ISRCTN57061725 https://doi.org/10.1186/ISRCTN57061725

The Scottish ePrEP Clinic Feasibility Study: Assessing the feasibility of providing HIV prevention medication online

Submission date 10/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/11/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/09/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

PrEP (oral HIV pre-exposure prophylaxis) is a HIV prevention medication taken by people who do not have HIV, before and after sex. It is an important part of Scotland's HIV transmission elimination strategy, moving towards zero new HIV transmissions. To get PrEP, people typically have to attend a sexual health clinic to test for HIV and sexually transmitted infections (STIs), discuss continuing PrEP with a healthcare professional, and receive more PrEP. This can be challenging for people and difficult for sexual health services to keep up with demand because these appointments can be up to four times per year. In order to address some of these challenges, we have developed an alternative way for people to get their PrEP online: the ePrEP Clinic.

The ePrEP Clinic is a way of getting PrEP that people can do without having to come into the clinic every time they need PrEP. It consists of postal self-sampling for HIV and STIs, an "asynchronous online consultation" (essentially an online medical questionnaire), and, if appropriate, provision of PrEP by post or in-clinic collection, depending on the user's preference. We developed the service over a series of research studies and are now at the stage where we are ready to test it out on a small scale.

Who can participate?

This is a relatively small study in which we are trying out the ePrEP Clinic by offering it to a group of PrEP service users. Therefore, we are only recruiting from a specific clinic in Glasgow, Scotland. The ePrEP Clinic is also limited in the complexity of care it can deliver. For example, it is not able to offer kidney function testing, which some people need at every PrEP appointment. Therefore, in this study, we are focusing on people who do not need frequent kidney function testing or any other care that falls outside of the ePrEP Clinic's capabilities. People's eligibility will be assessed by the study clinician on an individual basis, using our specific eligibility criteria.

What does the study involve?

1. Potential participants will be identified by the study clinician and introduced to the study by text message or a flyer in clinic. They then have the option to speak to the study clinician to

discuss participation, after which they can enrol.
2. As their next PrEP appointment approaches, the study clinician will order a self-sampling kit on the participant's behalf and send them a link to the online medical questionnaire by text message. The self-sampling kit is a specially designed kit that participants have delivered to their house. The participant then collects their own swabs, finger-prick blood sample, and urine sample, as needed. The samples are then posted to the laboratory by the participant, where they are analysed and the results are sent to the study clinician. These kits are already commonplace in many parts of the UK.
3. Once the study clinician has received the results of the HIV test and questionnaire, they will decide if more PrEP is appropriate and if any other clinical input is required (e.g. treatment for an STI). All clinical input will be delivered in line with standard clinical protocols.
4. If more PrEP is appropriate, the study clinician will post it to the participant or let them know it is ready to collect at the clinic, whichever the participant prefers.
5. The study clinician will then send the participant a link to an evaluation questionnaire.

What are the possible benefits and risks of participating?
There are no immediate benefits to taking part in this study; however, it is a necessary step in deciding if the ePrEP Clinic becomes a permanent option for PrEP appointments, which participants may go on to use in the future. Our previous research suggests that the ePrEP Clinic might be more convenient for people and reduce the number of times they need to go to a physical clinic per year.

Where is the study starting and how long is it expected to run for?
September 2024 to September 2025

Who is funding the study?
The study is part of The Scottish ePrEP Clinic research programme funded by the Scottish Government.

Who is the main contact?
Study queries can be directed to Dr Ross Kincaid (Ross.Kincaid@gcu.ac.uk). It is important to note that you cannot request to take part by emailing the study team.

