

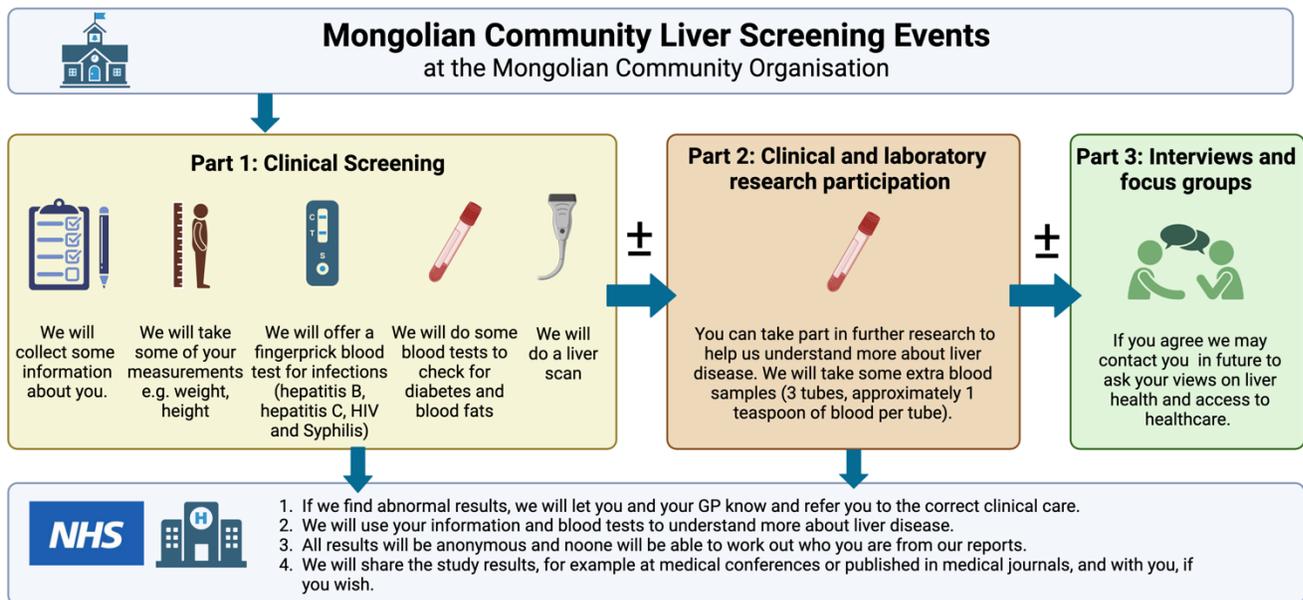
Hep-MoLo Study: Mongolian Community Liver Screening - Participant Information Sheet

We invite you to take part in a research study

- Before you decide to take part, it is important for you to understand why this project is being done and what it will involve.
- Please take time to read the following information carefully. You can discuss it with friends and relatives if you wish.
- Ask a member of the study team if anything is not clear or if you would like more information.
- You are free to decide whether to take part. If you choose not to take part, this will not affect care you receive in the future.



HEP-MOLO STUDY: how this study works



Brief Summary

- We are a group of doctors, nurses and scientists working to diagnose, manage and improve our understanding of liver disease, which is very common in Mongolia.
- We are doing this by running community liver screening events together with the Mongolian Community Organisation.

Why are we doing this study?

- Long-term viral hepatitis infection, caused by **hepatitis B, D and C viruses**, affects around 300 million people globally.
- **Viral hepatitis is very common in Mongolia** leading to one of the highest rates of liver cancer in the world.
- Many people don't know they have viral hepatitis because they don't always cause symptoms. However, it is important to diagnose viral hepatitis because treatment and monitoring are easy to access through the NHS and

can prevent future liver disease.

- Some people with viral hepatitis can develop liver damage and liver cancer, but we do not fully understand why only some people develop these complications.
- **Metabolic risk factors**, such as diabetes (a disease in which the body is unable to control blood sugar levels), high cholesterol (high levels of fat in the blood), being overweight or obese or high blood pressure, can cause problems with your heart and blood vessels, for example, stroke and heart attack. Metabolic risk factors can also cause fat to build up the liver, which can cause liver damage.
- By doing this study, we aim to better understand how viral hepatitis, liver fat and metabolic risk factors affect liver health.
- We also want to know if people living with hepatitis B attend healthcare services for regular monitoring, and identify reasons why they may or may not attend, to help improve healthcare service access for the Mongolian Community and people living with hepatitis B.

What would taking part involve?

