ISRCTN14920547 https://doi.org/10.1186/ISRCTN14920547

Recognising emotions and rehabilitation for families living with brain tumour

Submission date
20/04/2021

Recruitment status
No longer recruiting

Registration date
30/04/2021

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Brain tumours are unlike other cancers. They change things that make us who we are - memory, thinking, personality and interaction with others. Maintaining quality of life must be our aim, as these people are rarely cured.
Detecting emotions in friends and family is a key part of relationships. When patients can't engage with others it leaves them, and their carers, isolated and alone. Our studies suggest over half of patients with malignant brain tumours have emotional recognition problems.
Rehabilitation helps improve emotional recognition following head injuries by helping brain 're-organisation to recover lost skills. Researchers want to see if rehabilitation methods that work in patients following head injuries or stroke also work with brain tumour patients. The method is called 'FACES' and helps patients re-learn recognising emotions in others.
Treating neurocognitive problems that make brain tumours unique among cancer is a major unmet need. The ultimate aim is to develop a tailored clinical service that can provide evidence-based rehabilitation strategies to treat common emotional and cognitive problems. This study will focus on a specific common problem – social cognition and the ability to identify emotions in others. It is known that problems with emotional recognition lead to isolation.
The researchers are using a rehabilitation method that has already been validated in another randomised clinical trial for patients with brain injury (head injury and stroke). From that it is known that the intervention works, and what assessment methods should be used. But the nature of the brain damage from head injury and stroke (sudden injury with little deterioration) is different from brain tumours (slower development of problems with exacerbations due to surgery and gradual deterioration due to tumour growth). In addition, the patients are older (peak age for malignant brain tumours around 60-70 years vs. 40 years for the brain injury trial). Because there is no evidence that this kind of rehabilitation works in this group of patients, the researchers have decided to run this study as a feasibility study.
They have spent a lot of time working out when is the best time to use this intervention. They decided to apply this postoperatively as there is little time pre-operatively to run a 3-week rehabilitation intervention and they don't want to delay surgery. It is also known from other studies that up to 30% of patients will deteriorate and won't be suitable for active treatments following surgery. By recruiting postoperatively this cohort of patients won't be included.
The study will test 'FACES', a computer-based rehabilitation package. It is known that it provides benefit for patients with head injury and strokes who also have difficulties with recognising

emotions. The researchers will provide 'FACES' or a general brain training rehabilitation computer package for patients taking part. Patients will be shown how to use the computer package with the help of a trained assistant psychologist, so that they can use it at home for 9 sessions over 3 weeks, with each session lasting an hour.
This study will show whether patients using 'FACES' after having surgery for a brain tumour have improvements in their ability to recognise emotions and day-to-day function when compared with patients given the general brain training rehabilitation computer package. This will be assessed with tests of the ability to recognise emotions before and after using the computer packages and also by interviews with patients, their carers and family members to see what effect, if any, the computer-based rehabilitation had on their day-to-day interactions.

Who can participate?
Patients with high-grade glioma and who have been shown to have problems with detecting emotions in others, will be invited to join the study. Their carers can also participate.

What does the study involve?
The study will be in two stages:
Stage 1: A small group of patients (about 10) will try the FACES rehabilitation. This involves three training sessions each week for 3 weeks, done at home using a computer, supported by a psychologist. The researchers will compare results from tests at the beginning and end of the study to see if the rehabilitation works, and ask patients and carers how they found the study. This will let them know how to best run Stage 2.
Stage 2: In this larger study, at least 19 patients testing the FACES rehabilitation programme will be compared with a similar number of patients testing a general computer-based programme. The choice of rehabilitation programme will be made at random by a computer.

