Consent for participation in the clinical trial TESTATE PrEP

Analysis of the capacity of the PrEP service to reduce the burden of care and evaluation of retention to PrEP follow-up through a pilot online HIV and STI screening intervention.

It is important that you read this information before giving your consent.

Information and informed consent

First of all we would like to thank you for agreeing to participate in the study. This is a very important clinical trial, which aims to demonstrate that it is possible to reduce the burden of care on PrEP services and allow participants to follow up at home without having to travel to the PrEP service, without reducing medical supervision and monitoring.

The Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol (IGTP) is responsible for this study and the Institut Català de la Salut (ICS), specifically the Unitat d'ITS del Programa de malalties infeccioses de l'Hospital Universitari Vall d'Hebron-Drassanes is in charge of data processing.

The aim of the study is to prove that it is feasible and effective for PrEP users to screen themselves for HIV, chlamydia (*Chlamydia trachomatis* (CT)), gonorrhoea (*Neisseria gonorrhoeae* (NG)) and syphilis (*Treponema pallidum* (TP)) by taking the samples themselves, mailing them to the laboratory and consulting their results online. All this in a safe, confidential and cost-free way.

To do this, we will randomly divide the participants into two groups. These are called the control group and the experimental group. For 24 months, we will compare the control group of PrEP users in which we will not perform any intervention with an experimental group in which we will alternate face-to-face visits with self-testing, sending to the laboratory to test forHIV and other STIs, and consulting the results online. During the experimental procedure, medication will be given alternately in person or by registered mail.

In the case of the control group, all screenings will be face-to-face and the necessary tests will be done at the STI clinic. We will only ask you to complete two online satisfaction surveys to evaluate the control group process.

In the case of the experimental group, 50% of the annual in-person check-ups will be replaced by online home screening. We will send you the self-collection kit to your home or to the address you have provided us with at the time of your follow-up visit. It will be sent by registered letter. In the same letter you will be sent the medication for the next 3 months, depending on your PrEP modality, and the material for the sample collection. In the case of HIV, you will have to collect a sample of saliva with a swab, which has a sponge at one end and is very easy to use. For chlamydia and gonorrhoea you will have to collect a urine sample, a pharyngeal sample and an anal sample with a swab. Finally, in the case of syphilis, it will be done through a dried blood sample, which is obtained through a small prick on the finger. These sample collections may cause slight discomfort. User satisfaction in this experimental group will be evaluated at 12 and

24 months of the study.

All the necessary material is in the kit. The process is very simple and together with the kit you will receive some simple instructions and on the project website (https://testate.org) you will have explanatory videos.

Once the samples have been collected, you must send them by post to the coordinating centre of the study, we will analyse them in our laboratory and we will inform you of the results via the web.

The Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol (IGTP) is the institution responsible for the TÉSTATE study which is coordinated by the Centre d'Estudis Epidemiològics sobre les STIs i Sida de Catalunya (CEEISCAT) in collaboration with the Vall d'Hebron-Drassanes STI Unit, the Pharmacy Service of the Vall d'Hebron University Hospital, the Microbiology Service of the Germans Trias i Pujol Hospital (HUGTiP) and the Consortiumfor Biomedical Research in Epidemiology and Public Health Network CIBERESP. This study is funded by the Instituto de Salud Carlos III and the Departament de Salut de la Generalitat de Catalunya.

Initial procedure

If you agree to participate, you will sign this consent form and then you will be asked to answer a short questionnaire about your health and sex life (behaviours, preferences, etc.) and provide us with your full name, ID card, health card number, phone number and email address.You will have to answer these questions during the visit at the PrEP service using a tablet provided by the doctor. At the end of the questionnaire the computer system will automatically decide whether you are going to participate in the control group or in theexperimental group.

This visit at the doctor's office will be considered the baseline visit or first visit of the clinical trial.

Control group procedure

If the programme has directed you to the control group, none of the face-to-face screenings will be substituted. You will have all the necessary screenings and tests from the STI clinic. We will ask you to complete two more questionnaires to ask you about your satisfaction with PrEP follow-up at the clinic, one at 12 months after the first visit and the second and final one at 24 months. We will send you an email so that you can answer each of the surveys and give your feedback online. If after one week you have not responded to the questionnaire we will call you or send you a new email to encourage you to respond. If we still don't get a response, we will ask you to answer the survey in paper version at your next follow-up face-to-face visit.

The results of your HIV, chlamydia, gonorrhoea and syphilis tests, as well as your adherence to PrEP in the last three months, will be shared with the study research team.

