UNIVERSITY OF CAMBRIDGE

NHS Cambridge University Hospitals NHS Foundation Trust

SCARF-BT

PATIENT INFORMATION SHEET & INFORMED CONSENT FORM

SCARF-BT

Social Cognition Assessment and Rehabilitation for Families Living with Brain Tumour (SCARF-BT) – Lived Experiences Component

You are being invited to take part in a research study. Before deciding whether to take part, you need to understand why we need to do this research and what it involves for you. We'd like you to take time to read the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of the study and what will happen to you if you take part.
Section 2 gives you more detailed information about how the study is carried out.

Section 1: Why we need this study and what will happen

1. Why do we need to do this study?

Brain tumours can affect how the brain works. This can make interacting with others difficult, including friends and family. Detecting emotions in friends and family is a key part of relationships and communication. One way we recognise emotions in others is by looking at facial expressions. The effects of a brain tumour can make this recognition difficult, making it harder to engage with others. This in turn can leave patients with brain tumours, as well their carers, feeling isolated and alone.

Similar problems can occur in patients with head injuries and strokes. A computer-based rehabilitation method has been shown to improve the ability to recognise emotions for these patients. We think such rehabilitation may help with similar difficulties in patients with brain tumours. We want to see if this computer based rehabilitation, called 'FACES' can be used by patients with brain tumours. In the future, we hope to help patients like yourself re-learn how to recognise emotions in others and improve their quality of life by enjoying easier interactions with friends and family.

2. What is the treatment being tested?

We would like to test 'FACES', a computer-based rehabilitation package that we know provides benefit for patients with head injury and strokes who also have difficulties with recognising emotions.

Our study is split in to two stages:

Stage 1

In stage 1 we will provide 'FACES' for all patients taking part. We will see if patients can use 'FACES' after having surgery for a brain tumour. We also want to see if there are any improvements in their ability to recognise emotions and day-to-day function.

If patients are able to use this intervention we will move onto stage 2

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Stage 2

In stage 2 we will provide 'FACES' or a general brain training rehabilitation to patients. Whether patients use 'FACES' or the general brain training rehabilitation will be randomly chosen. This means that a computer program selects which patients use FACES and which of them use the brain training rehabilitation, in order to keep the comparisons between the two as fair as possible. Patients will have a 50% chance of receiving 'FACES' or general brain training rehabilitation. Half the patients taking part in stage 2 will receive FACES and the other half will receive general brain training

We will see if patients can use 'FACES' or general brain training rehabilitation computer package after having surgery for a brain tumour. We also want to see if there are any improvements in their ability to recognise emotions and day-to-day function after using the computer packages.

In both stages, all patients will use the computer package they have been allocated with the help of a trained assistant psychologist. Patients will be assessed with tests of the ability to recognise emotions before and after using the computer packages to see what effect, if any, the computer-based rehabilitation has. Patients and their carer/family member will also be asked to complete quality of life questionnaires before and after the rehabilitation.

Where necessary we will provide patients with a computer, for the duration of the study, to allow them to do the interventions.

Interviews / focus groups

We would like to conduct some 1:1 interviews and, also hold some focus groups, involving 6-8 participants, with both patients diagnosed with a brain tumour and their family member/carer to ensure that our study to test computer rehabilitation is meaningful.

We plan to conduct interviews / hold focus groups before the start of the study, after stage 1 and after stage 2. Interviews may be conducted face to face or remotely via telephone or video conference as appropriate.

3. Why have I been invited?

You have been invited to take part in an interview and/or focus group because you have a brain tumour and may have, also been involved in Stage 1 or Stage 2 of the study to test computer rehabilitation. We would like to ask you about your lived experience of coping with a brain tumour. We would also value your opinion about the study to test computer rehabilitation.

4. Do I have to take part?

No. Taking part in interviews and/or focus groups is completely voluntary. If you decide to take part you will be asked to sign a Informed Consent Form. However you are still free to change your mind and leave the study at any time without giving a reason.

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

If you agree to take part in the interviews and/or focus groups, you will sign the Informed Consent Form at the end of this document and be provided with a copy of this to take away and refer to later.

Following this, we will contact you to arrange an interview, or invite you to attend a focus group, where we will discuss your experiences of social interactions since your diagnosis and treatment for a brain tumour. We will also be asking you what you feel about the study to test if patients like you can use 'FACES' and what effect, if any, computer

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

rehabilitation has on patient's ability to recognise emotions and day-to-day function. This information is very important to help us to decide how best to proceed with stages 1 and 2 of the study and any future studies.

A variation of methods will be used for the interviews and focus groups including: face-to-face, telephone or videoconference, depending on the situation of each individual and will be discussed case by case. Interviews will last up to 60 minutes and focus groups up to 90 minutes depending on the need for breaks and how tired your feel.

