Brain Imaging to predict Toxicity in Elderly patients after Radiotherapy

BRITER study

Participant Information Sheet

You are invited to take part in a research study

Joining the study is entirely up to you and before you decide you should understand why this research is being done and what it would involve for you

This information sheet explains what the research is about and how you can help. Please take time to read the information carefully and feel free to talk to others about the research if you wish. Take as much time as you need to decide whether or not you wish to take part.

Please ask us if there is anything which is not clear or if there is any further information you would like.

1. **Why are we doing this study?**

When we first meet older patients with Glioblastoma in the outpatient clinic, it can sometimes be difficult to work out who will benefit most from particular treatments without experiencing too many side effects. We know that giving radiotherapy to the brain is an effective treatment for brain tumours but that it does involve side effects and that these can sometimes be more severe in older people. These side effects can affect certain people more than others however we are not aware of all the reasons why this is the case.

This study is being set up across a number of UK cancer centres to investigate whether it is possible to predict the degree of side effects from radiotherapy treatment by looking at a particular scan of the participant's brain before they start. The type of treatment you are offered as part of this study is exactly the same as you would be having if you do not take part in the study

2. Why have I been chosen to take part?

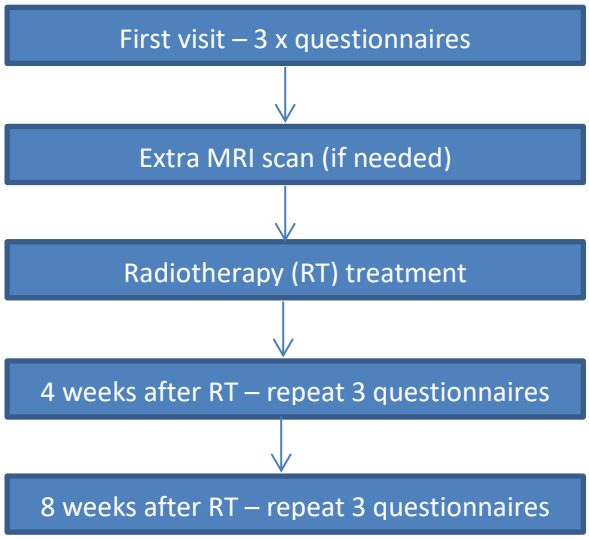
We have asked you to take part as you have recently been diagnosed with a Glioblastoma, are aged 65 or over, are able to have an MRI scan and have been offered radiotherapy to the brain as part of your treatment. Your doctor or nurse who is part of your usual care team recognised you could potentially be included.

3. Do I have to take part in this study?

The study is completely voluntary. It is up to you whether you want to take part or not. If you decide not to take part in the study the clinical care you receive will not be affected in any way. If you decide to take part you are still free to stop your participation and withdraw from the study at any time and for any reason.

4. What will happen to me if I take part?

If you decide to take part in the study the following flowchart explains the process.



The questionnaires are designed to assess how you manage at the moment, your mood and your quality of life. You are welcome to ask for help from friends, family or the nursing staff for help with the questionnaires. Your treatment plan will not be affected in any way and your responses to the study assessments will not affect your treatment decisions. If you are happy to be part of the study we would ask you to complete the enclosed consent form.

Your care team will also note down some details from your hospital notes including your age and gender, any previous medical problems and the type of treatment you have received. They will not record anything that could identify you.

As part of the study we need to look at the MRI scans you had during you diagnosis. Occasionally we may need to perform another MRI scan before you start your radiotherapy treatment. This may involve travelling to another site to have your scan performed. The scan will involve the same process as the MRI scan you had during your diagnosis but may take 5-10 minutes longer as we take some extra pictures. It may involve the use of a contrast dye which is administered through a small cannula into a vein in your arm during the scan.

