65 years irrespective of gender
2. Documented HIV diagnosis
3. PLHIV on antiretroviral treatment and stable
4. Received or completed isoniazid prophylaxis therapy
5. Physically fit to perform yoga therapy as self-assessed
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

1800

Key exclusion criteria

1. Pregnant
2. Seriously ill or moribund PLHIV
3. Practicing yoga therapy >150 minutes/week
4. COVID-19 positive patients

Date of first enrolment

01/04/2020

Date of final enrolment

31/05/2020

Locations

Countries of recruitment

India

Study participating centre

Anti Retroviral Treatment Center

VS General Hospital

Ellisbridge

Ahmedabad

India

380006

Sponsor information

Organisation

Public Health Foundation of India

ROR

<https://ror.org/058s20p71>

Funder(s)

Funder type

Government

Funder Name

Department of Science and Technology, Ministry of Science and Technology, India

Alternative Name(s)

Department Of Science & Technology | , Department of Science and Technology, , , , , Department of Science & Technology, Ministry of Science and Technology, India, Department of Science & Technology, Department of Science and Technology (India), DSTIndia, IndiaDST, Department of Science and Technology, Government of India, Department of Science & Technology (DST), DST,

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

India

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due as we are obliged to not share participant level data as per the HIV prevention act 2017.

IPD sharing plan summary

Not expected to be made available