The study is divided into 3 parts (see diagram on page 1). You can choose to take part in: part 1 only, part 1 and 2, part 1 and 3, or part 1, 2 and 3.

PART 1: CLINICAL SCREENING

- This part of the study is similar to what might happen in an NHS clinic, but instead we are performing screening tests in this community centre.
- We will ask you to complete a **questionnaire** which will take about 10 minutes to complete. This will help us understand more about your health and you can choose not to fill out any questions you feel uncomfortable answering.
- We will check your **metabolic risk factors**:
 - **Weight, height, waist circumference, blood pressure**
 - **Diabetes blood test** (venous blood test, see figure 1A, offered to everyone)
 - **Blood fats** (venous blood test, **Figure 1**, only people who are overweight, or aged ≥ 45)
 - These venous blood tests are optional, but test for important risk factors for heart attack, stroke and liver disease, so we recommend having the tests if you are eligible.
- We will do **rapid, finger prick tests (Figure 2)** for viral hepatitis (liver infections): **hepatitis B virus, hepatitis C virus**. We will also test for two other infections (HIV and Syphilis).
- If you have a **positive finger prick test**:
 - it is important to **confirm the result** with a **venous blood test (Figure 1)**, we will do this at the same time as the blood test for diabetes and blood fats, so that you only need one needle prick. This blood test is not optional.
 - As is standard practice, a positive test result for hepatitis B, C, HIV and syphilis will be fed back by the laboratory to the UK public health department (UKHSA).
 - We will also refer you to our specialist clinic (Mortimer Market Centre, Capper Street, London, WC1E 6JB), or another service if it is more convenient for you, so that you can have further assessment and advice.
 - We will collect some information about appointment attendance so we can understand how people use the service, and check that you have connected successfully with the clinic. We may also collect anonymised clinical information about further test results from your first clinic appointment.
- We will do a **liver scan**, called a Fibroscan™, that will give an immediate result for liver damage and liver fat. It takes about 10 minutes. It will require you to lift your top and show your tummy.
- All the tests will be carried out in a **private area**, and you will be able to discuss the results with our clinical team.

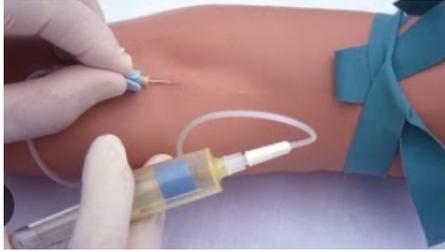


Figure 1: Venous blood test. Blood is taken from the vein using a butterfly needle, the same as regular clinical blood tests. We will do all the blood tests you need at the same time, so you only need one venous blood test.

Image from <https://images.app.goo.gl/DQfPQAs2Txcup3mKA>



Figure 2: Rapid fingerprick blood test. A small needle is used to prick the finger, and the blood is used to drop on to a rapid infection testing kit. This is similar to covid lateral flow tests. The results are available in 10-15 minutes.

Figure 3: Fibroscan™. A jelly-covered probe, like an ultrasound, is placed on your tummy. The scan is not painful and takes only a few minutes. It can tell us about liver scarring and liver fat.



Please do not eat or drink anything for at least 6 hours before you attend the screening event as this can affect some of the blood test results. We will provide refreshments after you have completed the screening.

PART 2: CLINICAL AND LABORATORY RESEARCH PARTICIPATION

- This part of the study will help us **understand why viral hepatitis (hepatitis B virus, hepatitis C virus) and metabolic risk factors (diabetes, high blood fats, overweight, high blood pressure) cause liver disease.**
- We will ask for your consent to take 3 extra blood bottles (**3 tubes**, equivalent to just over **one teaspoon of blood in each tube**) at the same time as you have a venous blood test in PART 1 (meaning no extra needle prick).
- We will **anonymously** store this blood at the **Francis Crick Institute**.
- We will use these blood tests to measure detailed blood fats and sequence human genes (your DNA) which affect how your body fights infection (immune system) and virus genes (virus DNA) in people who are living with hepatitis B virus.
- Although most of the tests will be done in the Francis Crick Institute, in rare circumstances specialist tests may require samples to be transferred to collaborating laboratories in the UK or overseas. Only the minimum amount of data required will be transferred with the samples, and this will be non-identifiable.

PART 3: INTERVIEWS AND FOCUS GROUPS

- This part of the study will help us understand reasons people may or may not get tested for viral hepatitis, and attend follow-up healthcare following a diagnosis of hepatitis B. This information may help improve healthcare services for people in the Mongolian community and people living with hepatitis B.
- Interviews and focus groups will not happen on the same day as the community liver screening event.
- Interviews will be via telephone and focus groups will be in person at the Mongolian Community Organisation (Kensington Aldridge Academy).
- We need both people with AND without hepatitis B to take part.
- If you indicate on the consent form you are interested in taking part, you are consenting for us to contact you with further information, but you are not committing to participating in this part of the study.

Do I have to take part?

- No, you do not have to take part.
- If you wish to take part, we will ask you to sign a consent form to record this.
- You are free to withdraw at any time, without giving a reason. If any new relevant scientific information becomes available during this study, which may impact your ongoing participation, we will inform you.

What are the possible benefits of taking part?

- You will be screened for metabolic risk factors (diabetes, high cholesterol, high blood pressure and overweight/obesity) which can affect your heart, blood vessels and liver health. You will also be screened for infections that can affect your liver and have a liver scan that will tell you about liver scarring and liver fat. Most of these will have same-day results and you will be able to discuss them with a healthcare professional and receive follow-up if necessary.
- You will contribute to improved knowledge and understanding of liver disease with an aim to help people in the Mongolian community and beyond.
- Learning from this project will help us and other teams to develop similar projects in future, so that we can reach more communities in the UK and elsewhere in the world.

What are the disadvantages of taking part?

- There may be some minor discomfort and bruising around the blood test site, which will disappear after a day or two without any treatment.
- Depending on how busy we are, you may have to wait while we prepare and perform the tests.
- We may find an abnormal result which can cause anxiety. However, we will provide information about the results and opportunity to talk to the clinical team about the results on the day, and organise further clinical follow up appointments, if necessary.

How will information about me be kept confidential?

- The Data Controller for this study is University College London.
- We will always protect your privacy.
- The following steps are taken to ensure confidentiality:
 - You will be given a unique identifier number so that we can keep your information anonymous (we do not need to use details such as your name or date of birth when analysing data).
 - All study data will be stored online in a secure database which conforms to NHS Digital Information Governance Standards and is restricted access to named researchers working on this study.
 - Please note that, very rarely, if you disclose information that makes us concerned that you or others may be at risk, we may need to break confidentiality and tell an appropriate professional (e.g. your GP).
- If we find any conditions that need further treatment or follow-up, we will contact you and may share the relevant details with other doctors (e.g. your GP) and nurses to make sure you receive the right care.

How will we use information about you?

- For the clinical part of the project, we will collect routine details that are used by hospitals and GP practices to identify you (name, date of birth, NHS number) and to make sure we can get in touch if we need to follow up abnormal results (address, phone number), or you have consented to be contacted for further research.
- Your details will be stored in secure systems. Your data will be pseudo-anonymised so that the research team will not be able to identify you. Only people who need to know (clinical team and authorised members of the research team) will be able to see your name or contact details.
- When the study is finished, we will keep some of the data so we can check the results.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. If you do withdraw, we may still use the information collected so far in the final analysis.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- Online: at www.hra.nhs.uk/information-about-patients/
- In person: by asking one of the research team
- By email: data-protection@ucl.ac.uk

Who is organising and funding the study?

This study is organised by doctors and researchers from University College London NHS Foundation Trust, University College London and the Francis Crick Institute. It is funded by the British Research Council.

The sponsor of the study is University College London/ University College London NHS Foundation Trust Joint Research Office.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and received a favourable outcome by the Brighton and Sussex NHS Research Ethics Committee.

What will happen to the results of this study?

- We hope the results of this study will be presented at national or international medical conferences and published in one or more medical or research journals, but no individual will be identifiable in any presentation or publication.
- We will send you a letter with the summary of the overall results of the study when it is finished.

What if something goes wrong for me?

If you have any concerns about the way you have been approached or treated during the study then please contact the lead researcher, Professor Philippa Matthews, to discuss this (contact details below). You can also contact the Patient Advice and Liaison Service (PALS) and University College London Hospital by calling 020 3447 3042, emailing, uclh.pals@nhs.net or visiting the website <https://www.uclh.nhs.uk/contact/patient-advice-and-liaison-service-pals>

How to contact us

If you have questions about this study, please talk to the lead researcher and the study team:

Philippa Matthews

Clinical Group Leader, The Francis Crick Institute, 1 Midland Road, London, NW1 1AT

uclh.hepmolo@nhs.net

You can contact the study sponsor University College London/ University College London NHS Foundation Trust Joint Research Office (uclh.randd@nhs.net)