# PATIENT INFORMATION SHEET & INFORMED CONSENT FORM

## SCARF-BT

### Social Cognition Assessment and Rehabilitation for Families Living with Brain Tumour (SCARF-BT) - Stage 1

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 this 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: Purpose of the study and what will happen**

**1. What is the purpose of the 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, and 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. In this study 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. We know it provides benefit for patients with head injury and strokes who also have difficulties with recognising emotions. We will provide 'FACES' for patients taking part. Patients will be shown how to use it with the help of a trained assistant psychologist, so that they can use it at home for 9 sessions over 3 weeks, each session lasting for one hour.

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

**3 Why have I been invited?**

You have been invited to take part in this study because you have a brain tumour and we believe computer based rehabilitation (FACES) may offer relief to patients with symptoms like yours, especially those who find it more difficult to interact with others (including friends and family) since having the brain tumour.
We are inviting patients that have been involved in the CogENT and/or SIND studies.

**4 Do I have to take part?**

No. Taking part in this study is completely voluntary. If you decide to take part you will be asked to sign an Informed Consent Form, however you are still free to change your mind and leave the study at any time without giving a reason. If you chose not to take part or to leave the study, your future medical treatment and normal standard of care will not be affected in any way.

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

If you agree to take part in the study, you will sign the Informed Consent Form at the end of this document and be given a copy of this to take away and refer to later.

Once you have signed a consent form to join this study, we will ask you some questions about your medical history and perform some tests to see if you have any difficulties recognising emotions after your brain tumour surgery. We will also ask you and your carer/family member to complete a quality of life questionnaire.

Then our trained assistant psychologist will arrange to help you use 'FACES' at home, when you are discharged from hospital to recover after surgery. You will use FACES 3 times a week for 3 weeks, with each session lasting one hour.

After these 3 weeks of recovering at home and using 'FACES' we will repeat the tests to see if you have any difficulties recognising emotions and the quality of life questionnaires to find out if 'FACES' has helped you.

We may also conduct interviews and/or focus groups with you and your carer/family member to understand your experience of using the computer rehabilitation (FACES) and any effect it had on your day to day interactions. Participation in interviews and/or focus groups is optional and if you are interested in taking part we will provide a separate information sheet. We will need to give your contact details to the researcher conducting the interviews (an NHS Clinical Psychologist). This researcher will then contact you to answer any questions, ask you to sign the separate consent form and arrange the interviews and/or focus groups.

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.

This study will not require any invasive procedures or changes in drugs and routine treatment. The only difference is the use of this computer package during a time when patients are not routinely seen by hospital staff as they are recovering from surgery at home.

As this is not a study of a drug or invasive treatment, we do not expect you to feel unwell or any side-effects from using the 'FACES' computer-based rehabilitation.

You should tell the study team if you feel unwell or different in any way. If you have any major concerns or are feeling very unwell please contact your study doctor immediately using the contact numbers at the end of this information sheet.

You should discuss your taking part in this study with any insurance provider you have (e.g. travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

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

There will be some extra tests to see if you have any difficulties recognising emotions which may make your hospital visits longer. We plan to carry out all such tests during other routine visits to hospital for your treatment, so that no additional visits are required.

There are no known risks of using 'FACES' in particular. However, headaches and visual symptoms can rarely affect some patients whilst using a computer.

Quality of life questionnaires will be completed before your clinic visit so that any possible distress caused by the topics raised can be addressed by the clinical research team during your clinic visit.

If during the interviews with you and your carers about your experience of using 'FACES' other incidental concerns are raised, we will find the appropriate support to address them.

Attending a hospital during the Pandemic

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. Although we hope you may experience relief in your symptoms or improvement in your experience of interactions with family and friends, this study is not designed to show any possible benefits. However, information collected as part of your taking part in this study may benefit patients with brain tumours in the future.

Previous research has shown that participants find completing quality of life questionnaires helpful in getting them to think about their problems and thinking about what they wanted to discuss in outpatient clinics.

We are offering all participants (patients and their family member/carer) the opportunity to attend a final feedback session. Participants in previous research have found this helpful.

## 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 recognising emotions.

## 9. What happens when the study stops?

You will return to normal standard of care once all the study assessments have been completed.

## 10. Expenses & Payment?

You will not receive payment for taking part in this study. We aim to perform the tests required to see if you have difficulties recognising emotions during your routine hospital visits and then we will help you use 'FACES' on your own computer at home or on the computer provided. Some of your hospital visits may be longer, any additional parking costs incurred 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**.

**Section 2: Study Conduct**

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

### 11. 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.

### 12. 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 no longer receive the study intervention. No further tests will be performed on you. Any data (which is not identifiable) already collected or results from tests already performed on you 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. Reasons for study withdrawal could include:

- You are unable to complete the visits or study documentation as required
- The study doctor feels you no longer appear to benefit from the intervention.

### 13. 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)*.

### 14. 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 organisation(s) will keep identifiable information about you for 15 years after the study

has finished to ensure your safety and allowing the study to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisation(s) 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 Sponsor s 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 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 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.

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 treatment you are receiving as part of this study.

**15. 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.

**16. 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.

**17. 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.

**18. 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: XXXXXX*

*Study Doctor/Principal Investigator*

*Name: XXXXXX* *Tel:* XXXXXX

*24-hour contact*

Hospital/Ward: *XXXXXX* Tel: XXXXXX

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 studys 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

**PATIENT INFORMED CONSENT FORM**

**Study Title: Social Cognition Assessment and Rehabilitation for Families Living with Brain Tumour (SCARF-BT) - Stage 1**

**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 1.1, dated 18 March2021, 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 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. | |
| 5 | I understand that my GP will be informed of my taking part in this study and sent details of the SCARF-BT study. | |
| 6 | I have read and understood the compensation arrangements for this study as specified in the Participant Information Sheet. | |
| 7 | 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. | |
| 8 | I have read and understood my responsibilities for the study. | |
| 9 | 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. | |

**Optional Consent**

| | | |
|---|---|---|
| 10 | I am interested in taking part in interviews/focus groups and agree to my contact details being shared with the researcher conducting interviews/focus groups | Yes / No |

**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.