Contact information

Type(s)
Public

Contact name
Dr Beth Bateson

ORCID ID
https://orcid.org/0009-0004-0023-7806

Contact details
Sandyford Sexual Health Services,
2-6 Sandyford Pl
Glasgow
United Kingdom

G3 7NB
+44 1412218130
beth.bateson2@nhs.scot

Type(s)
Scientific

Contact name
Dr Ross Kincaid

ORCID ID
https://orcid.org/0000-0002-3489-8897

Contact details
M436 George Moore Building,
Glasgow Caledonian University,
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA
+44 1413318419
Ross.Kincaid@gcu.ac.uk

Type(s)
Principal investigator

Contact name
Prof Claudia Estcourt

ORCID ID
https://orcid.org/0000-0001-5523-5630

Contact details
M421 George Moore Building,
Glasgow Caledonian University,
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA
+44 1413313099
Claudia.Estcourt@gcu.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
342338

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HLS/NCH/23/030, CPMS 65655

Study information

Scientific Title
The Scottish ePrEP Clinic Feasibility Study

Acronym
ePrEP Feasibility

Study objectives
The aim of this study is to assess the feasibility and acceptability of providing PrEP through the ePrEP Clinic by offering NHS PrEP service users the option to complete one of their PrEP appointments through the ePrEP Clinic pathway.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 09/09/2024, Glasgow Caledonian University Nursing and Community Health Research Ethics Committee (Glasgow Caledonian University, Cowcaddens Road, Glasgow, G4 0BA, United Kingdom; +44 1413313114; HLSEthicsNursing@gcu.ac.uk), ref: HLS/NCH/23/030

2. submitted 24/09/2024, NHS Research Ethics Committee (TBC, TBC, TBC, United Kingdom; TBC; approvals@hra.nhs.uk), ref: TBC

Study design
Single-centre feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
HIV transmission prevention

Interventions
Participants will complete the 'ePrEP Clinic' pathway instead of their usual in-clinic interim PrEP review. The ePrEP Clinic consists of postal self-sampling for HIV and STIs, an asynchronous online consultation (questionnaire-based), and provision of PrEP by post or collection from a sexual health service. Additional clinical care will be delivered as needed following standard clinical protocols.

Intervention Type

Other

Primary outcome(s)
Uptake and completion rate measured by tracking participants' completion of each of the pathway stages over the course of the study.

Key secondary outcome(s))
1. Clinical input required by participants measured by logging clinical input received throughout participation
2. Acceptability measured using a self-report questionnaire at the end of the study
3. Costs associated with the ePrEP Clinic pathway measured by conducting a costing analysis using study data (primarily, mapping participants' journeys through the intervention and the resources used)
4. Details of any challenges or lessons learned when implementing the study measured by maintaining a log throughout the study period

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Reside in the Greater Glasgow and Clyde health board
2. Existing Sandyford PrEP service user
3. Currently use tenofovir disoproxil and emtricitabine for PrEP (‘standard’ oral PrEP)
4. Willing and able to receive the postal self-sampling kit
5. Does not require enhanced kidney (renal) monitoring at that visit
5.1. Is aged 18-39 years
5.2. No known medical conditions that increase kidney risks
5.3. No known medications that interact with kidney function or are associated with kidney impairment
5.4. Does not have >1 + protein on previous urinalysis
6. No scheduled testing that cannot be delivered within the ePrEP Clinic (e.g. urinalysis, hepatitis B/C testing)
7. Not prescribed interacting medications
8. Not known to have viral hepatitis
9. Not known to have osteoporosis or be at significant risk of osteoporosis
10. Not pregnant or a cis woman not on contraception
11. No known ‘social complexities’ as determined by a clinician using local criteria
12. No significant PrEP adherence issues
13. Able to read English well enough to understand the study materials (including self-sampling instructions and asynchronous consultation), and provide informed consent

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
39 years

Sex
All

Total final enrolment
83

Key exclusion criteria
Anyone who does not fulfil all inclusion criteria.

Date of first enrolment
01/10/2024

Date of final enrolment
15/08/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Sandyford Sexual Health Services (NHS Greater Glasgow and Clyde)
2-6 Sandyford Place
Glasgow
United Kingdom
G3 7NB

Sponsor information

Organisation
Glasgow Caledonian University

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
Scottish Government

Alternative Name(s)
The Scottish Government, Scottish Executive, Riaghaltas na h-Alba

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive and potentially identifiable nature of the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes