Full/long title of study	Viral hepatitis in the Mongolian Community in London: An investigation of epidemiology and burden of disease to inform clinical and public health interventions
Short title	Hep-MOLO
Version and date of protocol	Version 1.0 30/05/2024_draft
Sponsor:	University College London (UCL)
Sponsor reference number:	174914
Funder (s):	UCL Biomedical Research Centre
IRAS Number:	341947
UCL Data Protection Number:	Z6364106/2024/10/37

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PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	1.0	16.01.25	Dr Emily Martyn Prof Philippa Matthews Prof Stuart Flanagan Dr Indrajit Ghosh Dr Julian Surey Dr Jessica Carter	N/A

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature: ....  **..... Date...**16/01/2025**..**

Print Name (in full): ..... Philippa Matthews**.....**

Position:

- Professor of Infectious Diseases, University College London;
- Consultant in Infectious Diseases, University College London Hospital & Central and North West London NHS Foundation Trust;
- Group Leader, Francis Crick Institute

On behalf of the Study Sponsor:

Signature: ....  **..... Date....**16/01/2025**..**

Print Name (in full): ..... Pushpsen Joshi**.....**

Position: ..... Research Governance Manager**.....**

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	341947
REC Reference No.	
Sponsor Reference No.	174914
Other research reference number(s) (if applicable)	Z6364106/2024/10/37
Full (Scientific) title	Viral hepatitis in the Mongolian Community in London: An investigation of epidemiology and burden of disease to inform clinical and public health interventions
Health condition(s) or problem(s) studied	Chronic viral hepatitis (hepatitis B virus, hepatitis C virus, hepatitis D virus infection) Metabolic dysfunction-associated steatotic liver disease (MASLD)
Study Type i.e. Cohort etc.	Observational, mixed methods, cross sectional study
Target sample size	Aim to offer clinical screening 500-600 participants Estimated to identify ~30-40 participants with blood borne virus infection
STUDY TIMELINES	
Study Duration/length	3 years
Expected Start Date	March 2025
End of Study definition and anticipated date	Definition: All data collected, and samples analysed. Manuscripts written or in preparation. Anticipated date: January 2028.
Key Study milestones	Community engagement survey - April – July 2024 Recruitment events: January 2025– December 2025 Clinical Data collection: January 2025 - December 2026 Clinical diagnostic laboratory assays June 2025 - December 2025 Research assays - November 2024 - December 2026 Data analysis - November 2024 - December 2026 Write-up and reporting - June 2025 - August 2027
FUNDING & OTHER	
Funding	University College London NIHR Biomedical Research Centre Core funding: The Francis Crick Institute. 1 Midland Road, London, NW1 1AT
Other support	Clinical resources and expertise: Mortimer Market Centre, Central and North West London NHS Foundation Trust, Capper Street, London, WC1E 6JB Find & Treat Team, University College London Hospital NHS Foundation Hospital, 250 Euston Road, London NW1 2PB Community partners: Mongolian Community Organisation, Dixon House, Garfield Way, London, W10 6TU Onom Foundation, 3 Bogd Javzandamba 15 khoroo, Ulaanbaatar 17011, Mongolia

STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	Matthews Group The Francis Crick Institute, 1 Midland Road, London, NW1 1AT
Data collected / Storage	Matthews Group The Francis Crick Institute, 1 Midland Road, London, NW1 1AT/ University College London, Infection & Immunity Division, Cruciform Building, Gower Street, London WC1E 6BT
KEY STUDY CONTACTS	
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Study Coordinator	Dr Emily Martyn Clinical Research Fellow Francis Crick Institute & University College London/ Infectious Diseases and Medical Microbiology Specialty Registrar Division of infection and immunity University College London Gower Street London WC1E 6BT e.martyn@ucl.ac.uk
Sponsor	University College London
Funder(s)	UCLH NIHR Biomedical Research Centre Maple House, 1st Floor Suite A 149 Tottenham Court Road London W1T 7DN Email: n.mcnally@ucl.ac.uk Tel: 020 3108 7907 Fax: 020 7679 0876
Committees	N/A
Sub-contractors	N/A
Other relevant study personnel	Prof Stuart Flanagan – lead for viral hepatitis at Central and North West London NHS Turst Dr Indrajit Ghosh – Specialty doctor in sexual health and inclusion health Dr Naranjargal Dashdorj – consultant hepatologist, co-founder of 'Onom Foundation' a non-governmental organisation established to deliver healthcare in Mongolia Ms Joy Ko - peer support worker for people living with hepatitis B virus infection at Central North West London Trust

	Dr Emily Martyn- specialist registrar in infectious diseases; Crick/ UCL clinical PhD fellow. Dr Jessica Carter - GP with special interest in infection and engagement with migrant communities Dr Aneesha Noonan - primary care clinician and National Primary Care Lead for Hep C elimination for NHS England Prof Sally Hargreaves -Professor in Global Health, leads a multi-disciplinary team with an interest in migrant health and infection Mr Julian Surey - Clinical Nurse Specialist in Blood Borne Viruses and Inclusion Health, Find & Treat, University College London Hospital Miss Elizabeth Waddilove - Laboratory Research Scientist, Matthews Lab, Francis Crick Institute Dr James MacRae, Head of metabolomics, The Francis Crick Institute Dr Jerome Nicod, Head of Genomics STP, The Francis Crick Institute Dr Jean-Baptiste Cazier, Head of bioinformatics and biostatistics, The Francis Crick Institute

KEY ROLES AND RESPONSIBILITIES

SPONSOR: University College London Hospitals/ University College London Joint Research Office

The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: University College London Hospitals NIHR Biomedical Research Centre

The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work. If further arrangements have been agreed with the funder, please refer to the funding agreement and insert.

CHIEF INVESTIGATOR (CI): Professor Philippa Matthews

The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPAL INVESTIGATOR (PI): Professor Philippa Matthews

Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

STUDY CLINICIAN/ CRICK RESEARCH LEAD: Dr Emily Martyn

Infectious diseases doctor, providing clinical support during the study and input into the study design. Responsible for coordinating sample analysis at the Francis Crick Institute and will take a lead role in analysis and write-up of data.

LEAD FOR VIRAL HEPATITIS: Professor Stuart Flanagan

Providing expert clinical input for chronic viral hepatitis management during the study. Task and Finish hepatitis B lead for London.

INCLUSION HEALTH LEADS: Dr Indrajit Ghosh and Mr Julian Surey

Specialists in outreach and blood borne viruses in inclusion health populations. Specialist input into study design, management and follow up during the study.

PRIMARY CARE SPECIALIST ADVISOR: Dr Jessica Carter

GP with special interest in migrant health, providing specialist input into primary health care and qualitative aspects of the study.

MIGRANT HEALTH LEAD: Prof Sally Hargreaves

Professor in Global Health leading a multi-disciplinary team with an interest in migrant health and infection. Advised on study design.

SENIOR LAB RESEARCH SCIENTIST: Ms Elizabeth Waddilove

Responsible for running the Matthews laboratory at the Francis Crick Institute, also manages oversight of governance and oversight of sample transport, storage and analysis.

LEAD FOR HEPATOLOGY and COMMUNITY REPRESENTATION LEAD: Dr Naranjargal Dashdorj

Consultant hepatologist, co-founder of 'Onom Foundation' a non-governmental organisation established to deliver healthcare in Mongolia. Dr Dashdorj has prior experience in running chronic viral hepatitis screening programmes in the United States and Sweden and provides links to the Mongolian community in the UK. She is also assisting in translation of study documents.

KEY WORDS

HBV, HCV, HDV, blood borne virus, Mongolia, Inclusion Health, screening

LIST OF ABBREVIATIONS

Abbreviation	Meaning
BBV	Blood borne virus
CAP	Controlled attenuation parameter
CNWL	Central North West London NHS Trust
EASL	European Association for the Study of the Liver
HbA1c	Glycated haemoglobin
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HDV	Hepatitis D Virus
HIV	Human immunodeficiency virus
LFTs	Liver function tests
MASLD	Metabolic dysfunction-associated steatotic liver disease
MCO	Mongolian Community Organisation
MMC	Mortimer Market Centre
NICE	The National Institute for Health and Care Excellence
PLWH	People living with HIV
PLWHB	People living with HBV
POCT	Point of care test
TE	Transient elastography
UCL(H)	University College London (Hospitals)
VL	Viral Load
WHO	World Health Organization

CONTENTS

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1 INTRODUCTION

Our project focuses on the Mongolian community in London, establishing clinical-academic-community collaboration to develop a pathway for diagnosis and clinical care into which we will embed translational research (**Figure 1**). There are ~5000 Mongolians in the UK, of whom 1300 are thought to be in London [data provided by Mongolian embassy, personal communication].

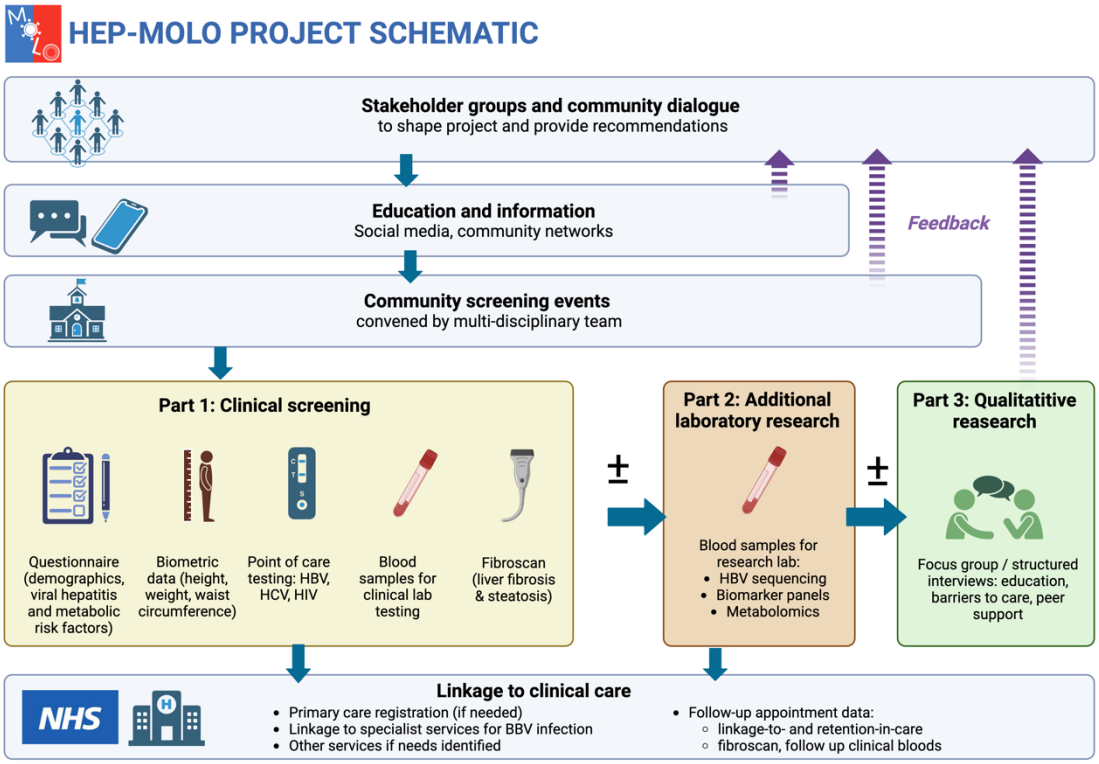


Figure 1: Schematic describing Hep-MOLO study workflow. Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; BBV, blood borne virus.

Clinical Landscape

Chronic viral hepatitis (hepatitis B virus, hepatitis C virus and hepatitis D virus) is a major global public health threat (causing 1.3 million deaths per year) (1). Mongolia has one of the highest rates of chronic viral hepatitis, and as a result, the highest rate of liver cancer globally, with 85.6 new cases per 100,000 people in 2020 (2). There is enhanced global attention on metabolic dysfunction-associated steatotic liver disease (MASLD), which affects 25-35% of the general adult population and is the leading indication for liver transplantation in adults over 65 years and women (3).

London has gained experience in pathways for testing blood borne viruses since the recent roll out of 'opt out' screening in Emergency Departments from 2023, which has led to many new people with a diagnosis of hepatitis B who are being contacted and linked to care (4). Thus, the infrastructure and experience in our local teams and services provides well for this new project, and we are uniquely positioned to add to the evidence-base for scaling up diagnosis.

Approach to clinical screening

In collaboration with London Mongolian community members, we will design and implement several health screening events, which focus particularly on chronic viral hepatitis and MASLD. During the events, we will raise awareness of chronic viral hepatitis and liver disease and offer enrolment into a linked research study (**figure 1**).

Clinical screening pathways (part 1)

We will use point-of-care, finger prick blood test to screen for blood borne infections, including hepatitis B virus (HBV), hepatitis C virus (HCV), Human Immunodeficiency Virus (HIV) and Syphilis. We will use a point-of-care, non-invasive, ultrasound-based test (Fibroscan, Echosens), to measure transient elastography (liver stiffness, an indication of liver inflammation, fibrosis or cirrhosis, which can ultimately lead to liver failure if untreated) and controlled attenuation parameter (a measure of liver fat which can contribute to liver damage). We will screen for metabolic risk factors, which may contribute to accelerated liver disease. We will record a questionnaire to understand demographic, metabolic and chronic viral hepatitis risk factors.

Optional enrolment into laboratory research (part 2)

For willing participants, we will take blood samples for testing at the Francis Crick Institute, allowing us to perform more detailed analysis of factors that may be relevant to the development and outcomes of liver disease.

Qualitative research (part 3)

We will ask participants if they are willing to be recontacted in future to take part in qualitative studies that will help us to understand attitudes and barriers to healthcare screening, linkage to relevant services, and retention in care among this population.

Impact and outcomes

There are immediate practical clinical benefits to individuals and to the community as a result of raising awareness, diagnosing viral hepatitis infection, and linking to specialist care. In the longer term, the research will also inform insights that will support interventions and deliver new mechanistic understanding, including exploration of new biomarkers, determining the relationship between laboratory parameters (host and viral) and development of liver disease, and characterising lipidomic profiles.

2 BACKGROUND AND RATIONALE

Chronic viral hepatitis (hepatitis B virus, hepatitis C virus and hepatitis D virus) affects 304 million people globally and is responsible for 1.3 million deaths each year due to liver cirrhosis and liver cancer (1). Ambitious international targets have been set for the elimination of chronic viral hepatitis as a public health threat by the year 2030. Chonic viral hepatitis infection is a neglected public health threat, with many barriers to diagnosis and treatment (5).

(i) Hepatitis B virus (HBV)

Worldwide, HBV is now one of the biggest drivers of liver disease, causing cirrhosis and liver cancer (2). We do not fully understand why some people living with HBV develop liver disease and some people remain relatively unaffected throughout life (6). Further knowledge on viral factors (e.g. viral genetic sequence) and host factors (e.g. immune factors, metabolic factors) may improve our understanding. Antiviral treatment is cheap, safe and effective but must be taken long-term as it suppresses the virus rather than curing it. To date, treatment has only been offered to a minority of people living with HBV (PLWHB) but the treatment landscape is currently changing, as new HBV global treatment guidelines have been published by the World Health Organisation in March 2024, and other leading international bodies are reviewing their regional guidelines (7). New recommendations relax and expand treatment criteria to make many more people treatment-eligible; identifying people living with infection and linking them to care will be crucial for the success of treatment campaigns.

(ii) Hepatitis C virus (HCV)

HCV is an important worldwide cause of liver disease and liver cancer. Over the past decade, new oral 'direct acting antiviral' (DAA) drugs have become available and HCV is now a curable infection with short course treatment (8-12 weeks) (8). However, access to DAA treatment has been limited in many populations, related to high costs and limited infrastructure for delivery. There is now a concerted effort to reach elimination targets using wider DAA roll-out. This is supported by marked success in offering wide community access to testing and treatment (8, 9).

(iii) Hepatitis D virus (HDV)

HDV is a coinfection that can be established only in the setting of HBV infection and causes accelerated liver disease. To date, HDV treatment options have been limited, but a new treatment is recently available (Myrcludex, Gilead), and there is a focus from public health agencies, clinicians and pharmaceutical companies on identifying and treating those with HDV infection (10, 11).

(iv) HIV & Syphilis

No disease exists in a silo. Routes of transmission for HIV and syphilis overlap with hepatitis B, C and D (sexual, mother-to- child, and blood). The World Health Organisation introduced the "triple elimination" agenda in 2023, to build cross programme efficiencies to strengthen and leverage elimination of HIV, syphilis and HBV, particularly in the context of mother-to-child transmission (12). Since we have access to a multiplexed HIV/syphilis point-of-care-test (POCT), we are a team skilled in screening and treating these conditions and effective

treatments exist for both HIV and syphilis, we will screen for these infections in the MOLO study.

Metabolic dysfunction associated steatotic-liver disease

Metabolic dysfunction-associated steatotic liver disease (MASLD) is defined as steatosis (fat in the liver) occurring with at least one criterion for metabolic syndrome (hypertension, diabetes, dyslipidaemia, obesity) (**figure 2**). In 2023, this nomenclature replaced non-alcoholic fatty liver disease (NAFLD), with the aim to reduce stigma and more accurately reflect the disease pathogenesis (13). MASLD is a global health problem affecting 1.7 billion people worldwide and, like viral hepatitis, can lead to cirrhosis and liver cancer (14). However, the interplay between MASLD and viral hepatitis, in particular HBV, is not well understood (15). The intersection between viral hepatitis and MASLD is therefore an area of expanding interest for risk stratification, particularly in the context of a global increase in the prevalence of both metabolic syndrome and MASLD (16, 17).

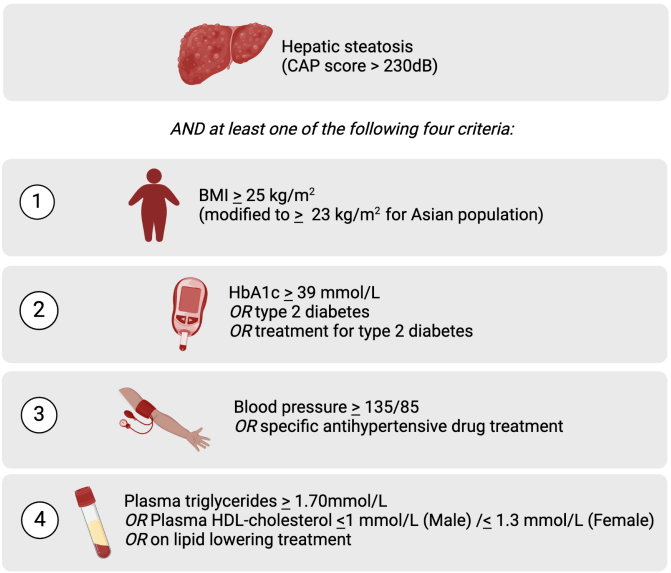


Figure 2: Schematic illustrating metabolic dysfunction-associated steatotic liver disease (13). Abbreviations: CAP - controlled attenuation parameter; BMI - body mass index; HbA1c - glycosylated haemoglobin; HDL - high density lipoprotein. CAP ≥ 230 (18).

Focus on the Mongolian Community

Mongolia is a high prevalence setting for chronic viral hepatitis infection (HBV, HCV and HDV), and consequently has one of the highest rates of primary liver cancer in the world (19). Viral hepatitis screening programmes undertaken in Sweden, Spain and the United States indicate a high prevalence of chronic viral hepatitis among the Mongolian community (HBV 3.6 - 9.7%, HCV 0.5-3.6%, HDV 0.9-33%) (19-22). These studies demonstrate the feasibility and importance of replicating this public health intervention in the UK.

There are no specific data for MASLD in Mongolia, however globally the trend is towards increasing prevalence and some studies have highlighted racial disparities in diagnosis and outcome (23),

highlighting the importance of understanding this disease in different populations. Investigating the relationship between chronic viral hepatitis and MASLD this well-defined group will allow us to unpick the underlying mechanisms behind disease progression and inform risk stratification for treatment and surveillance, supported by access to methods our group has already developed, and state-of-the-art laboratory techniques at the Francis Crick Institute.

Qualitative research approaches

Migrant populations can experience compounding challenges when accessing healthcare including stigma, language barriers, socioeconomic disadvantage, and navigating unfamiliar healthcare systems (24, 25). Thus, Mongolian communities in the UK are vulnerable not only to the outcomes of chronic viral hepatitis infection, but to the potential disadvantages of migrant populations. Alongside the clinical and research components of this project, we plan to collect qualitative data to explore the attitudes and barriers to accessing and remaining in specialist hepatitis care among this population. This data will provide an evidence base for future approaches and policy.

Community engagement and co-design

We have been working closely with Dr Naranjargal Dashdorj founder of the Onom Foundation, an organisation addressing inequality in healthcare and education in Mongolia, and Enkh-Oyun Amarbayasglan, the founder of the Mongolian Community Organisation in London, to design this study. In addition we have sought feedback from the wider Mongolian community via an online questionnaire, which we have used to inform the study design. We will continue to work closely and adapt to their feedback throughout the project and aim to form links for future healthcare projects with this community on the basis of this collaboration.

Rationale for the project

- Diagnosis and monitoring of viral hepatitis allows us to offer relevant treatment and monitoring to prevent adverse outcomes such as liver cirrhosis and cancer.
- There is enhanced global attention on MASLD, knowledge of MASLD in Mongolian population is lacking, and the interaction between MASLD and chronic viral hepatitis (in particular HBV) is poorly understood.
- Linkage of PLWHB to care and retention in specialist care is currently low (26-28) but improving engagement and awareness, and providing pathways to care linkage and retention will be key to individual and population health, supporting progress towards international elimination goals (29, 30). Ethnicity and age have been predictors of retention in care in some studies (26); identifying specific vulnerable groups will allow better use of resources to target individuals with the greatest barriers to continuity of care.
- This project sits alongside the recently implemented universal hepatitis screening programme in Emergency Departments in London (4), allowing us to investigate scale-up of multiple different pathways to diagnosis.
- Given that viral hepatitis commonly affects migrant populations, there is a pressing need for the development of programmes that provide accessible and culturally sensitive approaches.
- The project will provide an evidence-base for the development of other community-based screening initiatives.

3 AIM(S) AND OBJECTIVES

The primary aim is to estimate the prevalence of chronic viral hepatitis (HBV, HCV and HDV) and metabolic dysfunction-associated steatotic liver disease (MASLD) present in the London Mongolian community to help inform public health intervention and treatment strategies.

3.1 Primary Objectives

There are three domains to this study design contributing to the primary objectives (**figure 1**).

Clinical screening domain (part 1):

Among the London Mongolian community:

- Estimate the prevalence the number of people living with chronic viral hepatitis (HBV, HCV and HDV).
- Estimate the prevalence MASLD and presence of metabolic risk factors (obesity, hypertension, diabetes and dyslipidaemia).
- Develop community engagement and develop a stakeholder group to support the establishment of a screening and research programme for chronic viral hepatitis infection (HBV, HCV, HDV).
- To raise awareness of liver health, in particular chronic viral hepatitis (HBV, HCV and HDV) and metabolic dysfunction-associated steatotic liver disease (MASLD)

Laboratory research domain (laboratory test, part 2):

Among the London Mongolian community:

- Compare lipidomic profiles between PLWHB and MASLD, PLWHB only, people living with MASLD only and people without CHB or MASLD to investigate the interplay between the two major global causes of liver disease.
- Identify demographic, clinical and laboratory factors (e.g. viral sequencing, host immune and lipidomic profile, host HLA sequencing) associated with liver disease among people living with chronic viral hepatitis.

Qualitative domain (part 3):

Among the London Mongolian community:

- To understand attitudes, facilitators and barriers to testing and accessing healthcare for chronic viral hepatitis.

3.2 Secondary Objectives

Among the London Mongolian community:

- To use existing clinical pathways to connect individuals to appropriate local primary and secondary clinical services, namely a GP in their area of residence, clinical follow up for blood-borne virus infection (at Central and North London NHS foundation trust (CNWL) for baseline appointment), and any other clinical services if other needs are identified.
- To estimate the proportion of people living with HIV and syphilis.
- To evaluate linkage-to and retention-in-care among diagnosed with viral hepatitis.

4 STUDY DESIGN & METHODS OF DATA COLLECTION

This is an observational, mixed methods, cross sectional study, with three main domains:

(i) a **clinical domain** (part 1) providing community-based screening for blood-borne viruses and liver health, describing prevalence and characteristics of liver disease, and collecting relevant clinical metadata via a questionnaire,

(ii) a **laboratory research domain** (part 2) allowing us to collect additional blood samples and questionnaire data from those who consent, such that we can investigate laboratory parameters associated with viral hepatitis and liver disease,

(iii) a **qualitative domain** (part 3) to investigate lived experience of viral hepatitis and to understand and tackle barriers to diagnosis and clinical care.

4.1 Study Setting

We have developed a connection with the Mongolian community via the Onom foundation and Mongolian Community Organisation (MCO). These connections allow us to reach potential participants in advance of events to provide details of the clinical and research rationale for the project and invite attendance using existing networks and social media (eg Facebook, WhatsApp groups). All materials and communications will be translated into Mongolian by our study team.

The outreach screening events will take place in the venue of the MCO (Kensington Aldridge Academy). If, due to any unforeseen circumstances, this venue becomes unavailable during the study, we will select another appropriate setting that is accessible and acceptable to the Mongolian community, including waiting areas, refreshments, toilet facilities, and study flow to allow privacy and confidentiality. We will ask attendees to register their interest online prior to the event, allowing us to plan numbers and send out participant information sheets in advance. These events will be facilitated by members of the Find & Treat team, a specialist outreach service at University College London Hospital (UCLH). Clinical samples will be processed via UCLH and research laboratory work will be undertaken at the Francis Crick Institute. Qualitative focus groups will also be held at an appropriate accessible location, for example Kensington Aldridge Academy.

Reimbursement will not be offered for attending screening events as these are providing a clinical service and they will be held in accessible locations at convenient times to limit out-of-pocket costs to attenders. However, for participants who attend follow-up research events (e.g. focus groups) we will offer reimbursement for their time and costs.

4.2 Study population

We will recruit adults (aged 18+) from the London Mongolian community who attend the community viral hepatitis and liver health screening events.

Following this, we expect to recruit 8 groups (**figure 3**):

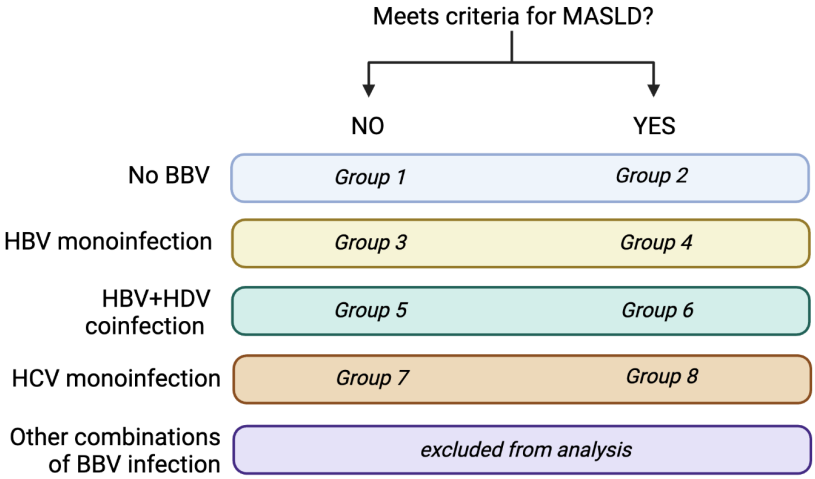


Figure 3: Schematic illustrating analysis groups. Other combinations include HBV+HCV, and human immunodeficiency virus (HIV) monoinfection or coinfections. Abbreviations: MASLD - metabolic dysfunction-associated steatotic liver disease; HBV - hepatitis B virus; HCV - hepatitis C virus; HDV - hepatitis D virus; BBV - blood borne virus.

4.3 Study procedures:

(i) Clinical domain (part 1)

There will be approximately 5 screening events. Trained members of ULCH blood borne virus (BBV) outreach team (Find & Treat) and members of the study team will be present at the event, including nurses, doctors, interpreters and peer support workers. Members of this team are experts at running clinical events in the community (e.g. based on experience of Covid programmes which offered SARS-CoV-2 vaccines but also provided BBV screening and linkage to care). At each event, we will provide education and awareness-raising about chronic viral hepatitis, available in written format and from face-to-face discussion, together with explanation of the purpose of the clinical and research activities.

Potential participants will be asked to avoid eating for 6-8 hours before the event as this will aid interpretation of the lipidomic data. This will be communicated to people who sign up in advance of the event and will be added to posters and promotional material. Lack of fasting will not exclude the participant on the study, but we will record this information on the accompanying questionnaire. Information on fasting time will be captured in the questionnaire and lack of fasting will not be an exclusion criterion. Refreshments will be provided for after the screening activities.

Attendees may undertake clinical tests as part of the screening event pending written consent. In addition, those participating in clinical screening will be informed that:

- We will share relevant information about their screening and results with general practice, including linking them to primary care registration if they are not already linked to services.

- For those who test positive for HIV, HBV, HCV or HDV we will contact their specialist care provider before the end of the study (~12 months post diagnosis) to ascertain clinic attendance, which will allow us to understand linkage and retention in specialist care.
- Anonymised data will be assimilated and shared (including in publication format) to support service development.
- We will retain anonymised data and samples long term such that material can be reused for future analyses relevant to chronic BBV infection and liver disease, subject to terms of consent and ethical permission (those who have consented for research).

Approach for all participants, after providing information:

1. Baseline data collection -
    - NHS identifiers: NHS number, name, date of birth - information to remain in clinical domain only.
    - Questionnaire (demographics, viral hepatitis and metabolic risk factors)
2. Point of care testing (POCT)* for HIV, HBV, HCV, syphilis.
3. Measurement of biometric data (weight, height, waist circumference).
4. For all those who are POCT positive, and a subset of at least 100 who are POCT negative (more if capacity allows), we will offer fibroscan assessment (non-invasive point of care test to assess liver health):
    - Transient elastography (TE) - assessment of inflammation / fibrosis
    - Controlled attenuation parameter (CAP) - assessment of steatosis
5. Venous bloods (see **table 1**)**
    - All participants:
        - Since Mongolians may be a high risk category for diabetes, (31) everyone will be offered a glycosylated haemoglobin blood test (HbA1c, in line with the NHS optimising tests in primary care document (32)). We will not test anyone with a pre-existing diagnosis of diabetes.
        - Lipid profile will be offered for those aged >40 years, BMI >23 or they have a family history of high cholesterol or heart disease (33). We will not test people already taking lipid lowering medication.
        - HBV serology for surface and core antibody, to establish if susceptible to HBV infection.
    - If HBV positive POCT: Hepatitis B surface antigen (HBsAg), HBV viral load, HBV core antibody, HBV e Antibody/Antigen, hepatitis D antibody, liver function tests.
    - If HCV positive POCT: HCV antibody, HCV RNA, liver function tests.
    - HIV positive on POCT: HIV antibody/antigen, HIV viral load.
6. Fibroscan and venous blood results from people with a positive POCT who were not able to have these tests on the day of finger prick screening may be collected at their subsequent hepatitis clinic appointment. We will also collect information on attendance at hepatology clinic appointments up until 1 year as evidence of linkage-to and retention-in-care.

*We have opted to do point-of-care-testing for three reasons:

1. Community preference

- Mongolian members of our study team and feedback from the community survey, expressing that the community would prefer as much information as possible on the same day
- Previous learning from similar community screening projects e.g. COMSAVA hepatitis screening, Spain and Chagas Hub, London (34, 35)

2. Decentralisation
    - Supporting an effort to decentralise hepatitis care to make it more accessible for people living with chronic viral hepatitis
    - It can also help us link people to care quickly
3. Clinical and Research stratification
    - Knowing the diagnosis on the day can help us focus on ensuring the correct information is given to participants with a new diagnosis, taking the appropriate confirmatory bloods and making a quick referral to hepatitis clinic
    - It will allow us to stratify recruitment into the study i.e. ensuring we take research bloods for all those with BBVs but limit the number of non-BBV controls.

**We have opted to do confirmatory BBV tests only on those with a positive POCT having reviewed the performance of the test kit (Test-it rapid HBsAg, Turklabs). An field study using 501 samples from people living with hepatitis B in France and Cameroon found it had a 98.3% sensitivity and a 99.5% specificity (36). With an estimated HBV prevalence of 10% and screening 500 people, this equates to less than 1 false negative test, which we can counsel for before the test.

Field evaluations of the INSTI Multiplex HIV/Syphilis test (Biolytical Laboratories, British Columbia, Canada), find 100% (95% CI, 98.1%–100%) specificity and 98.2% (95% CI, 93.4%–100%) sensitivity (37). The estimated prevalence of HIV in the general Mongolian population is <0.1% (36), therefore there is a small risk of a false positive result However, we will confirm every positive result with a blood test and have experts on hand for counselling of a positive POCT result.

A WHO assessment of the OraQuick anti-HCV test (OraSure Technologies, Pennsylvania, USA) revealed sensitivity 100% (97.8% to 100.0%) and specificity 99.4% (97.3% to 99.8%) (38) Age-adjusted chronic infection prevalence is estimated to be 6% , therefore this test should not give rise to any false negatives and 3 false positive results (39).

(ii) Laboratory research domain (part 2):

7. For all those who are POCT positive, and up to ~ 100 who are POCT negative, we will offer the opportunity to enrol in research, which includes:
    - 3 additional blood tubes for research (pathogen sequencing, metabolomics, biomarkers, immune profile, host genetic sequencing).
        - All those with chronic viral hepatitis infection who consent for research will have these additional bloods.
        - For those without BBV infection, we will only collect additional bloods on:
            - Maximum 50 of those without steatosis
            - Maximum 50 of those with steatosis

(iii) Qualitative domain (part 3)

During the screening event, participants will be asked to indicate whether they consent to future contact to be invited into a qualitative study. We will use methods similar to those previously published, in a study which investigated barriers and opportunities to HBV testing in a UK Somali population (40). Our team brings expertise in community engagement and qualitative data collection in both primary (Carter) and secondary (Flanagan) care settings and working with international communities (Matthews).

There will be 2-4 focus groups of 5-8 participants (number of groups will be limited by idea saturation, willing participants, time and cost). We will use purposive sampling to identify a range of community members of different ages, time in the UK, gender etc., who are likely to have a variety of views on chronic viral hepatitis testing and access to healthcare. To avoid the risk of accidental disclosure of infection status, we will only invite participants who are not living with a blood borne virus.

We will perform a semi-structured 1:1 interview of a sample (~5) people with chronic viral hepatitis to explore barriers and facilitators to diagnosis, linkage-to and retention-in-care, stigma and discrimination, and other topics relevant to chronic viral hepatitis diagnosis and management.

Data will be collected for both focus groups and interviews using semi-structured topic guides, which have been developed by the chief investigator and research team. The topic guide is not intended to be fully prescriptive, but instead show the order in which topics will be explored, and the main questions the research is seeking to answer but will be adapted according to the responses of the participants. 1:1 interviews will be conducted in a private and confidential environment, or via phone depending on the availability and preference of the participants and facilitators. Translation services e.g. language line or a physical interpreter will be used if preferred and as requested by the participant. Focus groups will discuss general views on topics such as testing and healthcare access and priorities in the community and will not identify participants hepatitis B status. Participants will be made aware of confidentiality in the PIS and consent form, and reminded of confidentiality required in the focus groups, particularly that discussions from the focus group should not be repeated.

In line with INVOLVE NIHR criteria, we will offer remuneration for travel costs (up to £37) and refreshments during the focus group, which will be held at a convenient, appropriate London location. There will be a Mongolian interpreter to help facilitate discussion. At each focus group we plan to have a facilitator and assistant.

Focus groups and interviews will be recorded using digital recording equipment. All audio recordings will be de-identified and anonymised during transcription, prior to sharing / publication.

4.4 Laboratory procedures

Venepuncture will be performed by a trained member of the research team. See **Table 1** for a summary of laboratory tests.

Test	All	Age ≥ 40 or BMI ≥23^	HBV POCT +	HCV POCT +	HIV POCT +	Syphilis POCT +	Additional Research only	Lab
POCTs*	☑							N/A
HBV serology#	☑		☑					NHS viro
HBV VL			☑					NHS viro
HCV antibody				☑				NHS viro
HCV VL & genotype				☑				NHS viro
HDV serology			☑					NHS viro
HIV test					☑			NHS viro
Syphilis test						☑		NHS viro
LFT			☑	☑				NHS biochem
HBa1c	☑							NHS biochem
Lipid profile^		☑						NHS biochem
Research samples$							☑	UCL/ Crick

Table 1: Blood test and sample bottle required for each participant and the lab where it will be processed. All columns to the right of "All" participants indicate *additional* blood tests for participants those categories. *Point of care tests (POCTs) for human immunodeficiency virus (HIV), syphilis, hepatitis B virus (HBV), hepatitis C virus (HCV). # All participants will receive HBV core and surface antibody only to establish if susceptible to HBV infection, only HBV POCT+ will receive hepatitis B surface antigen to confirm infection. $Research samples for sequencing, metabolomics, biomarkers, immunology, host genetics, transcriptomics. 2 whole blood/serum or plasma and 1 PAXgene tube will be collected. ^Only people who are not already taking lipid lowering medication will be tested. Abbreviations: HDV, hepatitis D virus; LFT, 'liver function tests' (Alanine Transaminase, Aspartate Transaminase, Gamma-Glutamyl Transferase, Alkaline Phophatase, Bilirubin, albumin); HBA1c, glycated haemoglobin; VL, viral load; SST, serum separator tube; EDTA, Ethylenediaminetetraacetic acid; viro, virology; biochem, biochemistry; haem, haematology.

NHS clinical tests will be processed according to the UCLH NHS laboratory protocol.

In the research lab at the Francis Crick Institute, we will receive the samples on the same day. If overnight storage is required prior to processing, samples will be held at 4°C. Samples will be separated and divided into aliquots to be stored at -80°C.

The project has been reviewed by the Human Biology Scientific Technology Platform at the Crick.

Samples will be prepared and processed in batches, with primary material handled and processed within an approved Containment Level 3 facility. Samples will only leave the CL3 environment when they have been treated to inactive infectious material based on existing laboratory protocols which have been improved by internal Crick Health and Safety and external review.

Research analysis will be undertaken including:

> HBV sequencing: we will aim to generate HBV sequences (aiming for full viral genome) from individuals who have tested HBsAg-positive, where possible based on viral load, using a combination of methodology that includes PCR amplification, and either short-read (e.g. Illumina) and/or long-read (e.g. Nanopore) sequencing, using the most recently optimised approaches, based on existing published methods (39, 40). Sequences will be analysed to determine the genotype of HBV infection, and to identify other polymorphisms that may be relevant to disease outcome (e.g. drug and vaccine resistance, polymorphisms associated with liver cancer, polymorphisms associated with the host immune response). We will store samples for possible future sequencing of other viruses (e.g. HIV, HDV, HCV).

> **Metabolomic / Lipidomic analysis:** In collaboration with the Metabolomics Scientific Technology Platform at the Crick, lipids will be extracted from serum samples using a modified Bligh-Dyer method and analysed via Liquid Chromatography-Mass Spectrometry (41). Data and statistical analysis will be completed by experienced data analysts in the Metabolomics Science Technology Platform. We will measure metabolites and lipids in serum samples to determine the relationship between these peripheral profiles and virologic outcomes, liver fibrosis/steatosis. Ideally these samples will be fasted (6-8 hours). We will provide information on this ahead of the study, and provide refreshments after the screening, but being unfasted will not preclude participants from entering the study.

> **Measurement of a panel of host and viral biomarkers** pertaining to the development of liver disease:

- **cytokine profile** (phenotyping host immune markers which may be relevant in outcomes of infection, using established platforms for analysis, such as O-link or MSD assay)
- **Host transcriptomic profile** (characterising host gene expression to understand differences according to metabolic factors, viral infection and fibrosis/steatosis level)
- **viral antigens** (quantification of HBV antigens including HBsAg, HBeAg, HBV core related antigen)
- **viral nucleic acids** (quantification and/or sequencing of viral DNA / RNA for any viruses detected in the sample)

> **Ascertainment of host genetic background** focusing on the MHC Class I region (HLA genes) which are known to be important determinants of immune response to vaccination and infection, but also generating information on the whole genome to undertake lineage correction.

We anticipate that most assays will be undertaken in-house at the Francis Crick Institute. However, certain assays are not available locally and we will therefore send samples to collaborating laboratories for additional tests (in the UK or internationally) such as quantification of HBV pregenomic RNA or core antigen. Any samples sent to other laboratories will be under the terms of a Material Transfer Agreement (MTA), and participant information / consent will include their permission for samples to be shipped if required. No identifying data will accompany samples shipped for research purposes.

4.5 Sample size

Our sample size will be determined by the size of the community who engages with the research. Based on an estimated Mongolian community of 1300 people living in London, we estimate 70% of these to be adults aged 18+ (n=910), and of these we will aim to recruit and engage 500-600 people. We will use local networks and social media (e.g. well-established facebook groups) to try to reach as many of the community of individuals aged 18+ with information and an invitation to participate. We will run up to a maximum of five screening events, screening approximately 100 per day to allow screening of 500-600 individuals.

Approximate estimated numbers per recruitment group based on published prevalence estimates with an expected screening number of ~500 (**figure 4**):

- People living with HBV (~7.5%) (19-22, 41, 42) (n= ~38)
- ~35% living with HBV/HDV coinfection (43) (n=~13)
- People living with HCV (~6%) (n=~30) (39)
- People living with MASLD (~30%) (44) (n=~150)

This will be a small study with limited statistical power. However, our primary objective is to establish the prevalence of hepatitis B and C virus infection in this study.

Using the formula for calculating sample size for prevalence studies n = Z^2P(1-P)/d^2, where:

- n: is the sample size
- Z: is the statistic for the confidence level (1.96 i.e. 95% confidence interval)
- P: is the expected prevalence (7.5%)
- d: is the precision (0.05, +/- 2.5%)

Using the above estimated parameters, a sample size of approximately 427 is needed to determine a prevalence of HBV of 7.5%.

Other analyses will be exploratory, investigating trends using correlation with lipidomic, transcriptomic and sequencing data which can be further analysed with a more targeted approach.

Given the low prevalence of HIV in Mongolia (~0.1%), we do not expect to pick up any new diagnoses in this screening programme. There are also low rates of HBV/HCV coinfection (0.4%), therefore it is unlikely we will pick up new diagnoses in this cohort (45). However, we will also recruit people living with HIV or other co-infections if we identify them and they are willing to participate in the research project.

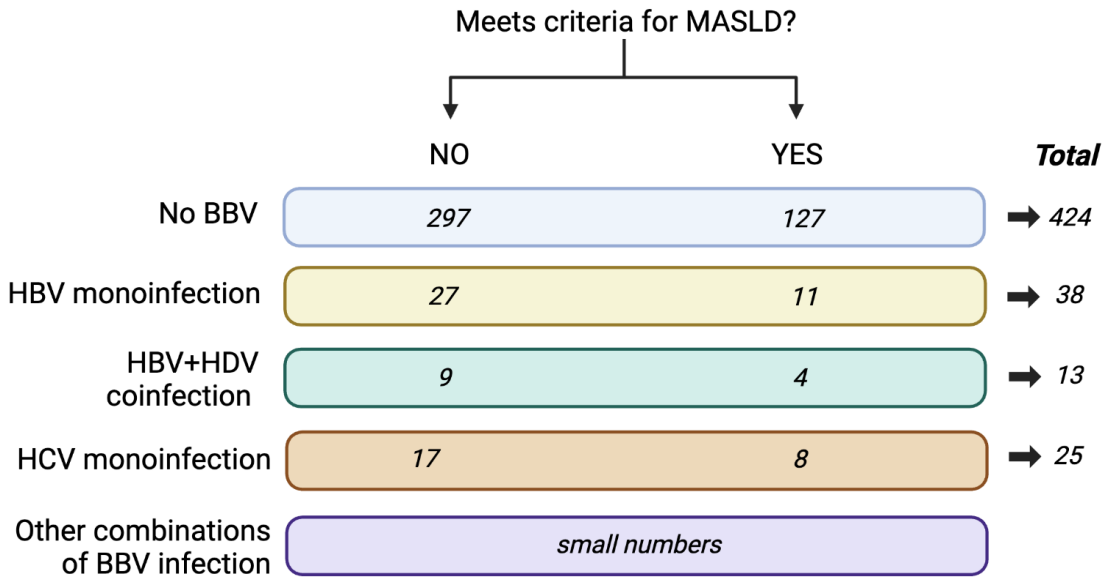


Figure 4: Schematic illustrating expected numbers in analysis groups based on published prevalence and a sample size of 500. N.B. we will only collect blood samples from up to 50 participants with no MASLD and no BBV (i.e. "healthy controls"). Abbreviations: MASLD - metabolic dysfunction-associated steatotic liver disease; BBV - blood borne virus; HBV - hepatitis B virus; HCV - hepatitis C virus; Other combinations include HBV+HCV, and human immunodeficiency virus (HIV) monoinfection or coinfections.

5 STUDY SCHEDULE

Enrolment process

To support the development of this protocol, we have reached out via the Mongolian Community Organisation (based in West London) to seek feedback around the concept and approaches to be taken by the study, using a SurveyMonkey questionnaire in Mongolian. We will continue to partner with this organisation throughout the project so that we are responsive to the community's needs and feedback.

In advance of our clinical screening events, meetings will be convened with members of the Mongolian community to engage with them in planning the specific details of outreach and screening activities, including details of communication strategies, community awareness, approaches to connecting and provision of culturally sensitive and accessible information.

Prior to screening events, potential participants will be contacted with written information (in Mongolian and/or in English) and study details alongside an invitation to attend a screening event. The study will be advertised via a Mongolian community facebook group and word of mouth and posters via the Mongolian Community Organisation. Participants will be asked to register interest in a secure google form, and the patient information sheet will be emailed or handed out in person in advance of the day. They will also be provided with a point of contact for further information about the project. We will allow enrolment of participants who have not pre-registered, since there will be

an information session ahead of the practical screening process. If the person is interested but needs more time to consider, we will give them details of the next screening event to attend.

Study enrolment will take place during the screening event, facilitated by a trained member of the clinical research team, alongside a Mongolian interpreter if required. Potential participants will be provided with written and verbal information, can ask questions, and confirm their participation in clinical screening verbally (as per standard of care for clinical procedures), and research participation with written informed consent.

Screening

Participants will be screened for eligibility, being able to take part if they are aged 18 years or older on the screening date and being able to provide valid informed consent. There are no other inclusion/exclusion criteria.

Data collection

Data will be collected through the following five-step pathway (for more detail of specific tests see section 4.3)

- Questionnaire (see appendix) - demographic, metabolic and viral hepatitis risk factors, comorbidities
- Biometric data: weight, height, waist circumference
- Point of care tests (fingerprick testing)
- Venous blood samples (see Table 1)
- Fibroscan (TE and CAP score)

Follow up

As previously mentioned in section 4.3, we will contact the referral clinic to ascertain information about appointment attendance up to one year post diagnosis to ascertain retention-in-care. We will arrange appropriate clinical follow up for conditions diagnosed during the outreach event:

1. Chronic viral hepatitis

- Participants found to have a new diagnosis of viral hepatitis (HBV/HDV/HCV) or HIV or syphilis, or those who are known but not under follow up, will be referred to specialist care.
- Our specialist viral hepatitis clinics at Mortimer Market Centre and University College London Hospital will lead in providing clinical follow-up and will provide a default appointment for individuals who need review based on the results of BBV screening. For any participants who wish to be referred to an alternative secondary/tertiary care provider, this can be arranged as per routine protocols for referrals between NHS centres. Our existing clinical team includes a peer support worker and members of the Find-and-Treat service who can provide additional support and information, including accompanying people to clinic visits if needed.

2. Hypertension

- Participants will be informed of their blood pressure results on the day. This information will be entered into a paper form for them to take away, and will be provided alongside basic lifestyle advice.
- We will follow NICE guidelines on hypertension diagnosis and management:
    - If >140/90, repeat blood pressure and take the lowest of 2 recordings. Suggest attendance for referral for ambulatory BP monitoring/ optimising current hypertension medications if already diagnosed with hypertension.
    - If >180/120, the blood pressure will be repeated. If it remains >120/180 for 3 readings, then they will be advised to attend Accident & Emergency for further assessment.

3. Raised BMI

- Participants will be informed of their BMI and given their results along with information on lifestyle advice to take away.
- A letter will be sent to the GP to inform them of the results.

4. Raised CAP score (steatosis/fatty liver)

- If elastography <8kPa, lifestyle and diet advice, refer back to GP for CV risk management.
- If elastography >8kPa, refer to hepatology clinic.

5. Deranged lipid profile

- The results will be communicated to the GP for full assessment (complete cardiovascular assessment, including renal and thyroid function tests) and offer starting or escalating lipid lowering therapy.

6. Deranged liver function tests

- These will be interpreted by the clinical team leading the study in context of the medical history and other demographic and laboratory data collected (Martyn, Matthews, Flanagan, Ghosh).
- There will be provisions made to repeat the tests and send further liver screens in clinic if necessary, liaising with relevant local primary or secondary care services

7. Cirrhosis

- Regardless of aetiology, they will be referred to a hepatology clinic.
- The participant will be informed of the result and the referral, and the GP will be notified.

Participant withdrawal

Participants who engage with clinical testing will be linked to services and provided with support and encouragement to pursue follow up as per usual clinical pathways.

For those who provide consent for research, they will be informed that they can withdraw from the research component of the study at any time, and this will not affect the standard of care they receive. If the participant chooses to withdraw from the study, they will have two options:

1. Withdraw from the study and not be approached for further information. However, the samples and data already obtained, including audio recordings from focus groups may still be retained and used.
2. Participant requests no further contact and for their samples and data to be destroyed. Data and samples will be destroyed if they have not already been used / published as part of an analysis.

End of study

This study will run for three years, which will provide us with time to undertake community events and screening, and to follow up with relevant laboratory studies, and a period of analysis and writing up reports.

6 ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

- Self-identifying as a member of the Mongolian community.
- 18 years or older on the day of screening.

6.2 Exclusion Criteria

- Does not have the capacity to consent.

7 RECRUITMENT

Community screening events will be planned and delivered in collaboration with community members. Where possible, attendees will receive patient information sheets and information prior to the event via community channels e.g. social media community pages. Further information about the importance of screening for chronic viral hepatitis, and the opportunity to take part in the research study will be available at the screening event. Members of the clinical research team will be present at the event to ask any questions. Community members can then choose to consent to enrol in the study and undergo the clinical screening process with or without additional research participation.

Reimbursement will not be provided for community screening events but will be available to a small number of participants who take part in follow-up focus groups / interviews.

Please refer to section 4.3(ii) and 4.5 for sample size discussion.

8 CONSENT

Trained clinical research team members will obtain routine clinical consent from participants who wish to undergo screening at the community event. Consents will be taken electronically using REDcap, but paper consents will be available if necessary. We have opted for this method of consenting because this is a remote outreach screening study and therefore this will reduce the amount of paper being used, thereby reducing any breaches of GDPR. This was deemed acceptable by the Mongolian Community Members on our design team.

9 DATA ANALYSIS

We anticipate there will be 8 main groups for analysis (**Figure 4**). We anticipate groups 1-4 will be the most common groups and therefore our initial analysis will focus on these combinations.

1. Descriptive statistics will be used to describe:
   - The prevalence of HBV, HBV+HDV, HCV infection and MASLD.
     - Appropriate weighting strategies will be applied and 95% confidence intervals calculated.
   - Population demographics.
   - The burden of liver disease based on elastography, CAP scores and derangement of liver function tests, in each group (**figure 4**)

2. Comparison of liver disease severity or viral parameters between groups, to understand the impact of MASLD on chronic viral hepatitis.
   - We will look for significant differences between groups using both quantitative data, and data divided using relevant clinical thresholds (e.g. based on published definitions for liver fibrosis and cirrhosis).
   - Primary analysis will focus on a comparison between PLWHB and BBV-negative controls and participants with/without MASLD, with comparisons matched for age and sex. Secondary / subgroup analyses will be determined by the numbers of participants identified in each of our eight classes, and other relevant exposures, accounting for whether we have statistical power to interrogate the dataset for the impact of other parameters (e.g. country of birth, alcohol or smoking history, presence of metabolic syndrome).
   - Statistical tests will include Fisher's Exact Test / chi-squared for univariate analysis of binary variables, Mann-Whitney test for quantitative variables.

3. Comparison of serum lipidomic profile and cytokine analysis to explore key differences between groups and correlations with liver disease.
   - In collaboration with the bioinformatics and metabolomics scientific technology platforms at the Crick, multi-dimensional statistical modelling e.g. primary component analysis will be used to analyse results from lipidomic analysis.

4. Analysis of viral sequencing data, to identify any associations between sequence genotype and polymorphisms are associated with liver disease severity and outcomes in chronic viral hepatitis.
   - Data analysis will be in collaboration with the biostatistics and Genomics science technology platforms at the Crick. HBV sequence data will be analysed using a pipeline developed in collaboration with the ARTIC team in Birmingham (with the view to using open-source code).

5. We will collect data on clinic attendance approximately 12 months after diagnosis to assess linkage-to- and retention-in-care. There are no consensus definitions in the HBV field, therefore, for the purposes of this study we will define these terms as follows:

- Linkage-to-care: person attendance chronic viral hepatitis appointment within three months of diagnosis (based on literature from the HIV field).
- Retention-in-care: More than one specialist appointment in one year since diagnosis. (In a newly diagnosed/ referred cohort, it is reasonable to expect more than one appointment in the first year).

6. Qualitative data analysis:
   - Qualitative data will be analysed using thematic framework analysis techniques. Transcription and coding will be performed by two members of the research team. Anonymised audio recordings and written accounts/field notes will be transcribed into Word documents, with transcription, coding and analysis being facilitated by appropriate software (e.g. NVivo).

Data will be analysed on R studio, Prism GraphPad and relevant software suitable for multiparametric analysis. Anonymised demographic, clinical and laboratory data may be pooled with data from other studies to facilitate cross-comparison between populations in different settings, and/or to expand datasets and improve statistical power for the identification of relevant biological signals.

10 PATIENT AND PUBLIC INVOLVEMENT (PPI)

One of the members of our team is a Mongolian hepatologist with expert insight into the Mongolian community and liver disease (Dr Naranjargal Dashdorj). We have also involved Enkh-Oyun Amarbayasgalan, a member of the London Mongolian Community (and leader of the Mongolian Community Organisation based in West London). These team members have advised and been involved in study design. A preliminary survey report was sent to community members to assess community health priorities, barriers and facilitators to attending community screening and views on research and was used to inform the study design. This survey report can be found at: https://doi.org/10.6084/m9.figshare.26312389.v1.

Participant and community engagement will be led by experts within our research team:

Dr Naranjargal Dashdorj: consultant hepatologist, co-founder of 'Onom Foundation' a non-governmental organisation established to deliver healthcare in Mongolia. Dr Dashdorj provides connections to the Mongolian community and brings experience from leadership of similar programmes in Sweden and the US. She has participated in national and international expert bodies, including WHO guidelines groups, and thus provides connections to support delivery of wider impact from this project.

Ms Joy Ko: peer support worker for people living with hepatitis B virus infection at Central North West London Trust. Ms Ko will bring experience in HBV advocacy and peer navigation and will support qualitative aspects of developing and delivering the project, and ensure participant voice is central to our design and recommendations.

Prof Sally Hargreaves: Prof Hargreaves brings expertise in migrant health and infection and has led community events focusing on a range of other infectious diseases, working in close partnerships with relevant members of diverse populations.

Dr Jessica Carter: as a primary care physician, Dr Carter brings insights into community medicine and can support the development of closer connections between general practice and the community. She is leading a range of projects focusing on qualitative research to inform care delivery in diverse communities, including a special interest in migrant health, and supporting decentralisation of care for people living with HBV infection.

