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Randomised Controlled Trial on Highly Active AntiRetroviral Therapy (HAART), social networks, and adherence in Mozambique

Submission date	Recruitment status	[_] Prospectively registered
22/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00272220

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized control trial of peer-delivered modified directly observed therapy for HAART in Mozambique.

Study objectives
Our hypothesis is that modified Directly Observed Therapy (mDOT) during the initial six weeks of HAART, supervised primarily by Human Immunodeficiency Virus (HIV) positive lay activists, will improve adherence and clinical outcomes compared with those that do not have supervised mDOT.

We also hypothesize that the benefits of mDOT will be achieved through a variety of mediators that will result from the social interactions the patients will have with the activists. These mediators include: improved social support, improved knowledge about HAART, reduced stigma, and improved self-efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Subjects Division (HSD), Washington, number 03-9137-G 01; 18/12/2003

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Adherence to highly active antiretroviral therapy (HAART)

Interventions
The project is a randomized controlled trial among a sample of HIV positive antiretroviral-naive patients newly starting HAART, randomized to either receive six weeks of modified DOT in addition to standard clinical and adherence support, or standard care only.

The package of standard care includes:
clinical and laboratory assessments related to starting and monitoring HAART, including follow-up consults every month for three months, followed by every three months thereafter, and Cluster of Differentiation-4 (CD4) testing at pre-initiation of HAART and every six months.

Pre-HAART adherence assessment, with a social worker, during which AntiRetroViral (ARV) treatment is explained, expectations clarified, and barriers to adherence identified and addressed. A method of patient localization is also required, which may include leaving a phone number or, in cases where phones are not available, a home visit. Treatment partners are recommended but not required.

Post-HAART adherence support is provided through counseling by all members of the healthcare team, including the physician or physicians assistant during regularly scheduled clinic appointments, and a pharmacist or pharmacy technician and social worker at the time of each medication refills. Additional visits are performed as needed by a social worker and activists, who may become involved in cases of poor adherence. Referrals to community-based organizations for adherence support may also be performed.

In addition to this standard package of care, the patients are randomized to the intervention group will receive six weeks of modified DOT. Modified DOT includes supervising, via direct observation, the morning weekday doses of patients medications in the clinic, while night time and weekend doses are self-administered.
The six-week timeframe for mDOT was chosen to cover the initial time of treatment when the importance of adherence may be heightened, when side effects leading to poor adherence may be most pronounced, and when chronic pill-taking behaviors may be reinforced. The direct observation will be performed primarily by DOT activists, who are full-time paid HIV-positive lay employees of the clinic whose primary job is to ensure the adherence of patients on HAART. During DOT sessions, their interactions with patients are to include, in addition to supervising and recording the swallowing of pills, counseling and educating patients regarding general HIV-related information, their treatment, and care plan. Patients not reporting to clinic to take their medication during DOT are located on the same day by the activists usually through home visits or phone calls (if possible). Such patients are also brought their dose of medication to take, and the activists reinforce the importance of good adherence.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Adherence to treatment: increase in both short (six months) and long term (one year) adherence to HAART treatment

Secondary outcome measures
Improvement in clinical outcomes associated with HAART therapy

Overall study start date
01/10/2004

Completion date

30/08/2006

Eligibility

Key inclusion criteria
1. Persons initiating HAART

2. Adults and children 18 years or older

3. Patients living near the geographical area of the study sites Beira, Mozambique, whereby making daily clinic visits if randomized to receive DOT would be possible

4. Agreement to participate in DOT if randomized to that arm of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
367

Key exclusion criteria
1. Psychotic or demented

2. Not willing or able to provide consent to participate

Date of first enrolment
01/10/2004

Date of final enrolment
30/08/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Psychology
Seattle, Washington

United States of America
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Sponsor information

Organisation
University of Washington/Health Alliance International (USA)

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Sponsor type
University/education

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ROR
https://ror.org/00cvxb145

Funder(s)

Funder type
Government

Funder Name
Health Alliance International funding through President's Emergency Plan for AIDS Relief (PEPFAR) 1.5, quick start HIV/AIDS Rapid Expansion Program and TAPS

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2007	28/01/2019	Yes	No