**PARTICIPANT INFORMATION SHEET**

**Patient preferences for the delivery of the non-alcoholic fatty liver disease (MASLD) clinical pathway: let’s move towards patient-centered care**

*We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve for you. Please take time to read this information. If anything is not clear, or if you would like more information, please ask us.*

**What is the purpose of the study?**

Metabolic dysfunction associated steatotic liver disease (MASLD) (previously known as non-alcoholic fatty liver disease, NAFLD) is the UK’s leading cause of liver disease. MASLD occurs when there is too much fat in the liver. In a small proportion of patients, excess fat in the liver may go on to cause inflammation and eventually scarring (cirrhosis) and liver failure.

For patients with MASLD to have good health outcomes they need to be fully engaged with their long-term care. This requires high levels of commitment, including attending long-term follow up appointments and understanding their disease stage.

There are no approved drug treatments so patients are asked to lose weight which can reverse MASLD if it has not progressed too far. Patients with MASLD often have linked conditions (diabetes/heart disease) requiring multiple medications and further healthcare appointments.

Several guidelines on MASLD have been published. These focus strongly on the patient ‘journey’ through the health system. However, none of these guidelines have asked the patients what they think the pathway should look like.

We will therefore undertake in-depth discussions with people with MASLD, and those at risk of developing MASLD, using a mixture of one-on-one discussions and focus groups (attended by approximately seven people per group).

Our aim is to create the first ‘blue-print’ for a patient-centered MASLD pathway. By designing the service around patients, we hope to maximise patient engagement and significantly improve both liver health and wider health outcomes for people with MASLD.

 **Why have I been invited?**

You have been invited to take part in this study because you have been identified as someone who either has MASLD, or is at risk of possibly developing MASLD in the future. We plan to speak to up to 40 people in total. To hear from people from a wide range of backgrounds we will aim to recruit from different regions across the UK and speak to both men and women, people under/over 50, people from a wide range of socioeconomic and ethnic groups, in addition to people with different stages of liver disease and experiences of the current system.

**Do I have to take part?**No, your involvement in this study is entirely voluntary. You can withdraw if you later change your mind without giving a reason. Withdrawal will not affect your clinical care in any way.

**What will happen to me if I decide to take part?**

If you decide to take part a member of our research team will arrange for you to attend either a one-on-one informal discussion (30-60 minutes if you are someone at risk of having MASLD; 60-90 minutes if you are someone who has MASLD), or a small, focused discussion group (up to two hours long). These can be online, in person or on the telephone. You will be taken through a consent form relating to this study and be given an opportunity to ask questions before signing.

We will ask your permission to take an audio recording of the meeting. A researcher will ask you about your preferences for care relating to the condition MASLD. We have created a guide to help provide some structure to the discussions but will also be flexible to allow us to follow up on any important topics. This should feel like a conversation, rather than answering questions where there is a yes or no answer.

After this meeting the audio recording will be sent to an external company to create a word-for-word written record of your interview (a transcript) for us to analyse. The researchers will analyse the transcripts for common themes to help create a comprehensive report of patient preferences for MASLD care.

We will ask for your consent separately to contact you up to nine months after your interview to look over your transcript to check you are happy with our interpretation, or to contact you for clarification of any points. After this we will not contact you again.

**Are there any possible disadvantages or risks from taking part?**This research involves talking about your preferences for care, therefore there are no risks involved.

**What are the possible benefits of taking part?**While you may not benefit directly from taking part in this study, the findings from this study will be used to try to design a model of care for people with MASLD that prioritises values and preferences of patients and is likely to benefit patients using the NHS in the future.

**Will my General Practitioner/family doctor (GP) be informed of my participation?**No, this is because your participation in this study will not affect your clinical care.

**Will my taking part in the study be kept confidential?**

Yes. All data will be ‘pseudo anonymised’ at the point of the audio recording. This means that instead of using your name, we will identify your data via a study ID, e.g. ‘participant 1’. The audio recordings and transcripts will not be directly linked to your name, date of birth, or address. To provide context to the responses, we will ask participants to complete a short form giving details on age, sex, levels of education, employment, severity of liver disease, other major health conditions and alcohol intake. This form will contain your study ID number only and no identifying information. The research team will not access your medical records. Direct quotes will be used in the study report, however we will ensure that you cannot be identified from these quotes.

During the study all electronic data will be kept under password protection on a computer belonging to the researchers. Signed paper consent forms, or paper forms containing background information for participants will be kept in a locked office in the Clinical Sciences Building, Aintree University Hospital. Only researchers directly involved in the analysis and interpretation of data will be given access to the audio recordings and transcripts.

**Will I be reimbursed for taking part?**Yes you will receive £25 per hour for your time. This can be transferred to your bank account or be given in the form of a shopping voucher. If you are travelling for a face-to-face meeting, we will re-imburse the cost of your travel.

.

**What will happen to my data at the end of the study?**

At the end of the study all paper forms will be made electronic and the original paper forms will be destroyed. The dataset linking your personal details to your study ID will be destroyed within 12 months of the study end date. All other electronic data will be stored on a password protected USB memory drive kept in a secure location at the University of Liverpool for a maximum of five years.

**What will happen if I don't want to carry on with the study?**

Participation is entirely voluntary, and you may change your mind at a later stage. Withdrawal will not affect the care you receive from the NHS. If you withdraw from the study, we will destroy the audio recordings of your interview and transcript of the recording if you gave an individual interview. This will not be possible for people included in groups discussions, however if you would like us to not include data provided in our analysis, we will honour this.

**What happens at the end of the study?**

The research team will produce a final study report which will be available on the study website (www.MASLDpp.co.uk), and on webpages for Liverpool University NHS Foundation Trust and the University of Liverpool. A summary of the findings will be posted or emailed to all participants who ask for this. The researchers will present the findings from this study in a peer-reviewed scientific journal and at a national and international conference. Results will be shared with the wider population via social media sites for the University of Liverpool and Liverpool University Hospitals NHS Foundation Trust and via the British Liver Trust. While quotes obtained during discussions may be used, participants will not be identified from any report or publication placed in the public domain.

**What if there is a problem?**

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Dr Theresa Hydes, theresa.hydes@liverpool.ac.uk**,** Tel: 0151 529 0228, or the Patient Advice and Liaison Service (PALS).

**Will I definitely be able to be involved in this study?**

For this study, we aim to recruit 40 participants. We are keen to get a good representation from men and women, people of different ages and ethnic groups, and with different stages of liver disease from several regions across the country. It is therefore possible that we will not be able to recruit everyone who would like to take part. However we would be more than happy to contact you about future research projects undertaken at the University of Liverpool if you are interested.

**How have patients and the public been involved in this study?**

A patient and public involvement group for people with MASLD were involved in the design of this study. They helped advice on recruitment, the content of the interview and discussion guides and reviewed the participant information sheet.

**Who is organising and funding the study?**The study is been funded by an Academy of Medical Sciences Clinical Lecturer Starter Grant.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics
Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by the South Central Berkshire Research Ethics Committee.

**Can I be involved in future related research studies too?**

Yes, Liverpool University Hospital NHS Foundation Trust and the University of Liverpool are involved in several research projects relating to MASLD. If you would like to be involved, please contact Dr Theresa Hydes, theresa.hydes@liverpool.ac.uk.

**Further information and contact details:**

Thank you for reading this information. If you would like to take part, or find out more information please email us or take a look at the study’s website.

Study webpage: [www.MASLDpp.co.uk](http://www.nafldpp.co.uk) Study email address: MASLDpp@liverpool.ac.uk.

**The research team:**

Dr Theresa Hydes NIHR Clinical Lecturer in Hepatology, University of Liverpool (Chief Investigator)

Dr Katie Williams Qualitative research assistant, University of Liverpool

Prof Deirdre Lane Professor in Cardiovascular Health, University of Liverpool

Prof Dan Cuthbertson Professor in Diabetes, University of Liverpool

Dr Helen Jarvis General Practitioner / NIHR doctoral research fellow, Newcastle University

Dr Louise Roper Principal Health Psychologist, Liverpool Heart and Chest

Dr Cyril Sieberhagen Consultant Hepatologist, Liverpool University Hospitals NHS Foundation Trust

Dr Ian Rowe Associate Professor of Hepatology, University of Leeds

Dr Mike Merriman General Practitioner partner, Millbrook Medical Centre

**Chief Investigator:**

Dr Theresa Hydes

Department of Cardiovascular and Metabolic Medicine

Institute of Life Course and Medical Sciences

Clinical Sciences Building (3rd floor)

University Hospital Aintree NHS Foundation Trust, L9 7AL

Tel: 0151 529 0228