Dr Indrajit Ghosh: Dr Ghosh is an experienced member of the Find and Treat team working to facilitate diagnosis of infectious diseases and provide patient-centric linkage to care, treatment and follow-up.

We will continue to liaise with community members throughout the research, taking on feedback about the running of the events and ensure the findings are disseminated in an accessible way to community members.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office and deemed sufficient to cover the requirements of the study. NHS costs will be supported via University College London Hospital [insert site name e.g. UCLH] and/or the Local Clinical Research Network.

The research component of the programme, 'Viral hepatitis infection in the Mongolian Community in London ('Hep-MoLo'): An investigation of epidemiology and burden of disease to inform clinical and public health interventions' has received funding from the NIHR UCLH Biomedical Research Centre Immunopathology and Immunotherapeutics Theme: (project funding £45,442). This funding is for the period 1st March 2024 to 28th February 2026.

Table 2: Approximate breakdown of research costs for the study

Budget period	**Item**	**Cost**
March 2025 – March 2026	Contribution to clinical research nurse salary, 1 year	£23K
September 2025 – September 2026	Focus groups	£5K
March 2025 – January 2026	Room hire, transport costs	£1K
March 2025 – January 2026	Reimbursement of participants, including travel costs, refreshments, vouchers	£1K
March 2025 – January 2026	Time for other team members (peer support worker, inclusion health team, project board costs*)	£5K
March 2025 – January 2026	Laboratory consumables for NHS testing	0
March 2025 – October 2026	Contribution to laboratory consumables for HBV sequencing and biomarkers	£10K
January 2025 – January 2026	Administrative costs Eg database, ethics, posters, participant information leaflets (plus translation)	£1K
March 2025 – January 2026	Security	£1K
March 2025 – January 2026	Interpreters	£1K

12 DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is [data-protection@ucl.ac.uk]. The data processor is UCL. The study will be collecting the following personal data:

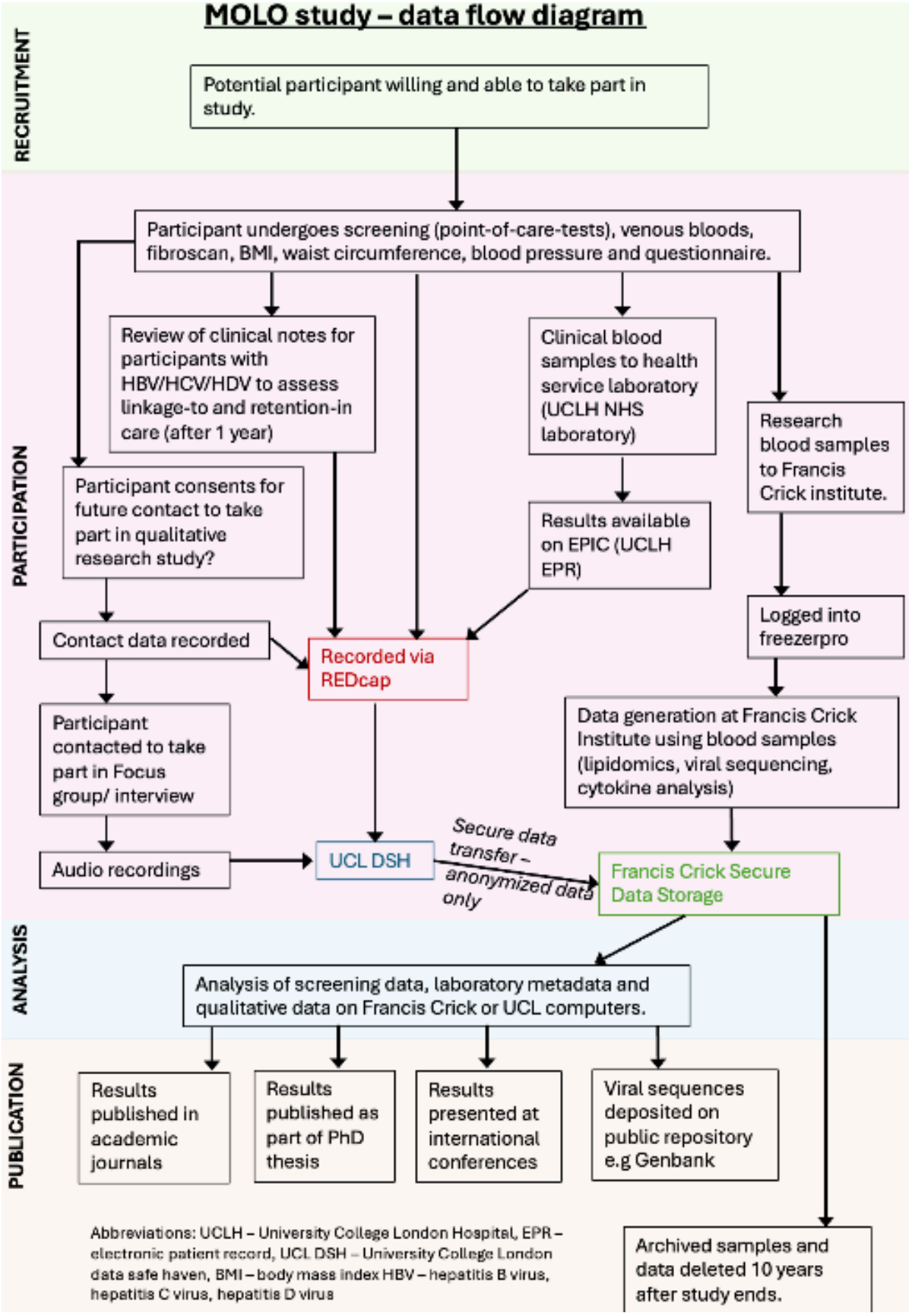
Information	**Special category (y/n)**
Age	N
Gender	N
Sexual orientation	Y
Country of birth	Y
Ethnicity	Y
Years of first arrival in the UK	N
Co-morbidities	Y
Current medication	Y
Alcohol intake	Y
Smoking status	Y
Dietary information	N
Hepatitis B vaccination status	Y
Any relatives living with chronic viral hepatitis	Y
HLA sequencing	Y
Voice recordings	N
Hospital number	N
NHS number	N
Address	N
Telephone number	N
Information about medical procedures which may increase viral hepatitis risk e.g. dialysis, obstetric care, operations, blood transfusions outside the UK	Y

All investigators and study site staff will comply with the requirements of the UK Data Protection Act (2018) and Human Tissue Act (2004) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles.

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensuring adequate data quality. The Chief Investigator will inform the sponsor should she have concerns, which have arisen from monitoring activities, and/or if there are problems with oversight/ monitoring procedures.

Data Flow Diagram

Figure 5: Data flow diagram describing the different data flow for clinical and research data.


MOLO study – data flow diagram
RECRUITMENT
Potential participant willing and able to take part in study.
PARTICIPATION
Participant undergoes screening (point-of-care-tests), venous bloods, fibroscan, BMI, waist circumference, blood pressure and questionnaire.
Review of clinical notes for participants with HBV/HCV/HDV to assess linkage-to and retention-in care (after 1 year)
Clinical blood samples to health service laboratory (UCLH NHS laboratory)
Research blood samples to Francis Crick institute.
Participant consents for future contact to take part in qualitative research study?
Results available on EPIC (UCLH EPR)
Contact data recorded
Recorded via REDcap
Logged into freezerpro
Participant contacted to take part in Focus group/ interview
Data generation at Francis Crick Institute using blood samples (lipidomics, viral sequencing, cytokine analysis)
Audio recordings
UCL DSH
Secure data transfer – anonymized data only
Francis Crick Secure Data Storage
ANALYSIS
Analysis of screening data, laboratory metadata and qualitative data on Francis Crick or UCL computers.
PUBLICATION
Results published in academic journals
Results published as part of PhD thesis
Results presented at international conferences
Viral sequences deposited on public repository e.g Genbank
Abbreviations: UCLH – University College London Hospital, EPR – electronic patient record, UCL DSH – University College London data safe haven, BMI – body mass index HBV – hepatitis B virus, hepatitis C virus, hepatitis D virus
Archived samples and data deleted 10 years after study ends.

Source data

Clinical data (part 1) collected on the day will be entered into a Microsoft form, stored on a secure NHS sharepoint. Once clinical blood tests have been obtained, the research doctor will use a "smart phrase" to automatically pull the relevant data into an entry on the UCLH electronic patient record (EPIC). This can be used to create a letter to send to the GP and patient (**Figure 5**).

Research data (part 2) will be recorded on to UCL REDcap case report forms (considered source data), stored on UCL Data Safe Haven. Each participant will be given a unique identifier (MOLO-screening day number-participant number). Consent and questionnaires will be filled out on the day of screening, but additional results may be inputted following screening as they become available.

Qualitative source data will be the digital audio files from focus groups/ interviews and will be deleted once transcription has been completed.

Access to data

Direct access to study data will be restricted to authorised members of the study team to enable them to carry out their duties. Linkage back to identifiable source data will only be possible through authorised team members. Access will also be granted to authorised representatives from the Sponsor, host institution and regulatory authorities to permit study-related monitoring, audits and inspections.

Data Storage, transfer and security

The Chief Investigator will be the Data Custodian of the study. All study data and associated documents, including consent forms, will be stored on a secure, password protected computer with limited access to only the research team.

