E-Health for Zero Infections - facilitating access to and use of Pre-Exposure Prophylaxis (PrEP) in the Netherlands

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The objective of this study is to assess the non-inferiority of an internet-based HIV PrEP-service and reduced frequency of monitoring visits in comparison to standard-of-care at the GGD.

Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON54198

Source
ToetsingOnline

Brief title
EZI-PrEP study

Condition

- Viral infectious disorders

Synonym
HIV, human immunodeficiency virus

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: Aidsfonds.

Intervention

Keyword: E-Health, HIV infection, Pre-Exposure Prophylaxis (PrEP), Prevention

Outcome measures

Primary outcome

The primary outcome is adherence to PrEP, determined by self-reported daily data on pill-intake and sexual behavior during the first 18 months of participation of each participant. Non-adherence is defined as a PrEP-less and condom-less anal sex act with a casual partner.

Secondary outcome

Secondary outcomes include the incidence of HIV and Hepatitis C virus infections, bacterial STIs, creatinine clearance, glycosuria and proteinuria, retention in PrEP-care, psychosocial indicators, and acceptance and usability of the internet-based PrEP service.

Study description

Background summary

The population impact of HIV pre-exposure prophylaxis (PrEP) largely depends on the uptake and consistent use of PrEP by people at high risk for HIV infection. In the Dutch National PrEP Programme (NPP), PrEP care consists of quarterly monitoring visits, which includes testing for HIV, sexually transmitted infections (STIs) and renal function, and provision of combination tablets of tenofovir disoproxil and emtricitabine (PrEP). PrEP care is available for men who have sex with men (MSM) and transgenderpersons (TGP) at low cost through the centers for sexual health (CSH) of public health services (GGDs). Offering PrEP care online and reducing the frequency of monitoring may increase access to PrEP.

Study objective

The objective of this study is to assess the non-inferiority of an

internet-based HIV PrEP-service and reduced frequency of monitoring visits in comparison to standard-of-care at the GGD.

Study design

Randomised, non-blinded, controlled, non-inferiority trial.

Intervention

The study takes place in four GGD regions in the Netherlands: Amsterdam, Haaglanden, Rotterdam-Rijnmond and Gelderland-Zuid.Participants will be assigned to one of four arms: (1) routine care with quarterly monitoring at CSH; (2) routine care with biannualmonitoring at CSH; (3) internet-based PrEP-care (i.e. video consultations and online-mediated testing for HIV, STIs and renalfunction) with quarterly monitoring; (4) internet-based PrEP-care with biannual monitoring. Each participant will be followed for 24 months.

Study burden and risks

All participants will be required to complete a brief daily online diary regarding pill intake, sexual acts and mood and questionnaires on sexual behavior, acceptability and usability of the service, and psychosocial indicators. All participants will be asked to provide a dried blood spots (DBS) from a finger prick at months 6 and 12. Participants with STI-related symptoms or (mental) health issues are encouraged to contact the CSH regardless of the timing for planned monitoring visits, but delayed diagnosis of asymptomatic STIs could occur among those assigned to biannual monitoring. Overall, the health risks of participants assigned to an intervention arm (arms 2, 3 and 4) are minimally higher than those of participants receiving the standard-of-care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Aged 18 years or older;
• Meet the eligibility criteria of the NPP i.e. MSM or transgender persons who in the 6 months prior to the PrEP-request/PrEP-consultation:
o Had anal sexual intercourse without a condom with a male partner with an unknown HIV status, and/or;
o Had anal sexual intercourse without a condom with a male partner with a known HIV-positive status and a detectable viral load, and/or;
o Was diagnosed with a rectal STI, and/or;
o Received a prescription for post-exposure prophylaxis (PEP);
• Living in the catchment area of one of the participating GGD regions;
• Have a smartphone, internet access and email address;
• Sufficient understanding of Dutch or English;

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• HIV infection;
• Acute of chronic Hepatitis B virus infection;
• Renal function problems:
o eGFR less than 60 mL/min/1.73m2;
o Other renal problems, as diagnosed by the physician;
• Use of medicines that interact with TDF/FTC e.g. NSAIDs.
• Other medical conditions that require special attention when using PrEP such as osteoporosis or other bone diseases;
• Unlikely, in the opinion of the clinician, to comply with the study

requirements or procedures;
• Participating in another study that affects the primary or secondary outcome measures of our study;
• Investigators or otherwise dependent persons.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-09-2021
Enrollment:	442
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2022
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05093036
CCMO	NL74494.018.20