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BrainApp: Exploring the use of a mobile app in adult patients with primary brain tumours

Submission date
25/08/2021

Recruitment status
No longer recruiting

Registration date
03/10/2023

Overall study status
Ongoing

Last Edited
02/11/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Brain tumours (BTs) are the leading cause of death in adults under 40. Although rare compared to other tumours, they can cause great disability and financial burden to both patient and caregiver. Even with specialist treatment, BTs usually progress, and many patients will not survive more than 2 years. Even in those patients who are well enough for treatment, at some point the tumour will often grow, causing new symptoms and requiring further treatment. Detecting this growth is currently done through scans (CT and MRI). However, these scans are time-consuming, expensive, and may not always give clear answers.

Many patients in whom the tumour grows will develop new symptoms, such as weakness down one side, speech, thinking or language problems. Computer-based analyses of speech, motion detection and visual features have been shown to differentiate between healthy individuals and those with other brain diseases (e.g. dementia). The increased use of “smartphones” and electronic tablets means that most adults now carry a device that can measure data on speech, movement, and balance; captured via “apps” which people download onto their device.

Our research team at Imperial College London is already undertaking a study, called Brain Wear, to investigate the feasibility of wearable devices in assessing the level of physical activity in BT patients. Inspired by Brain Wear, we have designed BrainApp, to explore the potential of mobile apps in monitoring physical features and quality of life (QOL) in BT patients. Although there are hundreds of health-related apps in the market today, there is limited evidence for their effectiveness and very few of them focus on BTs. With this in mind, we are collaborating with The Brain Tumour Charity (BTC) which has designed and released a free app (“BRIAN”) that allows users to enter information on their background, diagnosis, treatment and QOL, as well as perform mini-games (Challenges) that test co-ordination, memory, changes in facial features and speech.

This study will use the data collected in BRIAN, and assess how well patients and healthy volunteers are able to use the app, and whether the data collected through the app correlates with traditional measures of treatment and disease progression. We are particularly interested in whether changes in the measures collected in BRIAN pre-date conventional measures of disease progression, measured using scans. Ultimately, this may enable the development of a

tool that allows us to detect earlier signs of disease progression, and so offer earlier treatment and preservation of QOL; and hence the best course of action. Such a tool would also be non-invasive, cheap, quick, and able to be conducted at home.

Who can participate?
Fluent English speakers aged 16 and above either with a medically confirmed primary brain tumour diagnosis or who are generally well.

What does the study involve?
Participants will first download the free BRIAN app on to their own mobile devices via https://www.thebraintumourcharity.org/living-with-a-brain-tumour/brian/.
They then will need to fill in a questionnaire on their background and turn on fitness tracking. If they have a wearable fitness tracker, they can link this to BRIAN also. Every month at a minimum, all participants will be required to play games on BRIAN called Challenges. Participants with a primary brain tumour will also be required to fill in a quality of life questionnaire monthly at a minimum. These tasks can be done anywhere (with minimal background noise) and take 10-15 minutes to do. We aim to follow-up participants for two years, however, they are free to withdraw from BrainApp should they become too unwell or choose to no longer take part.

What are the possible benefits and risks of participating?
For participants who are well, they will be able to track and receive feedback on their hand coordination, visual memory, speech, changes to facial features and physical activity. They will contribute valuable information to one of the largest studies of brain tumours and artificial intelligence in the world, which ultimately aims to improve the lives of millions of individuals worldwide. However, there will be no direct benefits to their health.
For participants with primary brain tumours, they will be able to self-monitor their symptoms and quality-of-life more objectively and report a more comprehensive representation of their daily functioning to their clinical team. This is not possible or feasible with current standard follow-up procedures. This will potentially allow the clinical team to support patients more holistically with more extensive data collected in real-time. We cannot promise the study will help patients directly, but the information we get might help improve the treatment of people with brain tumours.
Participants will not need to travel or acquire any extra equipment to be part of this study and only require that the free BRIAN app be downloaded onto their own mobile device. If they have a wearable fitness tracker, this can be linked to BRIAN. This hopefully will ensure that participants do not feel overly-burdened by traveling to study sites. The use of a mobile app in the era of COVID-19 also minimises any risk of viral transmission.
As this is an observational study, and participants are only required to fill in questionnaires and complete mini mobile games on their own devices, we do not project there to be any risk involved in participation.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2021 to December 2026

