IC3 Liver Health Trial

INFORMATION FOR GENERAL PRACTITIONERS

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

WHAT IS THE PURPOSE OF THIS RESEARCH?

The burden of Hepatocellular Carcinoma (HCC) is increasing in Australia, with the age-standardised mortality rate increasing greater than any other cancer over the past four decades. This burden is particularly felt in rural and migrant groups who have a greater prevalence of exposures (e.g. viral hepatitis, alcohol, obesity) that lead to cirrhosis, which is the key predisposing risk factor for HCC. Cirrhosis is present in 85-90% of patients with HCC, and thus identifies an at-risk population who benefit from surveillance in order to increase early HCC detection, curative treatment options and survival. Together with GPs, Hepatologists and consumers, we have designed a comprehensive liver screening program to help identify cirrhosis and HCC in primary care. This randomised controlled trial aims to test the effectiveness, feasibility and acceptability of the screening program.

HOW WILL THIS STUDY AFFECT ME OR MY PRACTICE?

Some participants may wish to discuss liver health or liver cancer with you, no change to your current practice is required for these participants. We will ask for support from the practice manager and reception staff during recruitment of participants into the study to ensure the clinic is not disrupted by the recruitment process. We will reimburse the practice by the number of study participants involved. You might be contacted to be interviewed about your experience of being involved with the research project which will be recorded for research purposes.

Participating practices will be asked to allow the installation of the Torch Recruit software onto a practice server, the cost of which, will be reimbursed. This will run a search for potentially eligible patients for the trial, based on information in your electronic medical records (e.g. abnormal liver function tests, diagnosis of diabetes or viral hepatitis). The research team will use Torch Recruit to send letters or text messages from the practice to patients about the study, as the initial invitation process. All patient data will remain in the practice. More information about Torch Recruit is available here: torchrecruit.com.au

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Any information provided by you will remain strictly 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 Statement. Data will be shredded if paper based or deleted from all computers, hard drives and/or servers.

FEEDBACK & STUDY RESULTS

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.

IC3 - THE LIVER HEALTH TRIAL

WHAT DOES PARTICIPATION INVOLVE?

IF YOU DO AGREE TO TAKE PART, YOU WILL BE ASKED TO SIGN A CONSENT FORM

Your consent will allow the research team to identify potential patients using a Recruitment Software (TorchRecruit) embedded in your clinical software. Patients aged 45-75years old, with at least one risk factor for chronic liver disease will be invited into the study (e.g. diagnosis of chronic viral hepatitis, type 2 diabetes or known elevated liver enzymes).They will be eligible if they are identified by TorchRecruit, are well enough to participate and are not currently under the care of a gastroenterologist/hepatologist.

AN EXPERIENCED RESEARCH TEAM MEMBER WILL APPROACH PATIENTS...

via a GP-endorsed phone, letter or SMS and follow-up phone call to confirm eligibility. If eligible and interested, the participant will be invited to meet with the researcher at the GP clinic. The researcher will consent the participant to the study and they will be asked to provide consent to allow the release of liver health data from their GP records for the past 12 months and next 12 months.

ALL PARTICIPANTS WILL BE ASKED TO COMPLETE A QUESTIONNAIRE...

to provide the research team with information about themselves, their alcohol consumption, quality of life and their health, including risk factors for liver disease. The researcher will randomly allocate participants to one of two groups. Depending on their allocation, the researcher may order a blood test to check their liver health. The outcome of this test will determine if further follow-up is required, which will be facilitated by the research team in consultation with their GP. Both groups will receive a short consultation regarding lifestyle advice to reduce risk of advanced liver disease/ cirrhosis.

SOME PARTICIPANTS WILL BE ASKED TO ATTEND AN ULTRASOUND BY THE RESEARCHER...

Depending on the results of the blood test, some participants may need to have a special ultrasound to measure liver damage. This is done by the researcher at, or near the GP clinic, about 4 weeks after they first join the study. The results of this test will determine if regular screening or specialist referral is required. If referral is required, the research team will work with you to facilitate this.

ALL PARTICIPANTS WILL BE ASKED TO COMPLETE TWO SURVEYS OVER THE FOLLOWING 12 MONTHS...

about their experience in the trial, their quality of life, liver health and things they may have done to reduce their risk of liver disease.

ETHICS

This project has human research ethics approval from The University of Melbourne [2022-23168-29259-4]. 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.

E: research-integrity@unimelb.edu.au

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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)*

Prof Gary Jeffrey *(Hepatologist)*

Prof Alex Thompson *(Hepatologist)*

A/Prof Simone Strasser *(Hepatologist)*

Prof Darrell Crawford *(Hepatologist)*

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FURTHER INFORMATION & CONTACT DETAILS

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With collaborators/investigators/research team from.

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