To ensure accuracy, interviews and focus groups will need to be recorded. During interviews or focus group discussions we will ask that you and others do not give information that could identify anyone – such as names. If this happens by accident the researchers will edit this out. In this way we will ensure that any recordings, remain anonymous. These recordings will be transcribed (written down) by the researcher conducting the interviews and/or focus groups. Anonymised transcriptions (the recording written down without any information that could identify you) of the interviews and focus groups, may be shared with other researchers. We may also use direct quotes, from you or others in scientific publications, presentations to clinicians, other scientists, the public or press. These quotes will be anonymised so that it will not be possible to identify you or others. Any recording will be destroyed once the study analysis has been completed. Anonymised Transcriptions from these recordings will be kept and stored with the study information.

At the end of this study, you and your family member/carer will be offered a final feedback session to discuss any problems you are having and possible methods of addressing your problems.

6. What are the possible disadvantages and risks of taking part?

There are no risks in particular from taking part in the interviews and/or focus groups, but they will take 60-90 minutes of your time. We will try to arrange interviews on days that you are due to come into hospital as part of the routine management for you or your carer/family member. If you are invited to attend a face-to-face focus group we will try to offer you a location closest to your home. Alternatively we may conduct interviews and or focus groups remotely either by telephone or videoconference.

If incidental concerns are raised during the interviews and/or focus groups about your experience of taking part in this research, we will find the appropriate support to address them.

<u>Attending a hospital during the Pandemic</u>

Although there is a risk of hospital COVID-19 transmission, we do not think the risk is significant. Local policies are in place for patients attending a hospital for planned care to minimise the risk of disease transmission.

7. What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this study. However, information collected as part of your taking part in this study may benefit patients with brain tumours in the future.

We are offering all participants the opportunity to attend a final feedback session. Previous participants have found this helpful.

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

8. What are the alternatives for treatment?

Currently, there are no other alternative or standard treatments for patients with brain tumours who have difficulties with emotion recognition.

9. Expenses & Payment?

You will not receive payment for taking part in this study. We will try to arrange a face-to-face interview on a day that you are due to come into hospital as part of your routine care. Alternatively we can conduct the interview remotely if that is your preference. If you are invited to attend a focus group we will inform which method will be used: face to face, telephone or video conference. If face-to-face focus group is required, we will try to offer you a location closest to your home and reasonable travelling expenses will be reimbursed.

This completes Section 1 of the information sheet.

If you are considering taking part in the study, please continue to read the additional information in Part 2 before making any decisions.

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Section 2: Study Conduct

Please bear in mind that the following is information that we must provide all patients and carers involved in all research studies.

10. What if new information becomes available?

Sometimes during the course of a study, new information becomes available which might affect your decision to continue taking part in this study. Your study doctor will contact you to discuss the new information and whether you wish to continue taking part in the study. If you still wish to continue on the study, you will be asked to sign a new Informed Consent Form.

The study sponsor, the regulatory authority or the study doctor may decide to stop the study at any time. If that happens we will tell you why the study has been stopped and arrange for appropriate care and treatment for you.

11. What if I decide I no longer wish to take part in the study?

You are free to come off this study at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to take part any further, you will not be invited to any further interviews or focus groups. Any data (which is not identifiable) already collected will continue to be used in the study analysis.

The study doctor may also choose to withdraw you from the study if they feel it is in your best interests or if you have been unable to comply with the requirements of the study. A reason for study withdrawal could include your inability to complete the interview or attend a focus group.

12. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this study you should speak to your study doctor who will do their best to answer your questions.

In the event that something does go wrong and you are harmed by taking part in 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 or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).The University has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the *Patient Advice and Liaison Service (PALS)*.

13. 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 clinical 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 *up to 15* years after the study has finished to ensure your safety and allow the study to be reviewed by the authorities after it is finished.

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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

Cambridge University Hospitals will collect 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. 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/or 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 up to 15 years after the study has finished.

All information collected about you as a result of your taking part in the study will be kept strictly confidential. Your personal information (e.g. age, gender assigned at birth, ethnicity, area you live in (first part of the postcode) and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed to take part 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 along with your gender assigned at birth and age at registration to this study. Both your age and gender assigned at birth are considered to be personal information. We collect this personal information on study documentation to help ensure that the data we receive as part of your study taking part is correctly allocated to you. By cross checking these two unique references we can ensure the integrity of the data.

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.

When you agree to take part in this 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.

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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. 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.

We will need to inform your GP of your taking part in this study so that any medical decisions made by your GP account for any intervention you are receiving as part of this study.

14. What will happen to the results of the study?

The results of the study will be anonymous and you will not be able to be identified from any of the data produced. When the results of this study are available they may be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published a Clinical Studies Register website, a central registry for all conducted clinical studies.

Anonymous datasets from the study may also be made available to other researchers in line with national and international data transparency initiatives.

If you would like to obtain a copy of the published results please contact your study doctor directly who will be able to arrange this for you. We are planning to feedback your results to you after you complete the study.

15. Who is funding the study?

The study is being funded by the National Institute for Healthcare Research under their remit of 'Research for Patient Benefit' (Grant Reference: NIHR200495).

The study is managed by the Cambridge Clinical Trials Unit - Cancer Theme and sponsored by the Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge.

16. Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cambridge South Research Ethics Committee.

17. Further information and contact details

If you require any further information or have any concerns before/while taking part in this study, please contact a member of the study team during normal office hours (9:00am – 5:00 pm):

CNS Study Research Nurse.

Name: XXXXXX *Tel: XXXXXXXX*

Study Doctor/Principal Investigator

Name: XXXXXX *Tel:* XXXXXX

24-hour contact

Hospital/Ward: *XXXXXX* Tel: XXXXXXXX

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Alternatively, if you or your relatives have any questions about this study, you may wish to contact one of the following organisations that are independent of the hospital:

Brainstrust is a UK based charity and community which supports and helps thousands of patients and carers who are affected by a brain tumour diagnosis. They work to help patients and carers regain control and be confident that they are working towards the best outcome for their situation. They do this by sharing understanding of their local services, by providing our own services that include 24/7 email and telephone support, practical resources such as our brainbox and personalised resources that help our community feel a little less lonely. For more information have a look at www.brainstrust.org.uk or email hello@brainstrust.org.uk

The Brain Tumour Charity (originally called the Samantha Dickson Brain Tumour Trust) was set up in 1996. It is the UK's largest dedicated brain tumour charity, funding scientific and clinical research into brain tumours. It also offers support and information to brain tumour patients, whilst raising awareness and influencing policy. You can contact the organisation for advice, information or support on 0808 800 0004. You can access the information leaflets, discussion forum and support group details on the website at http://www.thebraintumourcharity.org/

MACMILLAN CANCER SUPPORT: a registered charity providing information about all aspects of cancer for cancer patients and their families. They have published several useful booklets on different types of cancer, chemotherapy, radiotherapy, and clinical studies in general. These booklets may be requested from Macmillan Cancer Support, 89 Albert Embankment, London SE1 7UQ. Alternatively, you may view the contents of these booklets on their website (www.macmillan.org).

In addition, MACMILLAN CANCER SUPPORT also provides advice from specialist cancer nurses on: FREEPHONE 0808 808 0000 (9am to 8pm, Monday to Friday, excluding Bank Holidays).

Contact details for Patient Liaison and Advice Service (or equivalent)

Addenbrooke's Patient Advice & Liaison Service
Tel: *01223 216756*
Email: *pals@addenbrookes.nhs.uk*
Address: Box 53, Cambridge University Hospitals, Cambridge Biomedical Campus, Hills Road, Cambridge, CB2 0QQ

FUNDED BY NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

UNIVERSITY OF CAMBRIDGE

NHS Cambridge University Hospitals NHS Foundation Trust

PATIENT INFORMED CONSENT FORM

Study Title: Social Cognition Assessment and Rehabilitation for Families Living with Brain Tumour (SCARF-BT) - Lived Experiences Component

Principal Investigator: Mr Stephen Price **Participant Number:** _____

If you agree with each sentence below, please initial the box **INITIALS**

1	I have read and understood the Participant Information Sheet version 2.0, dated 25 April 2022, for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my taking part in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of my personal data will be published.	
4	I understand that interviews and focus groups will be recorded and transcriptions from these interviews/focus groups may be shared with other researchers. Recordings will be anonymised, so that it will not be possible to identify me.	
5	I understand that direct quotes may be used in scientific publications, presentations to clinicians, other scientists, the public or press. Any direct quotes used will be anonymised, so that it will not be possible to identify me.	
6	I understand that sections of my medical notes or information related directly to my taking part in this study may be looked at by responsible individuals from the sponsors, regulatory authorities and research personnel where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
7	I understand that my GP will be informed of my taking part in this study and sent details of the SCARF study.	
8	I have read and understood the compensation arrangements for this study as specified in the Participant Information Sheet.	
9	I understand that the doctors in charge of this study may close the study, or stop my taking part in it at any time without my consent.	
10	I have read and understood my responsibilities for the study.	
11	I understand that the data and information collected about me will be used to support other research in the future and may be shared anonymously with other academic and commercial researchers external to the project, within the UK and beyond.	

I agree to take part in this study:

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes.

FUNDED BY NIHR | National Institute for Health and Care Research

This study is funded by the National Institute for Health and Care Research (NIHR) [RfPB Programme (NIHR200495]). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.