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Digitally enhanced targeted testing for HIV, hepatitis B and hepatitis C in primary care (TARGET-ID): feasibility study

Submission date
07/09/2024

Recruitment status
No longer recruiting

Registration date
08/10/2024

Overall study status
Completed

Last Edited
17/09/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Blood-borne viruses (BBVs) like HIV, Hepatitis B, and Hepatitis C can cause serious health problems, especially in disadvantaged groups. Many people do not know they have these infections, which worsens health inequalities. Current testing programs often use broad methods to find people who might have a BBV, resulting in many unnecessary tests and missed positive cases. To improve this, we have worked with a group of people who have direct experience with BBVs to design a better testing program. This program uses a computer algorithm, based on data from GP health records, to identify people who are more likely to have a BBV. We are piloting this new approach in selected GP practices to see how well it works.

Who can participate?
Adults aged 18 and over who are registered with one of the participating GP practices in London, Bristol, or Leicester and can discuss the test in English or with a suitable translator.

What does the study involve?
If you participate, a computer program will analyze your health records to estimate your risk of having a BBV. If you are identified as high-risk, you will receive a personalized text message with a video explaining the test and a link to schedule a blood test. If you prefer, you can choose a finger-prick test instead. If you test positive, support will be provided to help you access specialist treatment and care.

What are the possible benefits and risks of participating?
Patients testing positive for a blood-borne virus may benefit from early diagnosis and prompt access to specialist treatment and care and those with a negative test result will benefit from knowing their status and health prevention advice. There are no know health risks with this research. However, some of the questions asked in the interviews could be upsetting for some individuals. Patients are free to decline answering any question they may not feel comfortable answering.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
November 2020 to March 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) School of Primary Care Research (SPCR) (UK)
Gilead Sciences (UK)

Who is the main contact?
Dr Werner Leber, w.leber@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Werner Leber

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326061

Protocol serial number
IRAS 326061

Study information

Scientific Title

Undiagnosed HIV, Hepatitis B and Hepatitis C in primary care: Targeted testing using digital technology to increase identification and improve care pathways for higher risk and underserved communities (TARGET-ID): Randomised mixed methods feasibility study

Acronym
TARGET-ID

Study objectives
Implementing machine learning-assisted testing for blood-borne viruses (HIV, Hepatitis B, and Hepatitis C) in conjunction with peer support in general practice is feasible and acceptable to both staff and patients, and it results in a higher rate of BBV diagnoses compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted (United Kingdom)

Study design
Randomized mixed methods feasibility study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Identification of patients at risk of HIV, Hepatitis B and Hepatitis C.

Interventions
• A computer search will identify 200 patients per practice who are most at risk of the blood-borne viruses (BBV) HIV, hepatitis B and hepatitis C.
• A text message including links to an explanatory video and information on self-referral for blood testing.
• Up to three follow up calls to encourage study participation.
• Patients who test positive will receive a GP referral to a specialist.
• Optional GP referral to a local peer supporter is available for patients who have difficulty engaging with the clinic.
• Optional GP referral to a peer supporter for finger prick testing is also available to those anxious about testing at the practice.

• A practice GP or nurse champion will support study implementation, communicate with the study team, and assist with recruitment for qualitative interviews.

The control practice will continue to provide routine standard of care.

Intervention duration: 6 months.

Follow up will be 3 months

Three east London practices will be cluster randomised using 'R' and using the following minimisation criteria:
Practice list size: <10,000 patients, ≥10,000 patients
Teaching practice: Yes/No
Male HIV testing rate (number of male patients tested for HIV in the preceding 12 months /practice list size)

Intervention Type
Behavioural

Primary outcome(s)
Numbers of patients newly diagnosed with HIV, HBV or HCV measured using patient records at follow up

Key secondary outcome(s))
Measured using patient records at follow up:
Clinical outcomes
1. Numbers of patients diagnosed at an early stage of HIV (CD4 count at or above 350 cells per cubic millimetre of blood)
2. Numbers of patients diagnosed with Hepatitis B with liver cirrhosis
3. Numbers of patients diagnosed with Hepatitis C with liver cirrhosis

Viral outcomes
4. Initial viral load for HIV, HBV and HCV

Health service use
5. Numbers of patients identified at different levels of risk for each BBV
6. Numbers offered testing
7. Numbers accepted testing and had a test
8. Numbers accepted testing but did not attend following three invitations
9. Numbers declined testing
10. Numbers of non-responders
11. Positive tests and yield
12. Numbers referred to peer supporters
13. Numbers referred to specialist clinics
14. Numbers of patients who entered the clinic

Economic outcomes
15. Cost–effectiveness of the intervention compared to standard of care
16. Practice activities measured using observation of clinical meetings, data from practice GP or nurse champion

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Individuals aged 18 and above registered with one of the participating general practices, who can undertake the pre–test discussion in English or with a suitable translator.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Age under 18 years
2. Known BBV positive patients
3. Individuals with limited English abilities, who are unable to understand the info sheet or, who are unable to engage with the pre–test discussion for BBV testing

Date of first enrolment
01/04/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Mary University of London
Wolfson Institute of Population Health
58 Turner Street
London
United Kingdom
E1 2AB

Study participating centre

University of Bristol
Bristol Population Health Science Institute
Beacon House
Queens Road
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United Kingdom
BS8 1QU

Study participating centre
University of Leicester
Department of Respiratory Sciences
University Road
Leicester
United Kingdom
LE1 7RH

Study participating centre
University of Oxford
The Big Data Institute
Li Ka Shing Centre for Health Information and Discovery Old Road Campus
Oxford
United Kingdom
OX3 7LF

Study participating centre
Barts and the London NHS Foundation Trust
Blizard Institute
4 Newark Street
London
United Kingdom
E1 2AT

Study participating centre
Homerton University NHS Foundation Trust
Centre for the Study of Sexual Health and HIV
Homerton Row
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research (NIHR) School of Primary Care Research (SPCR)

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc., Oligogen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during this study are available upon request from Dr. Werner Leber at w.leber@qmul.ac.uk. We will obtain valid implied consent from patients undergoing testing. Patients who test positive for HIV, Hepatitis B, or Hepatitis C, as well as those participating in interviews, will provide written informed consent. Only pseudonymised and aggregated data will be shared. All data will be encrypted and transferred securely using safe file transfer protocols.

IPD sharing plan summary
Available on request

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes