

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 to show the target risk that can be reached if lifestyle factors are optimally treated has additional value in reducing CVD risk, among...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON40202

Source

ToetsingOnline

Brief title

Cardiovascular risk-factor passport in HIV.

Condition

- Viral infectious disorders

Synonym

cardio vascular disease risk, HIV infection

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiovascular risk factors, HIV infection, Life style intervention

Outcome measures

Primary outcome

CVD risk score

Secondary outcome

Number of cigarettes smoked per day.

Numbers of patients who stopped smoking.

Number of patients willing to be referred to a dietician.

Reduction in body weight.

Study description

Background summary

HIV infected individuals have a greater risk of cardiovascular disease (CVD) than HIV-negative individuals of the same age and gender. HIV infected persons who are current smokers and/or are overweight ($BMI > 25 \text{ kg/m}^2$) can participate in a lifestyle intervention programme to reduce their CVD risk as part of routine clinical care at the HIV outpatient clinic of the AMC. Achieving and sustaining lifestyle change is a major and perpetual challenge in medicine, however. With the present study we aim to investigate if providing visual feedback about an individuals* personal CVD risk (risk factor passport) and to show 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.

Study objective

To investigate if providing visual feedback about an individuals* personal CVD risk (risk factor passport) and to show 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.

Study design

Open-label randomized controlled study.

Intervention

Providing information about an individuals* personal CVD risk and to show the target risk that can be reached if lifestyle factors are optimally treated at baseline and after 3, 6, 9 and 12 months. The CVD will be displayed in a graphical presentation. The CVD risk will be calculated using an online tool that was specifically designed for use among HIV infected persons.

Study burden and risks

minimal risk

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-Participating in the lifestyle intervention protocol at the HIV outpatient clinic (HIV infected persons who are current smokers and/or who have overweight (BMI > 25 kg/m²)).

Exclusion criteria

None

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO

Date: 28-05-2014

Application type: First submission
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27830
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47110.018.14
OMON	NL-OMON27830