Lifestyle intervention with or without risk-factor passport to reduce cardiovascular disease risk factors at the HIV outpatient clinic.

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To investigate if providing visual feedback about an individuals' personal CVD risk (risk factor passport) and the target risk that can be reached if lifestyle factors are optimally treated has additional value in reducing CVD risk, among patients...

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

Samenvatting

ID

NL-OMON27830

Bron
NTR

Verkorte titel
-

Aandoening

HIV infected persons with an increased cardio vascular risk.

HIV infection, cardiovascular risk, lifestyle, intervention

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference between the intervention and the control group in the 5-year absolute CVD-risk score at month 12.

Toelichting onderzoek

Achtergrond van het onderzoek

HIV infected individuals have a greater risk of cardiovascular disease (CVD) than HIV-negative individuals of the same age and gender. Non-pharmacological lifestyle interventions to reduce CDV are deemed first choice in HIV infected patients to prevent polypharmacy and its potential complications. Research has shown that CVD risk factors are highly prevalent among HIV infected persons >45 years attending the HIV outpatient clinic of the AMC. HIV infected persons from the AMC will be approached to participate in a lifestyle intervention protocol, targeting smoking cessation and weight reduction, to reduce CVD risk as part of routine clinical care. Achieving and sustaining behaviour change is a major and perpetual challenge in medicine, however. Providing individuals with personalised health-related risk information with visual feedback about disease risks may be a method of increasing motivation for behaviour change.

With the present study we aim to investigate if providing visual feedback about an individuals' personal CVD risk and to show the target risk that can be reached if lifestyle factors are optimally treated ("risk factor passport") has additional value in reducing CVD risk, among patients who participate in a lifestyle intervention protocol at the HIV outpatient clinic of the AMC.

Both patients randomly assigned to the intervention group with the risk factor passport and the control group without risk factor passport will receive routine care according to the lifestyle intervention protocol at months 0, 3, 6, 9 and 12. In both groups, lipid levels and blood pressure will be measured at each follow-up visit. The 5-year CVD risk score at month 12 is the primary outcome measure.

Doel van het onderzoek

To investigate if providing visual feedback about an individuals' personal CVD risk (risk factor passport) and the target risk that can be reached if lifestyle factors are optimally treated has additional value in reducing CVD risk, among patients who participate in a lifestyle intervention protocol at the HIV outpatient clinic of the AMC.

Onderzoeksopzet

Months 0, 3, 6, 9 and 12.

Onderzoeksproduct en/of interventie

Both the intervention group with the risk factor passport and the control group without risk factor passport will receive routine care according to the lifestyle intervention protocol at months 0, 3, 6, 9 and 12. In both groups, lipid levels and blood pressure will be measured at each follow-up visit.

In addition to routine care, patients assigned to the intervention group will receive the risk factor passport. At baseline (month 0) the HIV counseling nurse will explain the presence of modifiable and un-modifiable CVD risk factors. Second, the patient will receive a risk-factor passport that will serve as a risk communication tool. The risk-factor passport shows a graphical presentation of the patient's calculated 5-year CVD risk. It will also show the target risk that could be reached if all the patient's modifiable risk factors are optimally treated. The nurse will calculate the patients CVD risk using the online DAD risk calculator, specifically designed for HIV infected patients (7, 8). The patients' CVD risk will also be calculated at follow-up visits at month 3, 6, 9 and 12 and the risk factor passport will be updated accordingly.

Contactpersonen

Publiek

Academic Medical Center
Meibergdreef 9, 1105 AZ Amsterdam
P.T. Nieuwkerk
Amsterdam
The Netherlands

Wetenschappelijk

Academic Medical Center
Meibergdreef 9, 1105 AZ Amsterdam
P.T. Nieuwkerk
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Adult (>18 yrs)

-Patients who are current smokers or patients who have overweight (BMI > 25 kg/m2)

-Participating in the lifestyle intervention protocol at the HIV outpatient clinic.

-Willing to sign written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-None

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40202
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4504
NTR-old	NTR4622
CCMO	NL47110.018.14
OMON	NL-OMON40202

Resultaten