ISRCTN10073032 https://doi.org/10.1186/ISRCTN10073032

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
Ongoing

Last Edited
28/01/2025

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 September 2025

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

Study website
https://shareresearch.org.uk/researchthemes/undiagnosed-hiv-hepatitis-b-and-hepatitis-c-in-primary-care/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Werner Leber

ORCID ID
http://orcid.org/0000-0003-1321-2566

Contact details
Wolfson Institute of Population Health
Centre for Primary Care
58 Turner Street
Lonodn
United Kingdom
E1 2AB
+44 20 7882 7084
w.leber@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326061

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Not yet submitted (United Kingdom)

Study design
Randomized mixed methods feasibility study

Primary study design
Interventional

Secondary study design
Randomised feasibility pilot

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
We will upload the patient information sheet to our study website: https://bit.ly/3MyOyZU

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 measure
Numbers of patients newly diagnosed with HIV, HBV or HCV measured using patient records at follow up

Secondary outcome measures
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

Overall study start date
19/11/2020

Completion date
30/09/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1200

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
England

United Kingdom

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
Bristol
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

Sponsor details
Joint Research Management Office
Dep W
Research Services
81 Mile End Road
Whitechapel
London
England
United Kingdom
E1 4UJ
+44 207882 7275
research.governance@qmul.ac.uk

Sponsor type
University/education

Website
https://www.jrmo.org.uk/

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.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Our communication and dissemination strategy will be guided by Kingdon's Policy Windows framework (e.g., Rose, 2020, https://doi.org/10.1016/j.envsci.2017.07.013) to optimise the environment and opportunity for policy change. Outputs targeted at civil society, health and social care, and industry/government will be framed to highlight undiagnosed BBV infection as a major health challenge (influencing the 'Problem Stream'); digitally-supported targeted testing as a solution ('Policy Stream'); the programme as a cost-effective intervention for Integrated Care Boards ('Politics Stream').

The study team have direct links with national / regional BBV initiatives ensuring our work is presented to those with authority to influence and implement policy and practice. For example, Professor Graham Foster is national clinical lead for HCV so can feed in directly to the NHS England HCV team; Professor Chloe Orkin and Professor Jane Anderson is past Chairs of the British HIV Association and highly active in public advocacy; Prof Orkin is also and a visible LGBTQ+ role model. Dr Werner Leber is a member of the Mayor of London's Routemap to eliminating Hepatitis C in London and the London Joint Working Group for Substance Misuse and Hepatitis Professor Chris Griffiths is a member of the NIHR ARC (Applied Research Collaboration) National Priority Health and Care Inequalities Consortium Management Group, enabling dissemination of findings across the national ARC network.

Our communication and dissemination strategy and programme will be further developed through the Community and Lived Experience Advisory Board and the Programme Management Group. Communication and Dissemination will be a standing item on the agendas of these groups from day one of the project (rather than being left to the project end).

Using messages tailored according to target audiences, we will disseminate findings using TARGET-ID and institutional social media accounts, university websites, and reports, study webinars. In collaboration with our Community and Advisory Board, we will produce research briefings and webinars for study participants, peer supporters as well as primary and secondary care staff.

Our findings will be submitted for peer review with The Lancet Infectious Disease or The Lancet Digital Health, and presented at conferences, nationally at the The Society for Primary Care Conference or the HepHIV Conference (Europen Centres for Disease Control and Prevention) and the ECCMID Conference (European Society of Clinical Microbiology and Infectious Diseases).

We will share findings thorough our multiple professional networks, including for example, the Royal College of General Practitioners, British HIV Association, the British Association for Sexual Health and HIV (BASHH), the Routemap to eliminating Hepatitis C in London and the London Joint Working Group for Substance Misuse and Hepatitis C.

We will work with NHS England and the UK Health Security Agency to improve digitally-enhanced case identification in primary care45 and secure data linkage with secondary care; and discuss the implications of our intervention for future research and implementation in practice.
We will liaise with Health Education England and its local providers to enable education and training for peer supporters and staff on delivering a fully integrated care pathway across primary care, secondary care and the community.
We will work jointly across our NIHR Applied Research Collaborations for North Thames, ARC West, and ARC East Midlands to include further work in ARC upcoming renewal applications, including further refinement of the programme, as informed by study findings.

Intention to publish date
30/09/2025

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