5. **What are the possible side effects, risks and potential harms of taking part in the study?**

Participating in the study requires you to complete the questionnaires that are given to you when you attend for your hospital appointments. This may mean your appointments are 5-10 minutes longer than they would be otherwise. It also may involve an extra MRI scan with the contrast dye. This is the same process as the MRI scan you had as part of your diagnosis. Further details would be given to you prior to the scan.

Your routine clinical care and follow up will not be affected in any way. No risks are anticipated in filling in these questionnaires however it is possible that some people may find answering the questions causes distress. If you have any concerns whilst completing the questionnaires please let us know and we can provide extra support and advice.

6. **What are the possible benefits of taking part in the study?**

There may be no direct benefits to you from taking part in the study. However the study will help to answer some important questions surrounding the issues that affect older patients with brain tumours and help us to choose between different treatment options in the future.

7. **Will I be paid for taking part in the study?**

You will not be paid to take part in this study however the study team will cover travel expenses if you need to go to a different site to have your MRI scan. No members of the study team are being paid to run the study.

8. **Who will be told I am taking part in the study?**

Your usual neuro-oncology care team and your GP will be aware you are taking part in the study. No one else will be told unless you choose to tell them yourselves.

9. **How is my information kept confidential?**

We will follow ethical and legal practice and all of your information will be kept confidential. All information that is collected about you during the study will be kept strictly confidential and will be stored in a secure manner compliant with the Data Protection Act. If you join the study, a unique study number will be used and there will be nothing to identify you in the data we store.

However, if you tell us about serious risk of harm to yourself or others we will need to break confidentiality - which means letting your GP or other teams know. We will tell you if we do this.

Brighton and Sussex University Hospitals Trust (BSUH) is the sponsor for this study 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. BSUH will keep identifiable information about you for less than 3 months after the end of the 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.

You can find out more about how we use your information by e-mailing sponsorship.approvals@bsuh.nhs.uk.

Your local oncology centre will collect information from you and your medical records for this research study in accordance with HRA instructions.

Your local oncology centre will keep your name, NHS number and contact details confidential and will not pass this information to BSUH. Your local oncology centre will use this information as needed, 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. Certain individuals from BSUH and regulatory organisations may look at your medical and research records to check the accuracy of the research study. BSUH 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.

Your local oncology centre will keep identifiable information about you from this study for 5 years after the study has finished.

BSUH will collect information about you for this research study from your treating oncology centre. Your treating oncology centre will not provide any identifying information about you to BSUH. We will use this information to try to answer the research question outlined in Section 1.

10. What happens if I want to leave the study?

If you join the study, you are still free to leave at any time. If you have already had your MRI and provided us with your completed questionnaires we would plan to keep the anonymised information. If you would prefer all anonymous information to be deleted then please let us know.

11. What happens with the results of the study?

Your identity will not appear in any report or publication. The study is being run across a number of UK cancer centres and, once completed, the anonymised results will be collected together and analysed. We will aim to present the results at medical conferences and/or publish in medical journals. We are happy to share the results of this study with you if you would like.

12. What happens if there is a problem?

If you have any concerns about any aspect of the way you have been treated during the course of this study you should immediately inform your local neuro-oncology clinical nurse specialist (see contact details overleaf).

The normal NHS complaints procedures are also available to you. The Patient Advice and Liaison Service (PALS) can be contacted on the following numbers for advice on general matters surrounding being involved in research aswell as if there are any problems.

13. Who is organising and paying for the research?

The research is being organised through Brighton and Sussex University Hospitals Trust, who are the sponsor for the study. The study is supported by The Sussex Cancer Fund and The Brains Trust.

14. What should I do if I want to take part?

If you decide to take part in the study please complete the enclosed consent form. If you have any questions about taking part in the study please do not hesitate to contact one of the study team on the numbers below.

Contacts for further information

If you have any questions about this research, or if you have found this information sheet distressing in any way, please feel free to call:

Please insert local centre	
PLEASE INSERT LOCAL CONTACT DETAILS HERE	

Thank you