CaPaBLE: Caregiver and Patient Less-Burden Life Evaluation

CAREGIVER INFORMATION SHEET

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You are being invited to take part in a research study. Before you decide if you would like to join, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. You are free to ask us if there is anything that remains unclear or if you would like more information.

SUMMARY

Why?
The aim of this study is to explore how your quality of life is affected by being a caregiver for a patient undergoing treatment for a brain tumour. We intend to use two different methods to measure this: currently used standard questionnaires and a new method known as the "Caregiver Generated Index" (CGI). We will use this to identify similarities and differences between these two approaches.

What?
The CGI is a personalised measure to explore the impact of an illness and treatment on caregiver quality of life (QoL). It is a three-step process and has been successfully used in patients affected by other cancers and other illnesses, but not previously with caregivers.

Who?
You are being invited to take part as you are the main caregiver of someone who has been diagnosed with a brain tumour who is undergoing active treatment.

Where?
You will be seen at your local treating centre for study visits. The three sites involved are: Imperial College Healthcare NHS Trust, Barts Health NHS Trust and Guys & St Thomas NHS Foundation Trust.

What is the purpose of the study?
We recognise that caring for someone who is being treated for a new brain tumour will cause changes to your usual routines and priorities, which can affect your quality of life. Currently, our only methods for understanding how this impacts your life are standard format questionnaires which do not allow for personalised responses. For this study our aim is to create a short questionnaire which focuses entirely on what you perceive to be areas that are important to your lifestyle. We will then test our results to see if the CGI method is as effective as the standard questionnaires in understanding how people's lives are affected by caring for someone being treated for a brain tumour.

Why have I been chosen?
You have been invited to take part in this study because you are helping to look after someone who is being treated for a brain tumour at Imperial College Healthcare NHS Trust, Barts Health NHS Trust and Guys & St Thomas NHS Foundation Trust.

Do I have to take part?
No, it is entirely your choice whether or not you take part. If you do decide to take part, you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. **Not participating, or later withdrawing, from this study will not affect the current, or future, clinical care of those you are caring for.**

What do I have to do?
Once you have agreed to take part in this study and have signed the consent form, a member of the study team will lead you through an initial assessment. This initial assessment consists of gathering information about your background (gender, age, ethnicity etc) and any underlying health condition which you feel is relevant for us to know about. Once completed, we will talk you through the CGI process, which consists of three steps. Once you have completed the first questionnaire (CGI), you will be asked to complete two standard questionnaires totalling 41 questions. This should take approximately 5 to 10 minutes. We will then carry out further assessments at 2 and 6 weeks and then at 3, 4, and 6 months. At the initial visit and study visits 3 and 5 we will also ask for you to do an additional questionnaire which consists of 5 questions. If the hospital you attend has a secure online platform, you will be given the opportunity to use this to fill in the required questionnaires. The consultation may be audio recorded and will be used to support other research in the future.

What are the potential benefits and disadvantages/risks of taking part?
There will be no direct benefit for you but ultimately, we hope that we will be able to validate the CGI so that this can be used to help provide more personalised care/ support to caregivers. We anticipate that the process of using the CGI and other questionnaires may highlight some areas of concern which may not have been raised. We would anticipate that this process would itself be beneficial however, we are happy to signpost you to support groups/ forums/ services if you feel this is what you need. We may ask you to attend extra clinics or meetings in addition to those that the one you care for needs to attend for standard care. If this is needed, you will be reimbursed for any extra visits made to the hospital outside of the one you care for usual follow-up visits. We will, however, try to offer the option to fill in questionnaires electronically, using your home computing device (if applicable), or to send

copies in via the postal system using provided stamped, addressed envelopes if these fall outside of the usual appointment schedule for the one you care for.

What will happen if I decide I do not want to carry on with the study?
Taking part in this study is entirely voluntary and you can change your mind at any time. Any decision you take to withdraw from the study will not affect the care of the one you care for, now or in the future. If you do withdraw from the study, information already collected may still be used.

What if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Investigator *(Dr Mathew Williams or Professor Mary Wells; matt.williams3@nhs.net/ mary.wells5@nhs.net).* The normal National Health Service complaints mechanisms are also available to you such as contacting the local Patient Advice Liaison Services (PALS; pals@imperial.nhs.uk, 020 3313 0088). A member of the team will be able to give you their contact information upon request. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office

Will my taking part in this study be kept confidential?
Participants will be assigned study ID number to keep their identifiable data pseudonymised. Any paper records of the study such as your consent form that has your name on it and the paper CRFs will be locked in a secure individual NHS site. The electronic data will also store in the NHS sites and only pseudonymised data from the NHS sites will be forward to Big Data Analysis Unit (BDAU), Imperial College London.

Imperial College London is the sponsor for this study, which is based in the United Kingdom. We 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 we are responsible for looking after your information and using it properly. Imperial College London will keep pseudonymised information from the study for ten (10) years after the study has finished in relation to data subject consent forms and primary research data. This will be held at Imperial College archives and Corporate Records Units (ACRU). Pseudonymised data be transmitted to the Sponsor at completion of the study.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf. 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 the principal investigator (*Dr Mathew Williams; matt.williams3@nhs.net*)

Legal Basis

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. 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.

International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Contact Us

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact via Imperial College London's Data Protection Officer email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ. 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 ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Collaborating NHS sites will keep your name and contact details confidential and will not pass this information to Imperial College London. The collaborating NHS sites will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Certain individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College London will only receive information without any identifying information. 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. The study site NHS will keep identifiable information about you from this study for 10 years after the study has finished. For Imperial College Healthcare NHS Trust patients this will be held at Imperial College Archives and Corporate Record Unit (ACRU). When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

What will happen to the results of the research study?
The results of the research will be analysed and published in scientific journals. No individual participants will be identifiable from any report or publication. We will happily provide you with a copy of the results after publication.

Who is organising and funding the research?
This study is sponsored by Imperial College London. The research is funded by Imperial Healthcare Charity, NIHR Imperial BRC and the RM partners.

Who has reviewed the study?
This study has been reviewed and approved by the Research Ethics Committee (Bloomsbury)

Contact for Further Information
Dr Mathew Williams or Professor Mary Wells can be contacted for further information and support: Radiotherapy Department, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF or for independent advice please contact:
Patient Advice and Liaison Service (PALS), Ground floor, Main Hospital Entrance, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF
Email: IMPERIAL.PALS@NHS.NET; Contact Number: 020 3313 0088 Monday to Friday, 09.00-17.00. *An answer phone system operates at busy times and out of hours. Please leave a message with your name and phone number and a member of staff will call you back within 24 hours.*

Thank you for reading this information and for considering taking part in this research.