The AIMS study.

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N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28192

Bron
NTR

Verkorte titel
N/A

Aandoening

HIV infection

Ondersteuning

Primaire 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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Internal Medicine,
F4- 217,
P.O. Box 22660
J.M. Prins
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380

Wetenschappelijk

Academic Medical Center (AMC), Department of Internal Medicine,
F4- 217,
P.O. Box 22660
J.M. Prins
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.