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BrainApp: 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

PATIENT INFORMATION SHEET
(Information for Patients)

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Contact
Dr Matthew Williams
Chief Investigator
Email: imperial.brainapp@nhs.net

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this

1. What is the purpose of the study?

Brain tumours can cause a range of difficulties for patients and their caregivers. Some tumours change over time and cause new symptoms. Current tumour detection methods with CT and MRI scans are time-consuming, expensive, and may not always give clear answers. However, recent developments in mobile technology have created an opportunity for us to explore the potential of mobile apps in assessing brain tumours over time.

Our project aims to explore the potential of The Brain Tumour Charity's BRIAN app that collects data on patient symptoms and physical features in order to understand brain tumours in a non-invasive way and more economically. BRIAN has been developed to help people cope with a brain tumour. It will help you - and those supporting you – to understand how you are doing and to make better-informed decisions. You can have a look at the app via this link: https://www.thebraintumourcharity.org/living-with-a-brain-tumour/brian/.

We are interested to see how data on speech, hand coordination, visual memory, and facial features collected from BRIAN are associated with brain tumour activity. We will relate BRIAN's information with patients' clinical encounters, quality of life, physical activity, brain scans and lab results. These will be compared with information from healthy volunteers. We hope it will help improve decision-making by doctors in the future.

This study is being undertaken as part of a PhD project by one of the physicians interested in the brain and mobile technology.

2. Why have I been chosen?

You have been chosen to take part in this study because your brain scans and lab tests show you to have a tumour that has arisen from the brain tissue itself, which is not hindering you from being ambulant or self-caring.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

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

You will be involved in this study for up to two years or until you become too unwell to participate. You only need to download the BRIAN app on your own mobile device, fill in a questionnaire on your quality of life, turn on fitness tracking and play games called Challenges (see **Table 1**). These tasks can be done anywhere (with minimal background noise), will not take more than 15 minutes at a time and do not require you to visit a clinic. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. **Table 1** summarises the journey you will take.

Table 1: Patient journey

Stage	Task
Information	You have received this participant information sheet (PIS) and have time to ask any questions in your outpatient Neuro-oncology clinic appointment. You will have the opportunity to ask any questions to the researcher before deciding whether to take part.
Download	If you are happy to participate, you will be asked to **download** the BRIAN app on your mobile phone or tablet via: https://www.thebraintumourcharity.org/living-with-a-brain-tumour/brian You can also access the same PIS on BRIAN.
Consenting	If you are happy to participate, you will be asked to read and sign a consent form on BRIAN. Your GP will be notified.
Registration	You will: 1. Complete the BRIAN **profile** (date of birth, sex, type of participant, and qualification) and enter information on your **handedness**, **medication**, **treatment**, **tumour** status and details of the clinical **trial** site. 2. You will link your **fitness tracker** (either via your mobile phone or wearable device e.g. Fitbit/ Apple Watch) on to BRIAN which will monitor your physical activity continuously. The recruiting researcher will record your **BRIAN ID** number and your medical details in an electronic **Case Report Form**. The researcher will electronically submit this form containing reports of your brain scan, treatment, underlying health conditions and pathology along with your brain scans to Imperial College Healthcare NHS Trust at enrolment then 6-months, 12-months and 24-months post-enrolment.
Interval	Every month at a minimum, you will need to do the following tasks on BRIAN which will take approximately 10 minutes: 1. Perform the four challenges: **Speech**, **Snap**, **Selfie** and **Stability** 2. Complete the EORTC **Quality of Life** Questionnaire. Please ensure you are in a quiet environment with no background noises/disturbances when performing these tasks. This is important to ensure good-quality information can be captured by your mobile devices. You will do this throughout the duration of this study, which is up to two years.
Ad-hoc	When you have a medical appointment related to your brain tumour, you will need to do the following on BRIAN, which will take approximately 15 minutes: 1. Complete your **treatments** and **appointments** log. 2. Perform **Speech**, **Snap**, **Selfie** and **Stability** challenges within five days before and after the appointment so we can correlate any medical events to your challenge results. 3. Complete the EORTC **Quality of Life** Questionnaire. 4. Update your **medication**, **treatment**, BRIAN **profile** or **tumour** status if there are any changes. You will do this throughout the duration of this study, which is up to two years.
Completion	When the study finishes, the BrainApp Study part of BRIAN will no longer be accessible to you, but you can still use the BRIAN functions to support you in your brain tumour journey.

