

Information sheet for participants

Part 2 research interviews

The BOLT study: Behaviours and Outcomes after Liver Transplant

Diet and physical activity behaviours, their determinants, and relationship with quality of life and cardiovascular disease risk factors after liver transplant: a cohort and qualitative study.

Name of researchers: Miss Lynsey Spillman, Prof Simon Griffin, Dr Angela Madden, Dr Linda Oude Griep, Dr Kirsten Rennie, Dr Michael Allison, Dr Katherine Nash, Dr Martin James.

Invitation to take part in our study

Since you are participating in our study which aims to find out about the diet and activity of people after a liver transplant, we would like to invite you to take part in the second stage of this project. This second stage aims to find out about the things that are influencing your diet and daily activity in detail from your perspective through an in-depth discussion with you, which is called a research interview.

Taking part in the study is voluntary and declining to take part will have no impact on your clinical care. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to talk to others about the study if you wish.

The first part of this participant information sheet tells you the purpose of the study and what will happen to you if you take part. The second part provides information about the conduct of the study. If anything is unclear, please ask for further information.

Part 1

What is the purpose of the research?

This study aims to find out about your experiences with diet and activity since your liver transplant by having a conversation with you about this after you have completed the questionnaires, physical activity measurement and dietary recall for the other part of this study. Speaking to you about this will help us to understand in more detail the things that

influence the way you eat and the activity you do, so we can better support people with diet and physical activity after liver transplant.

There are no right or wrong answers, what's important is for us to listen to your experiences from your perspective. We plan to talk to up to 25 people who have had a liver transplant and will bring all participants' experiences together to look for patterns and answer the question 'what influences diet and activity after liver transplant?' With this information we aim to improve the support and care we provide to people after liver transplant.

What would taking part involve?

Finding out about the study

We will contact you one-two weeks after telling you about this study to see if you would like to take part. This is to give you enough time to think about taking part, and to talk to your family and friends about taking part if you wish to. Taking part is voluntary and you may choose not to be contacted about the research and not to take part without providing a reason and without any impact on the care you receive from your liver transplant team.

Arranging the interview

If you would like to take part, the researcher will arrange the date and time to phone you. If interviewed after the first questionnaire, diet and physical activity measurements, the researcher will contact you again to invite you to a second interview when you have completed the follow-up measurements 6 months later.

Before the interview

You will be sent a link to an online consent form or, if no access to the internet or a suitable device, posted a consent form with a prepaid return envelope. The consent must be received by us before the interview can take place

During the interview

At the beginning of the call the researcher, who will be asking you questions, will introduce herself and check if you are still happy to participate and if you have any further questions. The interviews will be recorded using a Dictaphone so the researcher can listen and not be distracted with taking notes. The recording of the meetings will be written up after the interview into a transcript of the interview.

The interview is informal and although there is a guide with topics to talk about, we are interested in your experience with diet and activity after liver transplant, from your point of view. It is expected that the interview will last between 60 and 90 minutes but you may stop the interview at any time.

Will I receive payment for taking part in the research?

We are unable to pay for your time but to show our appreciation for your time and taking part we will give you a £25 gift voucher at the end of the final interview.

What are the possible benefits of taking part?

Although there are no direct benefits to you for taking part in this study, the findings from this study will be used to improve the care provided to people having a liver transplant to more effectively help them with diet and physical activity.

What are the possible disadvantages and risks of taking part?

Taking part in studies that involve exploring experiences can sometimes raise sensitive or distressing topics. If you feel you would like to talk to someone about any concerns or issues, or taking part leaves you with unanswered questions, please let the researcher know at the end of the interview or contact your transplant coordinator or doctor.

Part 2

Will my taking part in this study be kept confidential?

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the Sponsors for this study based in the United Kingdom. They will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. The Sponsor organisations will keep identifiable information about you for 15 years after the study has finished to allow the study to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: <https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information>, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk
- For University of Cambridge, please visit: <https://www.medschl.cam.ac.uk/research/information-governance/>, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

Cambridge University Hospitals will collect your name, date of birth, NHS number, address and contact details to contact you about this study, make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this study. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from you and your medical records. The only people in the Sponsor organisations who will have access to

information that identifies you will be people who need to contact you in relation to this study and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this study for 15 years after the study has finished.

All information collected about you as a result of your participation in the study will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed to participate in this study you will be allocated a Study ID Number. This is a unique study number which will be used on all your study documentation. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous study data, without any personal information will be published at the end of the study.

How will my information be kept confidential?

The interview recording and transcription will be given a number, rather than labelled with your name. The recording will be securely transferred to a professional transcription service, who meet standards of data security and confidentiality in line with University policies, to be transcribed (typed up). The recording and transcript of the interview will be stored securely at the MRC Epidemiology Unit within the University of Cambridge. The transcript will be made anonymous by removing any information that could identify you. The anonymised transcript will be stored at the MRC Epidemiology unit and made available to the University of Hertfordshire for data analysis but it will not be stored there long-term. The original transcript and recording will be securely destroyed after Lynsey Spillman has been awarded her PhD, as this study is being undertaken as part of the PhD.

When the study is reported your name or any details that might reveal your identity will not be reported so you remain anonymous. The report may include short quotes from the interview but these quotes won't contain any information that could identify you.

What will happen if I do not want to participate or choose not to carry on with the study?

Participating in this study is voluntary and you may withdraw from the study at any time. You may choose to stop the interview at any time. You do not need to give a reason for choosing to stop the interview, or choosing not to participate or to withdraw. You will receive the same care whether you choose to participate in the study or not.

What will happen to the results of this study?

The results will be written as a report and submitted to a journal that is read by healthcare professionals and/or presented at conferences. With your permission, you will be sent an anonymised summary of the results at the end of the study.

Who is organising and funding this study?

The study is being undertaken towards a PhD qualification for Miss Lynsey Spillman, who is a dietitian at Addenbrooke's Hospital. The research project is sponsored by the University of

Cambridge and Cambridge University Hospitals NHS Foundation Trust. The interview will be with Lynsey. The study is being funded by the National Institute of Health Research (NIHR).

Who has reviewed this study?

The study has been reviewed and approved by the West Midlands - South Birmingham Research Ethics Committee, a committee that looks at the details of the study to ensure it is safe, ethical and beneficial.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting your local Patient Advice and Liaison Service (PALS) department using the details below.

Addenbrooke's Hospital:

By letter: PALS and complaints department, Box 53, Cambridge University Hospitals NHS Foundation Trust

Hills Road, Cambridge, CB2 0QQ

By email: pals@addenbrookes.nhs.uk

By telephone: 01223 216756

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact details of the researchers

If you would like to take part, want more information or have any queries about anything concerning this study, please contact the research team using the telephone number, address or email address below.

Address:

BOLT study
MRC Epidemiology Unit
University of Cambridge School of Clinical Medicine
Box 285 Institute of Metabolic Science
Cambridge Biomedical Campus
Cambridge
CB2 0QQ

Telephone: 07823 438139

Email: BOLT@mrc-epid.cam.ac.uk