Experimental group procedure

If the programme has directed you to the experimental group, 50% of the face-to-face check-ups will be replaced by online check-ups. At the first visit with the doctor we will ask you to register on the website https://testate.org, answer a short questionnaire about your health and sex life (behaviours, preferences, etc.) and provide us with your full name, health card code, telephone, email and postal address so that we can send you a self-collection sample kit by registered post on the dates corresponding to the follow-up visits. The kit is a registered letter

that includes a postage-paid envelope for you to send your samples to be analysed at the Microbiology Service (Metropolitana Nord Clinical Laboratory) at the Germans Trias i Pujol University Hospital in Badalona to detect HIV antibodies or genetic material in the case of syphilis, chlamydia and gonorrhoea. If you were previously registered on the TESTATE website, you must also accept this new consent.

To guarantee confidentiality, the samples will be identified by a code that only you, the researchers and the health staff of the project will know. The identification number is unique and non-transferable. This code will be included with the kit and will be used to consult the test results. To maintain confidentiality, there will be no information on the outside of the envelope about the purpose of the envelope.

In the same envelope you will also be sent medication for three months, depending on your PrEP modality. If you take PrEP daily, you will be sent 3 boxes of medication. In the case of on- demand PrEP, you will be called at the time of kit preparation and asked how much you need for the next three months.

If we have not received the samples within 15 days of your due date for the PrEP follow-up visit, we will contact you by phone and encourage you to send them to us.

As soon as the results are available, you will receive an email and SMS notification. You will need the ID number that we send you with the kit to check the result. If the HIV result is positive, it will need to be confirmed with a conventional blood test. In the case of chlamydia and gonorrhoea, the result does not need to be confirmed. In the case of syphilis, the result needs to be confirmed with a conventional blood test. If the HIV result is negative, infection cannot be ruled out if it has occurred in the last three months (window period). In the case of chlamydia and gonorrhoea there is no window period. In the case of syphilis, the window period is 3 weeks. Your PrEP monitoring doctor will be informed about your results. If you test positive, you should contact the PrEP service to make an appointment as soon as possible.

If you do not consult your test results, we will send you reminders by email and SMS. In case of positive test results within one week, we will send you reminders by email and SMS.

If you have not made an appointment with the PrEP doctor since the results consultation, in addition to the reminders, we will contact you by email and/or telephone to make an appointment with the doctor.

Benefits

Participation in this study will allow you to know if you are infected with HIV, syphilis, chlamydia and gonorrhoea and will allow you to evaluate an alternative strategy for the follow-up of people taking PrEP, which is more convenient for users as it will reduce visits to the PrEP service and reduce the burden of care at the PrEP centre. Furthermore, the benefit is not an individual benefit but has an impact on the whole community and the health system.

Preservation of samples

Saliva, dried blood, urine, pharyngeal and anal samples shall be kept in the microbiology laboratory until the time of testing for HIV, syphilis, chlamydia and gonorrhoea. They will then be destroyed. You may request the destruction of your sample at any time. No DNA or other tests will be carried out on the collected sample.

Voluntary participation and participant rights

You have the right to refuse participation by revoking this consent at any time. If at any time you decide to stop participating in the trial, you will continue to receive routine PrEP follow- ups at your STI clinic. There will be no consequences or loss of potential benefits if you are unable or unwilling to continue with the study.

In accordance with the rights conferred by current legislation on Personal Data Protection, you may exercise your rights of access, rectification, limitation of processing, deletion, portability and opposition by addressing your request to the principal investigator of the study or to the Data Protection Officer (dpd@ticsalutsocial.cat). To exercise your rights in relation to your biological samples you should contact the principal investigator of the project,Cristina Agustí, by telephone at 93 497 88 91/696 71 41 36 or by email at derechos@testate.org.

You have the right to lodge a complaint with the Catalan Data Protection Authority about any action by the IGTP that you consider violates your rights.

Confidentiality

Statistical analyses of this data will be done confidentially using a code or pseudonym and no personal information will be used in the reports or files, whether they are published or not. There will be no transfer of your data to third parties.

At the end of the study, which is scheduled to last two years, all identifying data will be deleted and only the data strictly necessary for the scientific and statistical analyses required by the project will be kept, while guaranteeing the complete anonymity of the participants. The data will be processed in accordance with current legislation on personal dataprotection.

This study was approved by the Clinical Research Ethics Committee of the Germans Trias i Pujol University Hospital.

Declaration of consent

I have read this document and understood the purpose of the study. I have been informed about the different steps, risks and possible benefits of the study. I give my consent to participate in this study and understand that:

1. I am free to choose whether or not to participate in this study.

2. I may choose at any time to discontinue my participation.

3. I agree to the use of my oral fluid sample for an HIV test; oral, pharyngeal and anal for chlamydia and gonorrhoea tests; blood for a syphilis test.

4. I declare that the sample(s) I have provided for this study is/are solely mine.

Full name:

Telephone:

Health card number:

Identity Card:

E-mail:

Confirm e-mail:

Accordingly, I accept my participation in the TESTATE PrEP Project and sign accordingly at (place)..... on the date .....

Signature of the participant: