

# The AIMS study.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28192

### Source

NTR

### Brief title

N/A

### Health condition

HIV infection

## Sponsors and support

**Primary sponsor:** Department of Internal Medicine, Division of Infectious Diseases, Tropical Medicine and AIDS, Academic Medical Center, Amsterdam, the Netherlands

Department of Experimental Psychology, Faculty of Psychology, Maastricht University, the Netherlands and Department of Health Education and Promotion, Faculty of Health Sciences, Maastricht University, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

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 intracellular HIV-RNA.

### **Secondary outcome**

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.

## **Study description**

### **Background summary**

For an effective long-term suppression of HIV, prevention of resistance, 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 behavioral (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 RNA replication).

### **Study objective**

N/A

### **Intervention**

After a baseline period of 2 months during which adherence is registered using MEMS-caps, patients are randomized to receive the AIMS-intervention or not.

Next, 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 measurement.

Participants will complete a questionnaire at baseline, once at the end of the intervention period, and once during the follow-up.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

1. HIV-1 positive, using 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.

## Exclusion criteria

N/A

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2005
Enrollment:	200
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	01-09-2005
Application type:	First submission

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL141
NTR-old	NTR176
Other	: N/A
ISRCTN	ISRCTN97730834

## Study results

### Summary results

De Bruin M, Hospers HJ, van den Borne HW, Kok GJ, Prins JM. Theory- and evidence-based intervention to improve adherence to antiretroviral therapy among HIV-infected patients in the Netherlands: a pilot study. *AIDS Patient Care STDS*. 2005;19:384-94.