

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

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		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

## Primary study design

Interventional

## Study design

Randomised, active controlled, parallel group trial

## Study type(s)

Treatment

## 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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**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

### 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?
<a href="#">Results article</a>	results of pilot study results	01/06/2005		Yes	No
<a href="#">Results article</a>	results	01/07/2010	22/10/2021	Yes	No