Participants and the research team will fill electronic CRFs in a Redcap with restricted access and password protection, held within the UCL Data Safe Haven. The Data Safe Haven has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. At study enrolment the participant will be issued a participant identification code (participant ID) and that will remain the primary identifier for the participant (with date of assessment and initials as secondary identifiers). The participant's informed consent form (ICF) will carry their name, initials for each item consented, signature and date. ICFs and electronic CRFs will be stored on Redcap, held within UCL Data Safe Haven. All study specific research samples will be labelled with study abbreviation, participant ID, date of collection, and patient initials. Any email electronic transfer of data will be with secure NHSmail email addresses.

Semi-structured interviews/focus groups with participants will be audio recorded and labelled with the participants unique ID number. All names will be removed from audio recordings. Digital recordings and pseudo-anonymised transcripts will be maintained in a password protected database on a password protected computer. Digital recordings will be transcribed by a dedicated research assistant. Recordings will be stored on password protected computers within a locked office and deleted after transcription.

Confidentiality

All information related to participants will be kept confidential and managed in accordance with the Data Protection Act 2018. All study staff will comply with the requirements of the Data Protection Act 2018 (DPA 2018), the UK General Data Protection Regulation (UK GDPR), and The Human Tissue Act (2004) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

13 MATERIAL/SAMPLE STORAGE

In the study, blood samples (serum/plasma) will be collected from patients in accordance with the patient consent form and patient information sheet and shall include all tissue samples or other biological materials and any derivatives, portions, progeny or improvements as well as all patient information and documentation supplied in relation to them. Samples will be processed, stored and disposed in accordance with all applicable legal and regulatory requirements, including the Human Tissue Act 2004 and any amendments thereafter, and the applicable HTA Codes of Practice Departmental SOPs will be followed to facilitate regulatory compliance.

Clinical samples will be processed, stored and destroyed according to UCLH laboratory SOPs. Research samples will be stored at the Francis Crick Institute for 10 years. They will be de-identified and labelled with an anonymised code. Laboratory procedures are detailed in section 4.4.

Samples may be shared with collaborators according to Material Transfer Agreements.

14 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

The Sponsor considers the procedure for obtaining funding from UCLH NIHR Biomedical Research Centre to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies (list here, e.g. NHS REC Favourable Opinion/UCL Ethics approval and HRA Approval). **Before any site can enrol patients into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

15 ASSESSMENT AND MANAGEMENT OF RISK

There are several potential risks which we have identified and will attempt to mitigate:

1. ***Distress and possible stigma associated with testing positive for BBV infection***
    - Every effort will be made to ensure confidentiality during the screening process. This may be via screens and/or choosing a venue that will allow screening to take place in a separate room.
    - Specially trained clinical research staff with experience in giving positive results will be administering the test. They will explain the result, give written information, explain the next steps and signpost to additional available support. Our team has extensive expertise in community screening and diagnosis of BBV infection. The Find-and-Treat service and our peer support worker can provide additional information, advice and support, and can refer to other sources of support (charities, NGO etc) if required.
    - The protocol and procedures have been reviewed with members of the Mongolian community.

2. ***Loss to follow up***
    - Our blood borne virus team are skilled at making onward referrals to specialist hepatitis services following outreach events (47) and the study provides several opportunities for education, information, linkage to primary care, and provision of peer support.
    - We inform the participants of the next steps, provide them with contact numbers as a back-up.

3. ***Disclosure of risk of harm to self or others during the qualitative focus groups/ interviews and/or the screening procedures***
    - If a participant discloses information which may highlight a risk to themselves or others, confidentiality will be broken in the best interests of the participant.
    - The participant will be notified before confidentiality is broken, and we will highlight this in the patient information sheet and consent form.
    - If a research team member becomes concerned about a participant's risk of harm to the self or others, they will immediately raise their concern to a study clinician and inform the participant they are doing so. This will be detailed in the PIS and consent form. The clinician will urgently risk assess the patient and refer on as appropriate (e.g. Emergency Department psychiatry assessment, GP assessment or police, if deemed necessary).
    - Actions in the "distress protocol", adapted from another approved qualitative study, will be followed.

4. ***Risk of bruising/ local discomfort due to venepuncture or the use of a finger prick lancet***
    - The participant will be warned about a small risk of bruising/discomfort as a result of collecting blood samples, but this is extremely likely to be self-limiting and resolve quickly, if it does occur. Expert phlebotomists will take samples to reduce risks.

5. ***Community member or member of public becoming aggressive or upset during the event***
    - The risk is very low, given we will work with the community to ensure the acceptability of the project and participants will choose to attend the meeting based on information they receive before the event. However, security has been included in the budget.

6. Psychological distress during or after focus groups or interviews
- Discussions or questions surrounding discrimination and stigma, or other themes associated with chronic viral hepatitis diagnosis, management or access to healthcare may lead to psychological distress.
- Participants will be warned about the content of discussion before consent and before the focus group/ interview and be given the option to withdraw if they feel uncomfortable.
- Trained members of staff will coordinate the focus groups and interviews and will be around to provide discussions or debriefing after the event and a distress protocol will be followed in the event a participant indicates or exhibits signs of psychological distress.
- The “distress protocol” will be followed.

7. Risk of accidental disclosure of blood borne virus status in focus groups
- Participants for the focus groups will be selected based on a negative BBV test during the screening events to avoid accidental disclosure of BBV status.
- Trained members of the research team will facilitate the focus groups.
- Participants will be given ground rules at the beginning of the group, reminding them that everything discussed is confidential and should not be shared beyond the group.
- They will also be reminded that they do not have to share anything they don’t feel comfortable with during the session.

Participant information sheets will provide information about risks and a contact number for the research team, should the participants wish to call for more information.

16 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via UCL: research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

Potential incidents that may occur in this study:

- Data breach – incident report required. See 15.1
- Loss of samples – incident report required.
- Needlestick injury to staff member – incident report required. Staff member to wash wound, attend A&E immediately for assessment and inform occupational health. This risk will be minimised by ensuring up to date training on routine venepuncture, and delivering finger prick lancet training to staff members before study initiation.
- Security incident at event - incident report required.

16.1 Personal Data Breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer data-protection@ucl.ac.uk (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Sponsor via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.

16.2 Adverse Events and Serious Adverse Events Sponsor Reporting Requirements

Adverse events are any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. These do not require reporting to the Sponsor, but the severity, causality and expectedness will be recorded in the participant's medical records, CRF and AE log with a description of clinical symptoms and the event, including dates as appropriate.

SAEs (any event that results in death, is life-threatening, requires hospitalisation or prolongation of existing inpatient hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect) that have been determined to be **unrelated** to the research intervention by the CI/PI do not require reporting to the Sponsor, but will be recorded in the participant's medical records, CRF and site file. Additionally, **expected** SAEs that are likely to occur on a regular basis and offer no further new information to the safety profile, or are related to the disease area of the participants, do not require reporting to the Sponsor, but must be recorded as previously stipulated. Sponsors will however be notified where the frequency and severity of unrelated SAEs are unusual; research sites will report as per Sponsor reporting requirements.

In some instances, **unexpected and related SAEs** may occur in observational research, for example a participant may have an unrelated medical emergency e.g. collapse at the screening event. All reportable SAEs will be recorded in the medical records and CRF, and reported to the Sponsor via the JRO REDCAP research incident reporting form or research-incidents@ucl.ac.uk, within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the Sponsor as soon as possible.

16.3 Incidental Findings in Research

All research staff must follow participating sites' incidental findings policies, and training must be provided as part of initiation to the research study.

Potential test results and follow up scenarios have been detailed in the "follow up", under section 5 "Study schedule", which covers review by an expert team of clinicians and referral to primary care or onwards to relevant secondary care services as indicated. We have minimised "unnecessary" blood tests, to reduce the possibility of incidental findings.

16.4 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study
The CI and Sponsor will be notified immediately of any case where the above definition applies via UCL: research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form.

16.5 NHS Serious Incidents and near misses

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:
a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.
Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

16.6 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

17 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

18 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

19 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, effectively assigns all such intellectual property rights ("IPR") to UCL and discloses all such know-how to UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, as its own risk, in the furtherance of its normal activities or providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information of the infringement of an intellectual property rights of UCL or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

20 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Hospitals selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

21 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at University College London Hospital for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

NB: UCL do not archive student projects and therefore, the length of storage is not subject to the standard Sponsor requirements.

22 PUBLICATION AND DISSEMINATION

Authorship will be determined by the chief investigator and will adhere to the general standards for publishing. The data arising from the study belongs to UCL / The Francis Crick Institute and on completion of the study the data will be tabulated, analysed and a Final Study Report prepared, aiming for this to be made available in the public domain during2027. The results will be submitted to appropriate national/international meetings, and to relevant peer-reviewed journals and shared on social media and on our institutional websites. Participants will be notified with a summary of the study results by email or letter. The study protocol, full study report, anonymised patient level dataset and statistical code for generating the results will be made available to external parties on request. Resulting publications and/or abstracts will be emailed to the JRO.

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24 APPENDICES

24.1 Associated Documents

Document Name	Document Version	Document Date
Patient information sheet (main)	1.0_draft	9 August 2024
Patient information sheet (qualitative)	1.0_draft	9 August 2024
Main MOLO consent form	1.0_draft	9 August 2024
Qualitative consent form	1.0_draft	9 August 2024
MOLO Questionnaire	1.0_draft	9 August 2024
MOLO GP letter template	1.0_draft	9 August 2024
Results and advice	1.0_draft	9 August 2024
Poster	1.0_draft	9 August 2024
Distress protocol	1.0_draft	9 August 2024