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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

PARTICIPANT INFORMATION SHEET (Information for Healthy Volunteers)

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Contact

Dr Matthew Williams
Chief Investigator
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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 patients - and those supporting them – to understand how they 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 individuals like yourself. 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 you are above 16 years old and are generally fit and well. Information from you can be used in comparison with brain tumour patients.

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.

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

You will be involved in this study for up to two years. You only need to download the BRIAN app on your own mobile device, fill in a questionnaire on your background, turn on fitness tracking and play games called Challenges. These tasks can be done anywhere (with minimal background noise) and will take 5-10 minutes to do. **Table 1** summarises the journey you will take.

Table 1: Healthy volunteer participant journey

Stage	Task
Download	You will have seen the advertisement for this study and download the BRIAN app on your mobile phone or tablet via: https://www.thebraintumourcharity.org/living-with-a-brain-tumour/brian
Information	You will read the electronic Participant Information Sheet on BRIAN

Consenting	If you are happy to participate, you will be asked to read and sign an electronic consent form on BRIAN.
Registration	<p>You will:</p> <ol style="list-style-type: none"> 1. Complete the BRIAN profile (date of birth, sex, type of participant, and qualification) and enter information on your handedness and medication. 2. You will link your fitness tracker (either via your mobile/ tablet or a wearable device e.g. Fitbit/ Apple Watch) on to BRIAN which will monitor your physical activity continuously. <p>This will take no more than 10 minutes to do.</p>
Interval	<p>Every month at a minimum, you will need to perform the four challenges on BRIAN which will take up to 5 minutes: Speech, Snap, Selfie and Stability.</p> <p>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.</p> <p>You will do this throughout the duration of this study, which is up to two years.</p>
Completion	When the study finishes, the BrainApp Study part of BRIAN will no longer be accessible to you. However, you are free to access other BRIAN functions, especially if you are supporting an individual with a brain tumour.

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. Data that you provided up to the point of withdrawal 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 track and receive feedback on your hand coordination, visual memory, speech, changes to facial features and physical activity. You 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 your health.

8. What if something goes wrong?

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS resolution for NHS Trusts in England, which apply to this study. This does not affect your legal rights to seek compensation.

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 Chief Investigator.

The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

9. How will we use information about you?

We will need to use information from your BRIAN account for this research project. This information will be your BRIAN ID. 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.

10. 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.

11. 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 **XXX**

12. 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.

13. 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). Your doctor will not be paid for including you in this study.

14. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee (XXX)

15. Contact for Further Information

Email XXX or imperial.brainapp@nhs.net for further information and support. OR for independent advice please contact:

Patient Advice and Liaison Service (PALS)

XXX hospital

PALS address: PALS manager, XXX **Telephone:** XXX **Text phone:** XXX **Email:** XXXX

Thank you for your participation