Participant Information Sheet

Stage 2 in the development of a quality of life questionnaire for people living with primary sclerosing cholangitis (PSC)

We would like to invite you to take part in our research study, which is being undertaken as part of a PhD educational project at UCL. The study will involve participating in either a group discussion or an individual interview. This information sheet explains the aim of the study, and what it would involve for you.

Why is the study being done?
The overall study aims to develop a questionnaire to measure quality of life in people with primary sclerosing cholangitis (PSC). This is important as it will help us gain a better understanding of the experience of living with PSC and in future may be used to evaluate new therapies for the condition.

There are two stages to this study. In Stage 1 we spoke to people with PSC and clinicians to explore the day to day experience of living with PSC. This information sheet is about Stage 2 which will involve asking people with PSC to complete a provisional version of the quality of life questionnaire to look at how well the questions work. You do not need to have taken part in Stage 1 of the study to take part in Stage 2.

Why have I been chosen?
You have been chosen because you have experience of living with PSC.

Taking part in Stage 2 of the study
If you decide to take part, we will give you this information sheet to keep and ask you to sign a consent form. Even if you do decide to take part you are free to withdraw from the study at any time and without giving a reason. You do not need to inform us of this, but if you wish to do so, please contact Elena Marcus at elena.marcus.16@ucl.ac.uk or on 020 7679 9775.

What do I have to do?
If you agree to participate in this stage of the study, you will be asked to complete an anonymous background questionnaire about your health over the phone or online via the website Survey Monkey. This is to assess your eligibility to take part in the study.

If you are eligible to take part in the study you will then be invited to participate in ***one*** of the following activities:

1. Complete the provisional quality of life questionnaire on your own, either online (via Survey Monkey) or on paper (posted to your home address)

   OR

2. Participate in a one-to-one interview where you will complete the questionnaire with a member of the research team either at UCL or The Royal Free Hospital in central London. If you are unable to travel to London, we will offer a one-to-one telephone interview with a member of the research team.

We expect activity 1 to take up to 30 minutes to complete. We expect activity 2 to take up to 60 minutes to complete. During the interview for activity 2 we will ask you to comment on specific aspects of the included questions, whether you think any important issues have been missed or if any of the included questions are not relevant to you. The interviews will all be audio-recorded.

What will happen to the information that I give during the study?
We will use the information from the completed questionnaire and interviews to decide which questions should be kept in the final version of the questionnaire, whether any new questions need to be added and whether the wording of existing questions needs to be modified.

What will happen to the personal information that I give?
UCL is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for up to 3 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting data-protection@ucl.ac.uk

How long will I be in Stage 2 of the study?
You will be asked to complete a questionnaire which will take up to 30 minutes or to participate in one interview of up to 60 minutes.

Benefits of taking part
There will be no direct benefit to you for taking part in this study. However, by taking part you will help to improve knowledge of how PSC may impact quality of life, and also help in developing a questionnaire to specifically measure quality of life in PSC. We hope that this new questionnaire will enable improved evaluation of potential new PSC treatments.

Risks of taking part
We do not anticipate any risks or harm to you as a result of taking part in this study, although it is possible that these discussions may touch on some difficult or sensitive subjects. If you should wish further advice or support we will signpost you to relevant resources.

What if there is a problem?
If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Elena Marcus at elena.marcus.16@ucl.ac.uk or on 020 7679 9775. The Chief Investigator of this study is Professor Paddy Stone (email: p.stone@ucl.ac.uk, tel: 020 7679 9623). If you remain unhappy, or wish to make a complaint about the conduct of the study, you can contact the Chair of the West London & GTAC Research Ethics Committee, Reverend Keith Lackenby, and The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, email: NRESCommittee.London-WestLondon@nhs.net, telephone: 0207 104 8125,, or the Patient Advice and Liaison Service (PALS) at The Royal Free Hospital - email: rf.pals@nhs.net, telephone: 020 7472 6446/6447, fax: 020 7472 6463.

University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Confidentiality
All information that is collected about you during the course of the research will be kept strictly confidential. The only exception to this will be if you disclose any information which suggests possible risk to the safety of patients or staff. If this arises, you will be informed that confidentiality cannot be maintained in that particular regard, and the appropriate personnel will be informed. In all other cases, any personal information will have your name and address removed so that you cannot be identified from it. Only the research team will have access to the notes from the meetings. An additional external transcriber may listen to the voice recordings and type these up as written scripts, but this person will have signed a confidentiality agreement with UCL. All data will be handled, processed, stored and destroyed in accordance with the Data Protection Act (1998). Voice recordings will be downloaded from the portable recorder onto a secure university computer server, and the original recording deleted. After the transcribed material has been returned and checked for accuracy, the audio files will also be deleted from the university computer.

Results of the research study
We will present the results of the study to expert and support groups for service users, to liver health clinicians and researchers at academic meetings, to PSC Support and to The British Liver Trust. We will also seek to publish abstracts and papers in scientific journals. All information collected during the study will be combined to form the results, so no individual will be identified in any report or publication. If you take part in the study you will be asked if you wish to receive a written summary of the results.

Funding and review of the research study
This research has been funded by The British Liver Trust, reviewed by PSC Support and The British Liver Trust, and is being conducted by researchers in the Marie Curie Palliative Care Research Department at UCL. It has been reviewed and approved by the NHS Research Ethics Committee, 17/LO/1108, 7th August 2017.

Contact for further information
For further information please contact Elena Marcus via email: elena.marcus.16@ucl.ac.uk or phone 020 7679 9775. Other investigators involved in the study are: Prof Paddy Stone (email: p.stone@ucl.ac.uk, tel: 020 7679 9623), Dr Bella Vivat (email: b.vivat@ucl.ac.uk, tel: 020 3549 502) and Dr Douglas Thorburn (email: douglas.thorburn@nhs.net, tel: 020 3758 2000).

Thank you for taking the time to read this information sheet.

Your help makes our research possible.