What are the possible benefits and risks of participating?
There is no guarantee that the patients will benefit from taking part in this study. Although it is hoped that patients may experience relief in their symptoms or improvement in their experience of interactions with family and friends, this study is not designed to show any possible benefits. However, information collected as part of their 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. The researchers 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.
There will be some extra tests to see if patients have any difficulties recognising emotions which may make their hospital visits longer. The researchers plan to carry out all such tests during other routine visits to hospital for their treatment, so that no additional visits are required.
There are no known risks of using 'FACES' or the general brain training 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 the clinic visit. If during the interviews with them and their carers about their experience of using 'FACES' or the general brain training, other incidental concerns are raised, the researchers will find the appropriate support to address them.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2019 to March 2025

Who is funding the study?
National Institute for Health Research (NIHR) Research for Patient Benefit (UK)

Who is the main contact?
Mr Stephen J Price, sjp58@cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Stephen Price

ORCID ID
https://orcid.org/0000-0002-7535-3009

Contact details
Academic Neurosurgery Division
Dept. Clinical Neurosciences
Box 167, Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 746455
sjp58@cam.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270758

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SCARF-2019, NIHR2004995, IRAS 270758, CPMS 48505

Study information

Scientific Title
Social Cognition Assessment and Rehabilitation for Families living with Brain Tumour (SCARF-BT): a feasibility study

Acronym
SCARF-BT

Study objectives
Feasibility of screening for and then providing a rehabilitation protocol for emotional recognition in patients with brain tumours (glioblastoma).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2021, East of England- Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8140; cambridgesouth.rec@hra.nhs.uk), REC ref: 21/EE/0052

Study design
Single-centre interventional cohort study followed by feasibility randomized controlled study with parallel qualitative study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Defects of emotional recognition in brain tumour (glioblastoma) patients

Interventions
This study comprises two stages: Stage 1 where all patients will receive the FACES intervention and Stage 2 where patients will be randomised 1:1 to receive either the FACES intervention or a placebo control (general cognition control intervention. The parallel qualitative study will involve interviews and focus groups at three timepoints; before stage 1, after stage 1 and after stage 2.

STAGE 1:
This is a non-randomised study. All patients will undergo the FACES Intervention. Patients will complete assessments to measure deficits in emotional recognition before and after the intervention. Patients and their carers will also be asked to complete quality of life forms before and after the intervention.
At the end of Stage 1, a decision will be made by the study management group as to whether the Stage 2 study should go ahead. This decision will be made based on the following criteria:
Percentage of patients attending the Surgical Neuro-oncology Clinic that are screened for emotional recognition deficits pre-operatively
Percentage of patients with a deficit who are approached for the study
Percentage of patients recruited that can complete all the assessments
Percentage patients recruited that are able to complete the FACES intervention adapted for remote delivery with the assistance of a psychologist.
Less than 50% would be deemed unacceptable.

STAGE 2:
Patients will be randomised 1:1; half receiving the FACES intervention (active intervention) and the other half receiving the General Cognition Intervention (control intervention). As with Stage

1, patients will complete assessments to measure deficits in emotional recognition before and after the intervention. Patients and their carers will also be asked to complete quality of life forms before and after the intervention.

STUDY INTERVENTIONS:
FACES Intervention (active intervention):
This intervention has been previously described and validated in patients with traumatic brain injury. In essence, the intervention will be a one-to-one computer-assisted treatment facilitated by an assistant psychologist. It will consist of 3 x 1-hour interventions each week for 3 weeks. This will be started postoperatively and continued until patients start other treatments such as radiotherapy.

General Cognition Control Intervention (control intervention):
The purpose of the cognitive training intervention is to control for the one-on-one attention and personal interaction that participants in the active treatment group are receiving, without providing any type of emotion-related training. Previous studies have confirmed a 'placebo effect' and the necessity of a control intervention. General Cognitive Training will include a variety of online, publicly available computer games that targeted speed of processing, visual scanning, attention, memory, reasoning, and problem-solving skills all with the aid of an assistant psychologist.

Qualitative study:
To ensure the proposed intervention and outcome measures are meaningful for people with brain tumours, the researchers will undertake one-to-one interviews and/or focus groups. They have opted for both interviews and focus groups, where feasible, to offer participants choice and because both formats provide complementary but different data.

A variation of methods will be used for the interviews and focus groups including face-to-face, telephone or videoconference. The focus groups/interviews will be undertaken at three stages of this project. Each will have specific objectives and aims:

Before the start of the study the researchers will involve patients that would be eligible to participate in stage 1 of the study and their carers. This group will explore the following topics:
1. What is the patient's and their family's lived experience of coping with disorders of social cognition?
2. What do the participants feel about the proposed study – what potential barriers and enablers to trial participation can they see. This will be used to optimise the intervention before Stage 1.

After Stage 1: the researchers will involve the patient group (including the carer/family member) that had been recruited to Stage 1 of the study. They will explore:
1. Experiences of being involved in the study and study interventions
2. How the researchers may improve the delivery of interventions and assessments
3. How they will approach future patients to Stage 2 and discuss randomisation

After Stage 2: the researchers will involve the patient group (including the carer/family member) that had been recruited to Stage 2 of the study. They will explore:
1. How can the researchers improve the delivery of this intervention to routine clinical practice to make it acceptable to patients?
2. What changes would they need to implement in a larger Phase III trial?
3. How do the outcome measures reflect patient experience – is there a discrepancy between changes in outcome measures and what patients experience?

Intervention Type
Behavioural

Primary outcome(s)
Stage 1: the cohort study
1. Completion of the Faces intervention (defined as completing all 9 sessions) recorded at the end of the 3-week intervention (post-intervention)
2. Changes to the administration, conduct and content of the rehabilitation intervention measured by recording the data on a patient-by-patient basis at the end of the 3-week intervention (post-intervention)
3. The acceptability of the intervention measured during interviews/focus groups through a parallel qualitative study before the start of stage 1, after completion of stage 1 and after completion of stage 2
4. Percentage of patients completing the following validated outcome assessments at baseline and post-intervention:
Emotional recognition measured using:
4.1. Diagnostic Assessment of Non-verbal Accuracy-2, Adult Faces (DANVA2-AF)
4.2. Emotion Recognition and Social Inference: The Awareness of Social Inference Test (TASIT), (part 1, EET subtest)
4.3. The Toronto Alexithymia Scale-20 (TAS-20)
5. The percentage of patients and carers able to complete the following quality of life questionnaires at baseline and post-intervention:
5.1. Patients: quality of life measured using EORTC QLQ30+BN20
5.2. Carers: effect on family measured using CQOLC

Stage 2: placebo-controlled feasibility randomised controlled trial
The outcome measures for this stage will be:
1. Screening rate: the number of patients who undergo screening (the numerator) and the number of potentially eligible patients that attend clinic (the denominator), recorded at screening
2. The screened patients meeting the eligibility criteria that provide informed consent for the study, measured by recording the percentage of screening at baseline
3. Patients who have completed all sessions for the FACES intervention (active intervention) and General Cognition Intervention (control intervention), measured post-intervention
4. Percentage of patients completing the following validated outcome assessments at baseline and post-Intervention:
Emotional recognition measured using:
4.1. Diagnostic Assessment of Non-verbal Accuracy-2, Adult Faces (DANVA2-AF)
4.2. Part 1, which includes emotion recognition, of Emotion Recognition and Social Inference: The Awareness of Social Inference Test (TASIT)
4.3. The Toronto Alexithymia Scale-20 (TAS-20)
Acceptability is explored with the parallel qualitative study (see below)
5. Patient-reported quality of life measured using the EORTC QLQ-30 with the BN20 brain tumour module measured at baseline and post-intervention
6. The impact of these problems on patient's families is assessed by asking interested family members to complete the Caregiver Quality of Life Index-Cancer (CQOLC) at baseline and post-intervention

Parallel Qualitative Study:
At interviews and/or focus groups with both patients and their carers at three timepoints the following specific questions will be explored:

1. Before the start of stage 1: the researchers will involve patients that would be eligible to participate in stage 1 of the study and their carers. They will explore the following topics:
1.1. What is the patient's and their family's lived experience of coping with tumour and disorders of social cognition?
1.2. What do the potential participants feel about the proposed study – what potential barriers and enablers to trial participation can they see? This will be used to optimise the intervention before Stage 1.
2. After Stage 1: the researchers will involve the patient group recruited to Stage 1 of the study and their carers. They will explore:
2.1. Experiences of being involved in the study and study interventions?
2.2. How the researchers may improve delivery of interventions and assessments?
2.3. How will they approach future patients to Stage 2 and discuss randomisation?
3. After Stage 2: the researchers will involve patients recruited in Stage 2 of the study and their carers. They will explore:
a. How can they improve delivery of this intervention to routine clinical practice to maximise its acceptability to patients?
b. What changes would we need to implement in a larger Phase III trial?
c. How do the outcome measures reflect patient experience – is there a discrepancy between changes in outcome measures and what patients experience?

Key secondary outcome(s))
To provide an early indicator that the intervention may make some difference and would be worth exploring in a larger multicentre study, the researchers will calculate the difference in scores pre and post intervention for the selected validated outcome assessments (listed in the primary outcome measures), for both the active (FACES) intervention group and the control group, measured at baseline and post intervention.

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Patients:
1. Patients pre-screened as part of the CogENT and SIND studies, scoring 11 or less on the emotional recognition test within the OCS-Bridge screening tool done pre-operatively (consistent with having a deficit pre-operatively)
2. Signed Informed Consent to SCARF-BT study
3. Aged 18 years and older
4. Imaging evidence of a high-grade glioma as assessed by a neuro-oncology MDT
5. MDT and treating clinician recommend either biopsy or debulking of the tumour; 6. Patients scoring 11 or less on the emotional recognition test within the OCS-Bridge screening tool done post-operatively (consistent with having a deficit post-operatively)
7. Patients with WHO Performance status 0-2
8. Patients suitable for oncological intervention (involving radiotherapy/ chemotherapy/ combining radiotherapy and chemotherapy)
9. For Qualitative Study only: speaks fluent English as the use of interpreters can alter patients exact words
10. For Qualitative Study only: willing to participate in the interviews and/or focus groups

Carers:
1. Written informed consent
2. Family member/someone they care for with Brain Tumour who is participating in this study
3. Able and willing to complete the caregiver Quality of Life questionnaire
4. For Qualitative Study only: speaks fluent English as the use of interpreters can alter patients exact words
5. For Qualitative Study only: willing to participate in interviews and/or focus groups

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients unable to give written consent or who lack capacity to consent
2. Patients for palliative/best supportive care only, following surgery
3. Pre-morbid developmental or acquired/traumatic neurologic disorder (e.g. autism, stroke, severe head injury or dementia/cognitive impairment)
4. Pre-morbid major psychiatric disorder (e.g., schizophrenia)
Impaired vision and/or hearing that would interfere with task participation (determined by interacting with participant on screening and medical history)
5. Patients have impairment of facial recognition (i.e. prosopagnosia) using the OCS-Bridge screening tool score of >5 on immediate assessment
6. Impaired facial recognition (i.e. prosopagnosia) using a separate test from the OCS-Bridge screening tool, where a score of ≤5 on immediate assessment of neutral face recognition would suggest a deficit requiring exclusion

Date of first enrolment
31/03/2021

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Research and Development Department
Box 277
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Lived Experience Interviewees carers version v1.1	18/03/2021	30/04/2021	No	Yes
Participant information sheet	Lived Experience Interviewees patients version v1.1	18/03/2021	30/04/2021	No	Yes
Participant information sheet	Stage 1 carers version v1.1	18/03/2021	30/04/2021	No	Yes
Participant information sheet	Stage 1 patients version v1.1	18/03/2021	30/04/2021	No	Yes
Participant information sheet	Stage 2 patients version v1.1	18/03/2021	30/04/2021	No	Yes
Participant information sheet	Lived Experience Interviewees carers version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Lived Experience Interviewees patients version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Stage 1 carers version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Stage 1 patients version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Stage 2 carers version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Stage 2 patients version 1.3	03/09/2021	08/10/2021	No	Yes
Participant information sheet	Lived Experience Interviewees carers version 2.0	25/04/2022	07/09/2022	No	Yes
Participant information sheet	Lived Experience Interviewees patients version 2.0	25/04/2022	07/09/2022	No	Yes
Participant information sheet	Stage 1 carers version 2.0	25/04/2022	07/09/2022	No	Yes

Participant information sheet	Stage 1 patients version 2.0	25/04/2022	07/09/2022	No	Yes
Participant information sheet	Stage 2 carers version 2.0	25/04/2022	07/09/2022	No	Yes
Participant information sheet	Stage 2 patients version 2.0	25/04/2022	07/09/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.1	18/03/2021	30/04/2021	No	No
Protocol file	version 1.3	03/09/2021	08/10/2021	No	No
Protocol file	version 2.0	25/04/2022	07/09/2022	No	No