ISRCTN97730834 https://doi.org/10.1186/ISRCTN97730834

Theory- and evidence-based intervention to improve adherence to antiretroviral therapy among human immunodeficiency virus (HIV)-infected patients: the AIMS study

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 22/10/2021	**Condition category** 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

Secondary identifying numbers
NTR176

Study information

Scientific Title
Theory- and evidence-based intervention to improve adherence to antiretroviral therapy among human immunodeficiency virus (HIV)-infected patients: the AIMS study

Study objectives
For an effective long-term suppression of HIV, prevention of resistance, Acquired Immune Deficiency Syndrome (AIDS), and AIDS-related death, high levels of adherence to the treatment are essential. Many interventions to improve adherence have been developed and investigated, but at most with moderate effects on adherence and health outcomes. Furthermore, none of these interventions used MEMS caps (the best adherence measurement instrument currently available) to measure adherence. Therefore, we have developed a new intervention strategy: the Adherence Improving Management Strategy (AIMS or AIM-Strategy). This intervention has been developed using behavioural (change) theories and a review of previous intervention techniques that have been found effective to improve adherence. The use of MEMS caps is a part of the intervention.

However, the intervention has yet to be investigated among a large and heterogeneous group of patients, and with both measures of adherence as well as virological outcomes (residual Ribonucleic Acid [RNA] replication).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
After a baseline period of 2 months during which adherence is registered using MEMS caps, patients are randomised to receive the AIMS-intervention or not. Once the AIMS intervention starts, and after 3 - 4 months (depending on the standard visiting schedule of the individual patient) the intervention will end and both groups will stop using the MEMS cap for two months.

At month 7 - 8, patients in both groups will use the MEMS cap for one final follow-up period of two months. At 0, 2, 5, 7 and 9 months blood will be collected for intracellular HIV-RNA and plasma HIV-RNA measurement. Participants will complete a questionnaire at baseline, once at the end of the intervention period, and once during the follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The primary purpose of the proposed study is to investigate whether or not adherence to HAART can be significantly increased by HIV-nurses using the AIM-Strategy, and whether this is sustained over time
2. Whether or not these improvements result in a decrease of plasma and intracellular HIV-RNA

Secondary outcome measures
1. Furthermore, a questionnaire will be used to see which cognitive variables of the patients are related to (non) adherence and to evaluate whether or not the intervention successfully changes those cognitive variables that cause non-adherence
2. Finally, a process evaluation will be conducted among patients, HIV-nurses and physicians to investigate the advantages (e.g., insight in adherence, detection of treatment problems, improved communication) and disadvantages (e.g. duration intervention sessions, user-friendliness of equipment) of the use of AIMS versus providing standard care

Overall study start date
01/09/2005

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. HIV-1 positive, using highly active anti-retroviral therapy (HAART)
2. Treatment experience for at least 6 months, with a maximum of 5 years
3. Sufficient knowledge of the English or Dutch language (verbal and in writing)
4. No current psychiatric, drug or alcohol problems
5. More or less stable housing
6. Able to give informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Total final enrolment
133

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/09/2005

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Added as of 11/07/2008:

Funder Name
University of Maastricht (The Netherlands) - provided funding for PhD student performing the study

Funder Name
Academic Medical Centre Amsterdam (The Netherlands) - provided MEMS-caps from the HIV outpatient clinic

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results of pilot study results				

Results article		01/06/2005		Yes	No
Results article	results	01/07/2010	22/10/2021	Yes	No