Should you decide not to proceed with the study before its completion, you can withdraw your participation via the BRIAN app anytime. The research function will no longer be available to you and no more BrainApp study data will be collected. However, you are free to use other functions to support your daily activities. Your medical care will not be affected. Data that you provided up to the point of withdrawal will be retained for research.

Should you become too unwell to participate, your carers and/ or relatives can remove the BRIAN app from your device for you. Data that you provided up to this point will be retained for research.

5. What do I have to do?

You do not need to make any adjustments to your lifestyle, work or medication when you participate in this study. You will not need to travel or acquire any extra equipment to be part of this study and only require that a free software be downloaded onto your own mobile device. If you have a wearable fitness tracker, you can link that to BRIAN at the **Registration** stage (see **Table 1**).

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

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.

7. What are the possible benefits of taking part?

You will be able to self-monitor your symptoms and quality-of-life more objectively and report a more comprehensive representation of your daily functioning to your clinical team. This is not possible or feasible with current standard follow-up procedures. This will potentially allow the clinical team to support you more holistically with more extensive data collected in real-time. We cannot promise the study will help you but the information we get might help improve the treatment of people with brain tumours.

You will not need to travel or acquire any extra equipment to be part of this study and only require that a free software be downloaded onto your own mobile device. If you have a wearable fitness tracker, you can link it to BRIAN also. This hopefully will ensure that you do not feel overly burdened by traveling to study sites. The use of a mobile app in the era of COVID-19 also minimises your risk of viral transmission.

8. What happens when the research study stops?

When the study finishes, the BrainApp Study part of BRIAN will no longer be accessible to you, but you can still use the BRIAN functions to support you in your brain tumour journey.

9. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr. Matthew Williams at imperial.brainapp@nhs.net).

The normal National Health Service complaints mechanisms are also available to you such as contacting the local Patient Advice Liaison Services (PALS XXX NHS Trust, Tel: XXX).

10. How will we use information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from your medical records and BRIAN for this research project. This information will include your:

- NHS number (study site only)
- Name (study site only)
- Date of birth (study site only)
- BRIAN ID (study site and sponsor)
- Case Report Form ID (study site and sponsor)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

11. Legal Basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

12. International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

13. Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

14. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

15. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/, or
- by asking one of the research team members, or
- by sending an email to imperial.brainapp@nhs.net, or
- by visiting the study website at https://www.computationaloncology.net/

16. Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

17. What will happen to the results of the research study?

The results of the research will be analysed and published in scientific journals. No individual participants will be identifiable from any report or publication. We will happily provide you with a copy of the results after publication. You will not be identified in any report/ publication.

18. Who is organising and funding the research?

The research is being organised by Imperial College Healthcare NHS Trust and Imperial College London. It is supported by the UKRI Centre for Doctoral Training in AI for Healthcare http://ai4health.io (Grant No. EP/S023283/1) and Imperial Healthcare Charity. Your doctor will not be paid for including you in this study.

19. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by the South West - Cornwall & Plymouth Research Ethics Committee (REC), Health Regulator Authority and Health and Care Research Wales (Reference 21/SW/0104).

20. Contact for Further Information

Email Matthew.williams@imperial.ac.uk or imperial.brainapp@nhs.net for further information and support. OR for independent advice please contact:

Patient Advice and Liaison Service (PALS)

Charing Cross Hospital

PALS address: Patient Advice and Liaison Service (PALS), Ground floor, Main Hospital Entrance, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF **Telephone**: 020 3313 0088 Monday to Friday, 09.00-17.00. *An answer phone system operates at busy times and out of hours. Please leave a message with your name and phone number and a member of staff will call you back within 24 hours.* **Email**: IMPERIAL.PALS@NHS.NET;

Thank you for your participation