Who is funding the study?
UK Research and Innovation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295289

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
21CX6825, IRAS 295289, CPMS 49953

Study information

Scientific Title
Feasibility, acceptability and relationship to standard measures of near-patient sensing through a mobile app and machine learning - an observational non-randomised phase II trial in patients with primary brain tumours

Study objectives
Aim:
To assess the feasibility, acceptability, and performance of a mobile app in collecting data on quality of life (QOL), physical activity and sleep, for predicting disease progression in brain tumour patients.

Objectives:
1. To generate a prospectively collected dataset of patient measures obtained through mobile devices in brain tumour patients and healthy volunteers.
2. To assess compliance and performance of micro-challenges (hand coordination, visual memory, speech and facial features) in study participants using a mobile application.
3. To assess differences and systematic variation in micro-challenge performance between healthy volunteers and brain tumour patients.
4. To assess factors associated with micro-challenge performance in brain tumour patients, the relationship between micro-challenges and standard measures of QOL and disease progression.
5. To assess the diagnostic performance of different machine learning models in detecting brain tumour progression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2021, South West - Cornwall & Plymouth REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0104

Study design
Observational non-randomized multi-centre phase Il trial

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Primary brain tumours

Interventions
This is a phase II non-randomised observational study recruiting primary brain tumour (BT) patients and healthy volunteers. It is aimed at assessing the performance of a machine learning classifier developed from a multimodal dataset in predicting BT progression. We aim to recruit two parallel subject cohorts over two years. The first cohort (A) will consist of cancer centre patients, whilst the second cohort (B) will be healthy volunteers. The study will involve the use of a mobile application developed by The Brain Tumour Charity (BTC), called BRIAN, as the primary assessment tool; along with electronic case report forms (eCRFs) and brain scan images. Data from Cohort A will be obtained via the BRIAN mobile application, eCRFs and brain scan images; whereas data from Cohort B will be obtained solely via BRIAN. BRIAN is a mobile application developed by BTC that allows individuals to anonymously record their experience living with a BT and share this information with both researchers and doctors. All subjects in this study will use BRIAN as the main assessment tool.

A. What do participants need to do using the BRIAN app?
1. BRIAN Profile: Record date of birth, sex, subject type (patient or healthy volunteer), country of residence and qualifications.
2. Handedness: Record whether left- or right-handed

3. Medication: Record medication name.
4. Trial information (Cohort A only): Record their clinical trial name, eCRF number, location, start date and end date.
5. Tumour log (Cohort A only): Record tumour type, grade, location, status, baseline radiology report and baseline histology report as well as date of diagnosis (estimated date if patient unable to recall exact date).
6. Treatments & appointments log (Cohort A only): Record appointment type, date, time, and radiology report (if applicable), as well as hospital/ clinic where they are being treated. This will allow us to relate any changes to assessments with clinical events and enable retrieval of histopathology and radiology reports from cancer centres.
7. QOL assessment with EORTC QLQ-C30/BN20 combined questionnaire : – Only Cohort A will be required to complete this questionnaire.
a. EORTC QLQ-C30 covers five functioning scales (physical, social, role, cognitive, and emotional functioning), eight symptom scales (fatigue, nausea/vomiting, pain, dyspnoea, sleep disturbances, appetite loss, constipation, and diarrhoea), financial impact, and overall QOL, and the scores are linearly converted to range between 0 to 100. High scores in the functioning scale and global QOL indicate better function whilst a higher score in the symptom scale indicate higher symptom burden. See: https://www.eortc.org/app/uploads/sites/2/2018/08/Specimen-QLQ-C30-English.pdf.
b. EORTC QLQ-BN20 questionnaire covers a further 11 scales to assess neurological deficits (visual disorder, motor dysfunction, communication deficit), future uncertainty, and disease- and treatment-related symptoms. Similar to the EORTC QLQ-C30, the raw scores are converted to a 0-100 scale and a higher score for this questionnaire represents a poorer QOL. See: https://www.eortc.org/app/uploads/sites/2/2018/08/Specimen-BN20-English.pdf.
8. Micro-Challenges:
a. Stability: Users will need to keep a circle in the middle of the screen for 20 seconds by gently and gradually tilting their mobile device to maintain the same position. This will be used to assess users' visual and motor coordination.
b. Snap: Review 20 pairs of images and decide whether they match or not (Fig 3). This will be used to assess users' visual memory.
c. Speech: Read aloud a paragraph of text while being recorded by BRIAN (Fig 4). This will be used to assess any vocal and language changes over time.
d. Photo: Take a photograph of your face (a "selfie") and upload it. This will be used to assess for any facial feature changes.
9. Fitness tracking: Participants can opt to link either their wearable fitness trackers or smartphone fitness trackers with BRIAN. This allows us to assess how users' physical activity and sleep vary over time and with treatment, as both are commonly affected in Brain Tumour patients.

