Information sheet for patients

Project Swallow

Living well with oesophageal cancer

Thank you for considering taking part in our project to support patients with Oesophageal cancer. Taking part in this study is entirely voluntary. Before you make your decision, we would like you to understand why we are carrying out the research and exactly what this would involve for you.

This information leaflet will take about 10 minutes to read in full. Please take time to read it and then to decide if you want to join the study. It is important that you understand the information and what joining the study will mean for you. If you have any questions, or feel that anything has not been clearly explained, please do contact us for more information. You can contact us by e-mail, post or phone. We are also happy to meet in person to answer any questions you may have.

Contact us:

projectswallow@ucl.ac.uk or **020 7794 0500, ext: 31498**

Patient information sheet (PIS) Version 6 11/10/18
IRAS: 236919 JRO: 17/0725 REC: 18/LO1717

The aim of our Study

We want to understand want it is like to have oesophageal cancer in order to create a smart phone app to help support patients during their treatment. We want to hear from people who have experience of oesophageal cancer as either a patient or a carer. We want to learn what support would really improve your lives and we hope that by using your views we will be able to create a more useful smart phone app.

What will I have to do?

If you choose to join the study, we will invite you to take part in a small group discussion which is called a focus group. The focus group will be a face to face meeting of 5 to 10 patients or carers and will take place in a University College London (UCL) building (north London). We will ask you to complete a short questionnaire asking about your age, ethnicity, employment and experience of using the internet. This will take about 5 minutes and it is to make sure we have a broad range of views.

The focus group will last up to two hours and will be led by two members of the research team. There are a few topics that we would specifically like to cover, but there will also be time to interact and to discuss any other interesting ideas that come up. We may show you some example of different support information, to see what you think of them.

We will also ask you about your experience of oesophageal cancer and how well supported you feel. Some of this information is sensitive, and we will ask everyone in the group to respect people's views. If any issues arise during the focus group that you do not feel comfortable discussing then please let us know, and we will change the topic or pause the focus group if necessary. We also ask that anything you hear in the focus group to remain confidential, to encourage participants to speak up.

Do I have to take part?

No, you can choose whether to take part in the study or not. There will be no effect on the care you receive from your doctor, whether you choose to take part or not, or if you wish to withdraw from the study. If you do decide to take part you will be asked to sign a consent form.

Can I withdraw from the study?

Yes, you can withdraw from the study but **only before the focus group has happened**. It will not be possible to remove your input to the focus group afterwards due to the way in which the data is collected and analysed.

Will all the information about me be kept confidential?

Yes, all the information about your participation in this study, including your personal details, questionnaire responses and views expressed during the focus group will be kept confidential. Any personal information provided will be handled and disposed of according to the general data protection regulations (GDPR).

Your Data protection rights and GDPR

University College London (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 1 year 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:
http://www.ucl.ac.uk/jro/conduct-study/regulatory-approvals-.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we

are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

The research team may disclose your identity as a consequence of anything being raised that indicates someone may be at risk from harm.

You can contact a data protection officer at data-protection@ucl.ac.uk.

UCL will collect information from you for this research study in accordance with our instructions. UCL will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The NHS site will pass these details to UCL along with the information collected from you. The only people in UCL who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

What data we need from you

Personal data

If you decide to join the study we will need your name and contact details which will be kept confidential. Any personal data (e.g. participant name and contact details) is kept very securely and only the chief investigator and principle investigator will have access to it. Personal data is kept for a maximum of 12 months after the study is finished and will be deleted as soon as possible. The personal data will never be shared with other researchers. Any publication of the study will only contain anonymised data, so there will be no way of identifying individual participants

Research data

We will audio record the focus groups so that we don't lose any of your valuable views and ideas expressed. These recordings will be converted into a written format by the transcription company "UKtranscription" who we have a confidentiality contract with. Once transcribed the original audio recording will then be deleted. We will only keep a copy of the anonymised (all names of people and locations will be removed) transcripts for up to 20 years (in accordance with UCL's Records Retention Service). In order to maximise the usefulness of the data collected we may share it with other research studies, charities or NHS trusts but this will always be in a completely anonymised form.

What are the possible benefits of taking part?

Taking part in this study will not have any direct health benefits. However, you may find it interesting and useful to hear other people's view on, and experiences of, oesophageal cancer.

Your opinions will be extremely helpful to our research and will form the basis for us to develop digital tools that truly support people with oesophageal cancer and may give benefit to people with oesophageal cancer in the future.

We will provide a £20 Marks and Spencer shopping voucher as a token of appreciation for your time. Participants can also claim back for travel expenses up to £17 and or other additional costs that might otherwise prevent someone from attending such as childcare. We kindly ask you to discuss additional costs with us beforehand to guarantee reimbursement.

What are the possible risks of taking part?

There are no perceived risks to your health in taking part in this study. Each focus group will have two members of the research team facilitating the discussions. Every participant will have a chance to express their opinions. We expected all the participants to treat each other with respect. If a participant breaches this rule they will be asked to leave the focus group and will be withdrawn from the study.

If there is any indication or signs that a patient has become distressed, then focus group will be paused. The affected patient will be asked if they want to take a break and be offered support and a drink in a neighbouring room by one of the facilitators. If the patient remains distressed then they will be offered a support outlet depending on their personal issue selected from a variety of different outlets including, Macmillan, Bereavement counselling, Age UK, Samaritans and ICOPE. They will also be advised to speak to their GP or clinical team to discuss other options if they so wish.

What will happen to the results of this study?

We hope to submit the results of this study to an academic journal for publication. We will also create a shorter summary of the results. If you would like to have a copy of either the publications or the results summary, then please let us know via email. If you are also interested in contributing to the next stage of the study (testing the smart phone prototype) then please contact us via email.

Who is leading this research?

The team is made up of doctors at UCLH, researchers at UCL, patients previously affected by cancer, an IT software company and Macmillan (who are funding the project). The study is being led by researchers in the eHealth Unit, at the Department of Primary Care and Population Health which is part of University College London (UCL).

Professor Elizabeth Murray is the Director of the Unit and the Head of Department. She is leading this study with Dr Henry Goodfellow, who is training to become a GP.

Who is funding the research?

The research is funded by Macmillan, a cancer support charity.

Who has approved the research?

The research was approved by the REC committee (see link below), which is part of the NHS health research authority and provides ethical approvals for research projects in England.

https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/

Who do I contact if I have any problems?

If you have a concern or complaint there are procedures in place to support you. If you are worried or anxious about any aspect of this study, please contact the research team who will do their best to answer any of your questions. If you still remain unhappy, you can make a formal complaint through the National Health Service (NHS) complaints procedure. Details can be obtained through the University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS) on 0207 3447 3041, email: PALS@uclh.nhs.uk, address: PALS, Ground Floor Atrium, University College Hospital, 235 Euston Road, London, NW1 2BU.

THANK YOU FOR TAKING THE TIME TO READ THIS LEAFLET AND FOR CONSIDERING TAKING PART IN THIS STUDY.

University College London 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 UCL 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.

Contact Details:

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or

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