Information sheet for participants

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

We would like to invite you to take part in this study which aims to find out about the diet and physical activity of people after a liver transplant, and the things that influence diet and activity levels.

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. If you would like to take part or have any questions about the study please contact us, the researchers, via email at BOLT@mrc-epid.cam.ac.uk or phone 07823 438139. 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 we will ask you to do if you take part. The second part provides information about the conduct of the study, such as how your information will be stored. If anything is unclear please ask for further information.

Part 1

What is the purpose of the research?

Unwanted weight gain, high cholesterol, high blood pressure and diabetes are common problems after liver transplant. People with these problems are more likely to be unwell compared to those without them. It makes sense that good diet and physical activity are important to stay healthy, but we need to know what people eat, how active they are, and what influences their diet and physical activity after liver transplant. We wish to understand whether diet and physical activity after liver transplant are different to the general public,

for example due to things like fatigue and transplant medication, and which aspects of diet and activity are most important for health and wellbeing after transplant. With this information we will be able to provide more effective care to liver transplant recipients.

This research aims to find out:

1. What people eat and what physical activity they undertake after a liver transplant.
2. Why people eat the way they do and are physically active or inactive after a liver transplant.
3. Whether diet and physical activity are linked to quality of life and risk of heart disease after a liver transplant.

Knowing this will mean we can help people to stay healthy after transplant by giving better advice about diet and physical activity. It will also help us to know if it would be beneficial to develop a structured programme to support people with diet and physical activity after liver transplant and what this should include.

Can I take part in the study?

To be eligible for this study you need to:

- Be over the age of 18.
- Be able to speak, read and write in English.
- Have had a liver transplant, with or without a kidney transplant, at Cambridge University Hospitals NHS Trust (Addenbrooke's Hospital) 6 months to 3 years ago.
- Be able to provide informed consent to take part in the study.

If you have had a pancreas or bowel transplant along with your liver transplant you will not be eligible to take part. The reason we have decided not to include these people is because the diet recommended is different for these people compared to people having a liver transplant with or without a kidney transplant.

Finding out about the study

This information sheet explains the details of the study. There is also a study website which will be kept up to date with new information about the study, www.mrc-epid.cam.ac.uk/bolt/.

If you would like to take part or have any questions about the study please contact the research team via email at BOLT@mrc-epid.cam.ac.uk or phone 07823 438139. Participating is voluntary and you may choose not to be contacted by us without providing a reason and without any impact on the care you receive from your liver transplant team.

What would taking part involve?

This study has been designed so that you can complete the study measurements at home. We will ask you to complete some questionnaires, wear a device on your wrist that measures your physical activity level, recall your food and drink intake over a 24-hour period on four occasions, weigh yourself if you have scales at home and have a sample of blood taken, if possible at the same time as your blood samples are taken for your liver transplant

appointment. We will not ask you to attend an appointment to have the blood sample taken, it will only be taken if you are already attending an appointment for your liver transplant clinic review.

The table below explains these measurements and procedures in more detail. We will not be monitoring responses to the questionnaires or dietary recall in real time. This means we will not be able to offer support to you based on your questionnaire or diet recall responses. If you would like support with this please call your liver transplant coordinator on 01223 216672 or dietitian on 01223 216655. We will also provide some links to other support and information at the end of the questionnaire in case helpful to you.

Procedures to be undertaken for the study	**Description of procedure**
Questionnaires	We'll ask you to fill in questionnaires about: • Your background information, such as your marital status, ethnicity, smoking status and family history of heart disease. • How well you feel. This measures your quality of life. • What physical activity you have done over the previous 4 weeks. • Factors that influence your physical activity and diet. • The ways that you have coped with the liver transplant experience. • Questionnaires that measure depression, anxiety and stress. If you have access to the internet and a computer or tablet, we will send you a link to these questionnaires. If you do not have access to the internet or an appropriate device or would prefer to fill in a paper copy of the questionnaire, we will post this to you with a prepaid return envelope. The questionnaires take about 30 minutes to complete.
Dietary recall	We will ask you to recall your food and drink intake for the previous day on four separate occasions, three week days and one weekend day, over a three week period. This takes between 30-40 minutes to complete each time. If you have access to the internet and a computer or tablet we will ask you to do this using an online programme. We will send you a web link to access this programme on a computer or tablet. The programme

	asks you about your meals, snacks and drinks and includes pictures of portion sizes. There will be a video about how to use the programme when you click on the web link. If you do not have access to the internet or an appropriate device or do not feel able to complete the recall online, we will arrange a time for a researcher to call you to complete the dietary recall over the phone.
Wrist-worn device that measures physical activity	We'll post a device to you, called an accelerometer, to wear on your wrist like a watch. We'll ask you to wear this for 7 days and then post it back to us in a pre-paid envelope. It can be posted in a normal post box so you do not need to go into a post office. We will provide instructions about how to wear this.
Weight	If you have scales at home we will ask you to weigh yourself and record this when you complete the questionnaires. We will send you instructions of how to weigh yourself.
Blood sample	We will arrange for an additional sample of blood (up to 10ml) to be taken, if possible, at the same time as the blood samples taken for your liver transplant clinic review. If you attend the liver transplant clinic in person, a researcher trained and experienced with taking blood samples will take it if you are not having blood samples taken for the liver transplant clinic review.

With your permission, we may contact you after you have completed the measurements described above to discuss taking part in an interview about the things that have influenced your diet and physical activity since your liver transplant.

We will invite you back to repeat the measurements described above again after 6 months (follow-up measurements). Completing these measurements again after 6 months will allow us to look at how things have changed over time and see if any changes are linked with changes in other measurements, such as your blood pressure and cholesterol levels.

Future research

With your permission, we plan to undertake further research in the future to be able to investigate if your diet, activity levels and risk factors for heart disease are linked with your future health, including cardiovascular events such as heart attack, cancer, stroke and

death. This is important to know so we can understand the relevance of diet and activity behaviours, and risk factors for poor health, such as high blood pressure and overweight or obesity, after liver transplant. This knowledge will help us to understand how best to support people who have a liver transplant in the future.

To obtain information about your health in the future from the Health Quality Improvement Partnership (HQIP) and NHS Digital we will share your name, NHS number, date of birth and address with them. HQIP will send us information about any cardiovascular events, such as heart attack or stroke you may have had. NHS Digital will send us information about any hospital admissions and cancer diagnoses you may have experienced. NHS digital will also provide us with information about people who may have passed away (mortality data). This information includes date and cause of death on behalf of the Office for National Statistics and is sourced from civil registration data. The information received will be linked with your data from this research study. It will be processed for the purpose of research. We will also request and receive recent address and GP information from NHS Digital to enable us to keep in touch as people move over the years.

We will provide updates about the storage and use of your data using this website: www.mrc-epid.cam.ac.uk/bolt/

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 send you a £25 gift voucher when we have collected all the information for the study, after the follow-up study measurements are complete.

Will I be given any feedback from the study?

After the follow-up measurements we will send you information about your physical activity. This will include the amount of time you spent doing sedentary activity, such as sitting, and doing moderate-vigorous physical activity, such as walking. We will tell you how this compares to the recommendations for physical activity and give some tips, if necessary, on how to increase your activity levels. When you have finished reporting your dietary intake at the end of the follow-up measurements, you will be able to click on a link to see a summary of your diet and how this compares to UK guidelines, and get tips to improve your diet, if necessary. If you are completing the dietary recall over the phone we will send you this information. With your permission, when the study is complete we will send you a summary of the findings.

What are the possible benefits of taking part?

Whilst taking part may not benefit you directly, the findings from this study will be used to improve the care provided to people having a liver transplant. You might find it beneficial to receive feedback about your diet and physical activity.

What are the possible disadvantages and risks of taking part?

It is very unlikely that you will be harmed by taking part in this type of research study. The insertion of a needle to obtain a blood sample can be uncomfortable and there is a chance of bruising. The researcher taking the blood is trained and experienced with this procedure.

The study may leave you with questions about your diet or physical activity. If you would like further information or support with this, please 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 three 15 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

For participants having blood sample taken via Cambridge University Hospitals NHS:
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.

For participants having blood sample taken via Nottingham University Hospital Trust and University Hospital Southampton Trust:

Nottingham University Hospitals NHS Foundation Trust/ University Hospital Southampton NHS Trust will keep your name, NHS number and contact details
to contact you about this study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this study. We will pass personal information about you (name, date of birth, NHS number, address and contact details) to the Sponsor Organisation (Cambridge University Hospitals) to monitor your long-term health as described above under the 'future research' heading. 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.

What will happen to my blood sample?

Your blood sample will be given your unique study ID and transported to the Nutritional Biomarker Laboratory, which is part of the University of Cambridge. The Carotenoid levels in your sample will be measured. Carotenoids are pigments found in plants that act as antioxidants in the human body. They are a marker of fruit and vegetable intake. Once your carotenoid results are available they will be uploaded to the study database.

Blood samples will be stored by the MRC Epidemiology Unit, University of Cambridge and may be used in other research in the future, including genetic analyses, and may be shared anonymously with other researchers including researchers overseas (including outside the EU) or in commercial companies.

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

Participating in this study is voluntary, you do not have to take part, and you may withdraw from the study at any time. You may choose to stop the measurements at any time. You do not need to give a reason for choosing not to participate or to withdraw from the study. You will receive the same care whether you choose to participate in the study or not. If you wish to withdraw from the study after completing the study measurements you can contact us using our details under the heading 'contact details of the researchers' at the end of this document or using the details on the study website: www.mrc-epid.cam.ac.uk/bolt/

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 day to day running of the study and collection of research information will be largely undertaken by Lynsey with support from the research team. 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 (contact number: 07375 609758 or 01223 330315). 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

University Hospital Southampton
By letter: Patient support services, Mailpoint 8, Southampton General Hospital, Tremona Road, Southampton, SO16 6YD
By email: patientsupportservices@uhs.nhs.uk
By telephone: 023 8120 6325

Nottingham University Hospital
By letter: NUH NHS Trust, c/o PALS, Freepost, NEA 14614, Nottingham NG7 1BR
By email: pals@nuh.nhs.uk
By telephone: 0800 183 0204:

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 researchers using the telephone number 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 or 01223 330315
Email: BOLT@mrc-epid.cam.ac.uk
Study website: www.mrc-epid.cam.ac.uk/bolt/