B. Case report forms
ECRFs will be designed using REDCap (Research Electronic Data Capture), which is a data collection tool with a simple secure web-based interface designed for clinical researchers (Imperial College London is a registered partner with the REDCap consortium). MRI and histopathology reports, along with co-morbidities and details of treatment received will be obtained from REDCap eCRFs for Cohort A only. Participating cancer centres will be instructed to return the eCRFs via REDCap at subject enrolment, then 6-months, 12-months, and 24-months post-enrolment.
C. For patients in Cohort A, we ask centres to complete eCRFs and transfer imaging at enrolment, then 6-months, 12-months and 24-months post-enrolment. This can be done in one of two ways:
a) Trusts can transfer them using the standard secure NHS Image Exchange Portal (IEP), and then we will anonymise and export to research store locally using a process that has already been

approved by ICHT and Imperial College London in terms of Information Governance.
b) Trusts can anonymise and transfer electronically, using the secure NHS OneDrive. This ensures that Trusts can use their own approved process, and so satisfy their own Information Governance requirements.

Intervention Type
Other

Primary outcome(s)
Diagnostic performance of a machine learning model, measured as accuracy, recall, precision, and F1 score measured every 6 months

Key secondary outcome(s))
1. Compliance in micro-challenge use, measured as one completed entry in the BRIAN app per month per subject
2. Relationship between micro-challenge scores and participants' clinical progression and treatment every 6 months
3. Quality of life scores from the EORTC QLQ-C30 and BN20 questionnaires every 6 months

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Age 16 and above
2. Fluent English speakers
3. Willing and able to undertake study-specific measures
4. Able to provide either electronic or written consent
5. Formally diagnosed with a primary brain tumour (either based on histology or assessment of imaging at a neuro-oncology MDT) or healthy volunteers
6. Brain tumour patients with a performance status of 0, 1, or 2.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria

1. Subjects lacking capacity to consent based on patient's doctor's opinion
2. Diagnosis of secondary brain tumour (i.e cancer that starts somewhere in the body and spreads to the brain)
3. Refusal to participate
4. Subjects with performance status of 3 or more
5. Subject not in possession of personal mobile device compatible with the BRIAN app

Date of first enrolment
15/09/2022

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
Imperial College Healthcare NHS Trust
Department of Radiotherapy
Fulham Palace Road
London
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W6 8RF

Study participating centre
St Marys Hospital
Imperial College Healthcare NHS Trust
The Bays
South Wharf Road
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United Kingdom
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Study participating centre
The Royal London Hospital
Barts Health NHS Trust
80 Newark STreet

London
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E1 2ES

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
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NR4 7UY

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

We are not able to share full IPD datasets, as these would almost certainly be disclosive. However, we will aim to share a subset of anonymized data to enable other researchers to work on it. In addition, we will archive the data in the Brain Tumour Data Accelerator where it will be accessible to other researchers through application to a Data Access Board

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Healthy volunteers version 3.0	01/09/2021	12/11/2021	No	Yes
Participant information sheet	Patients version 4.0	01/09/2021	12/11/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	01/06/2021	12/11/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes