How to promote PrEP adherence? A trial for participants of the Amsterdam PrEP project

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23409

Source
Nationaal Trial Register

Health condition

Adherence to PrE-exposure prophylaxis

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

good adherence at 12 and 24 months. Good adherence is measured by tenofovir levels in dried blood spot. Good adherence is defined as a level of ≥700 fmol/punch, which corresponds to a use of four or more tablets per week of tenofovir/emtricitabine 29.

Secondary outcome

1. To assess the use of the AMPrEP App (control group) and the AMPrEP App PLUS (intervention group)

2. To compare acceptability and usability of the AMPrEP App (control group) and the AMPrEP App PLUS (intervention group)

3. To compare self-reported adherence from questionnaires, from the AMPrEP App (control group) and the AMPrEP App PLUS (intervention group) and from pill-counts in both groups

4. To evaluate risk compensation in both study groups

5. To determine the rate of HIV seroconversion in both groups

6. To determine the perceived level of HIV protection in both groups

7. To determine the level of adherence self-efficacy in both groups

8. To evaluate perceived adherence support of the AMPrEP App (control group) and the AMPrEP App PLUS (intervention group)

9. To assess whether demographic variables, drug use, sexual risk behaviour, STI prevalence, perceived HIV risk and beliefs on PrEP efficacy are independent predictors of adherence, as measured by tenofovir levels in dried blood spots

Study description

Background summary

We will perform a randomised controlled trial (RCT), nested in the AMPrEP project. The study will not be blinded.

Recruitment and enrolment

Recruitment and enrolment will take place at the 3- or 6-month visit of daily PrEP users. A week before or at the scheduled visit, participants will be informed about the adherence RCT and be invited to participate. They will receive the participant information. During the visit, there will be ample time to answer questions about the adherence RCT. If the daily PrEP user agrees to join the adherence RCT, written informed consent will be obtained.

Participants are randomized to the intervention arm with access to the AMPrEP App PLUS, or the control arm with no intervention (with access to the “standard” AMPrEP App). A baseline self-administered questionnaire will be completed.

Randomisation

Randomisation is performed by using a computer randomisation program, in a ratio 1:1 to the intervention group and the control group, at the 3-month or 6-month visit.

Follow-up and assessments

Follow-up visits will take place according to the schedule of the AMPrEP project. During the visits, there will be no extra study procedures apart from a short questionnaire at 5 time-points (paragraph 6 of this appendix).

At the 3-month (or, if not possible at 3-month time point, at 6-month), the 6-month, the 9-month and the 12-month visit and the 24-month visit, a blood sample is taken for tenofovir levels in dried blood spots.

Study objective

To assess whether individualized feedback of self-reported PrEP medication adherence increases subsequent PrEP use, as measured by tenofovir levels in dried blood spots, in participants using daily PrEP.

Study design

March 2016 until August 2016: Recruitment of participants

August 2016 until June 2018: follow-up and data collection

Beginning of 2017: Interim analyses

June 2018: End of the study

June 2018 until December 2018: Data analyses

Intervention

Intervention: the AMPrEP App PLUS

The intervention to improve adherence that will be tested in this RCT consists of individualized feedback provided in an AMPrEP App PLUS, based on the adherence date that the participant himself has provided. The feedback will consist of four parts. The first part involves automated personal messages. The participant will receive a message when: (1) he has not completed the information that he is asked to complete in the application for 3 days in a row or (2) he indicated that he did not take his pill for 3 days in a row. Moreover, he will receive an automated personal message when (3) he indicated that he took the medication for 7 days in a row, followed by (4) messages every time after indicating he took the medication for 30 days in a row.

Secondly, a new tab with graphic visualization of adherence and trends in adherence will be added to the App. In this tab, participants can see trend in their adherence behavior per week or month. Thirdly, a bar chart that indicates the proportion of days with PrEP use per month will be included.

The final part of the App is a private tab for taking daily notes. This part is added to facilitate the use of the App. The researchers will have no access to the information of this part of the App.

This intervention is developed with input from the community engagement group and the participant group of the demonstration project.

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Eligibility criteria

Inclusion criteria

All of the following:

• Participant of the daily PrEP group within AMPrEP and prefers to continue daily PrEP use

• Has installed and used the regular AMPrEP App on smart phone or tablet

• Willing and able to comply to RCT procedures

• Willing and able to give written informed consent

Exclusion criteria

None

Study design

Design

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

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2016
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-02-2016
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	NL5413
NTR-old	NTR5741
Other	METC AMC : METC 2014_407

Study results