



IC3 Liver Health Trial

PARTICIPANT INFORMATION BROCHURE

We invite you to take part in this research study. Please read this brochure which provides important information about the study and what it involves.





WHAT IS THE PURPOSE OF THIS RESEARCH?

The liver is the largest organ in the human body, it plays a key role in filtering your blood. However, many Australians don't know if their liver is healthy. Liver damage can lead to health problems like liver disease, cirrhosis (*si-roh-sis – scarring of the liver tissue*), and even liver cancer.

Anyone can get liver damage, but people who are overweight, drink too much alcohol, have type 2 diabetes or viral hepatitis might be at higher risk.

People with higher risk may benefit from regular screening tests. Screening is an effective way to find liver damage including liver disease and cancer early –before you have any symptoms.

Australia does not currently have a program to check liver health. This research is trialing a program to check liver health and see if you need to see a specialist (hepatologist) or enter a screening program for complications of liver disease.

WHAT WILL YOU BE ASKED TO DO?



SIGN A CONSENT FORM

Once you have agreed to take part, you will be asked to sign a study consent form, and 1 additional optional consent form to allow us to look at some of your medical records relating to liver health. You will also have the option to give us access to your liver health information stored in state healthcare databases. This will allow us to check details of any liver

health tests you may have in the next 10 years. With your consent, the consultation with the researcher may be audio-recorded for quality control of the study procedure.



ANSWER SOME QUESTIONS ABOUT YOUR HEALTH

The researcher will ask you some questions about you and your health. It is possible you may find some of these questions sensitive or intrusive. Please let us know if you have any concerns. They will take some measurements and record your height and weight. After this you will be placed at random in one of two study groups. Randomisation means that you are put into a group by chance, like the toss of a coin. Neither you, your doctor or researcher can choose which group you will be in.



PUT INTO ONE OF TWO GROUPS

Both groups will have a consultation with the researcher to discuss lifestyle factors, liver health and cancer risk. If you're in one of the groups, you will also give a blood sample to test your liver health. Depending on the results of the test, you may need to have a special ultrasound which is painless, non-invasive and can measure scarring and changes in your liver. This is done by the researcher at or near your GP clinic, about 4 weeks after you first join the study. The results of this test will tell us if you should have regular screening of your liver (every 6 months) or if you need to see a specialist. These tests and/or special ultrasound will be at no cost to you.



FOLLOW-UP QUESTIONNAIRES

You will be asked to fill in up to three questionnaires over the next 12 months. They will each take around 10 minutes. A text message or email will be sent to you as a reminder to complete the surveys. If you prefer, we can call you to complete them over the telephone. If you are in the group that does not provide a blood sample at the start of the study, you will have the option to have a blood test after your 12-month questionnaire to check your liver health.



WHY HAVE I BEEN INVITED?

We are inviting all people at this clinic aged 45-75 who may be at higher risk of liver damage. Anyone can get liver damage, but people who are overweight, drink too much alcohol, have type 2 diabetes or viral hepatitis might be at higher risk.



HOW WILL THIS STUDY AFFECT ME?

We have designed this study to minimise any adverse effects from being involved. The blood test and special ultrasound have minimal risks and will be done by trained professionals. If you have concerns, please discuss this with the study team or your GP.



DO I HAVE TO TAKE PART?

No. Participation is completely voluntary. You are able to withdraw at any time without giving a reason.



HOW IS THIS STUDY BEING FUNDED?

This study has been funded by a dedicated grant from the Medical Research Future Fund (MRFF).



WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Any information provided by you will remain confidential. All data will be stored securely at the University of Melbourne and disposed of 15 years after results are published, according to the National Guidelines. Data will be shredded if paper based or deleted from all computers, hard drives and/or servers.

OPTIONAL FUTURE RESEARCH

If you are in the group giving a blood sample to test your liver health, we also ask your consent to store your blood sample (including your DNA) and some anonymised information about you, for use in future studies by our team.

These future studies will be looking at liver damage and how we can improve people's health. Your sample and answers would only be used after ethical approval for the future study. We will only use your data anonymously, and you won't be referred to in any publications from these new studies. You can choose not to give consent for this by indicating your decision on the consent form. We would then dispose of excess samples after this research study is complete. At the end of the study, you may be invited to participate in an audio-recorded interview about your experiences in the study which is optional. You may also be invited to contribute to future research by the researchers involved in this project.

FEEDBACK

We welcome feedback. This can be provided to the study coordinator (see Further information and Contact details). A summary of the study results will be available to you by email or post at the completion of the study. Please indicate on the consent form if you would like to receive a summary of the study results.



ETHICS

This project has human research ethics approval from The University of Melbourne [2022-23168-STEMM-1]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. All complaints will be treated confidentially. In any correspondence please provide the name of the research team and/or the name or ethics ID number of the research project.

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We are a team of researchers and consumers who are dedicated to reducing the impact of liver damage and liver cancer in Australia and internationally. The study is led by:

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Prof Jon Emery (*Academic GP*)

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Prof Alex Thompson (*Hepatologist*)

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FURTHER INFORMATION & CONTACT DETAILS



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With collaborators/investigators/research team from.

