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# Wrist Worn Trackers for monitoring activity in brain tumour patients

**Submission date**
03/07/2018

**Recruitment status**
No longer recruiting

**Registration date**
04/09/2018

**Overall study status**
Completed

**Last Edited**
01/03/2019

**Condition category**
Cancer

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

## Plain English summary of protocol

Background and study aims
Most patients with primary (developed in the brain) or secondary (spread from another cancer outside of the brain e.g. lung) brain tumours develop weakness and balance problems as part of their illness, and report significant tiredness, which can be related to both the tumour and the treatments given such as radiotherapy and/or chemotherapy. However, we have little detailed information on the impact of treatment on patient physical activity levels, nor how patient activity levels relate to quality of life, the toxicity of the treatment and whether the underlying tumour is responding to treatment or progressing.

Oncologists currently use a measure known as performance status to determine a patient's general well-being and fitness, and it is utilised to guide treatment recommendations such as chemotherapy and radiotherapy. This is a simple scale that runs from 0 (entirely well) to 5 (dead). The problem with the performance status scales is that they were developed over 50 years ago and are subject to bias, meaning that there is significant variation in the way different health care professionals, and even patients will rate their own performance status. Despite these limitations, important clinical decisions in brain tumour management are based on performance status, including fitness for new treatments and eligibility to take part in clinical trials.

We already know that in patients with high-grade gliomas (an aggressive form of brain tumour), activity level is a good additional way of health care workers being able to accurately judge the performance status. What is less well known is if the role of physical function can predict how patients are managing with their treatment, and if changes in physical activity are an early indication of when the disease starts to progress.

There have been significant recent advancements in wearable technology e.g FitBit or Apple watch ‘wrist worn tracker’ devices which now allow us the opportunity to gather high-quality, physical activity data from patients in a non-obtrusive manner.

Our hypothesis is that physical activity (PA) levels and their changes may indicate disease relapse in patients with primary and secondary brain tumours. Our aim is to assess the compliance and acceptability of patient-worn devices, such as wrist-worn trackers, to monitor this. We will also

look at the levels of and changes in PA of patients, and the relationship between PA and conventional methods of monitoring disease relapse and progression, toxicity and quality of life.

Who can participate?
Patients aged between 18 and 90 years old with either high-grade glioma (HGG), low-grade glioma (LGG) or metastatic brain cancer, or matched normal healthy volunteers (main caregivers).

What does the study involve?
The participant is provided with an Axivity AX3 wrist-worn accelerometer device (similar to a wristwatch), which monitors their physical activity whilst they undergo their standard treatment and into the follow-up period. The patient is asked to wear the device for as long as they feel comfortable during the day and night, as it only needs to be taken off whilst swimming or taking a bath. We aim to collect a minimum of 6 months of data from each patient, though patients are free to withdraw from the study if they become too unwell, or should they choose to no longer take part. The device is CE marked, and meets the health and safety requirements required for clinical research.

What are the possible benefits and risks of participating?
The benefit of taking part in this study is to provide researchers with vital data for analysis, with the hope of being able to incorporate physical activity monitors into future Neuro-Oncology trials and standard follow-up, to better monitor brain tumour patient's in the outpatient setting. Although there is no live feedback mechanism about physical activity to the patient at present, this is planned for after the study. There are no known risks to participants taking part in this study.

Where is the study being conducted?
Charing Cross Hospital (as part of Imperial Healthcare NHS Trust)
Fulham Palace Road
Hammersmith
London
W6 8RF

When will recruitment begin and end?
From July 2018 until July 2022.

Who is funding the study?
Brain Tumour Research Charity (BTRC) (UK)

Who is the main contact for this study?
Dr Matthew Williams
matt.williams3@nhs.net

# Contact information

### Type(s)
Scientific

### Contact name
Dr Matthew Williams

### ORCID ID

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
0.44

# Study information

### Scientific Title
Brain Wear - Wrist worn trackers to monitor physical activity data in patients with primary and metastatic brain tumours. A Phase II feasibility study

### Acronym
BrainWear

### Study objectives
To assess
1. The compliance and acceptability in the use of patient-worn devices
2. The absolute levels and changes in patient physical activity (PA) levels as part of oncological treatment and interventions, and the relationship between PA and conventional measures of toxicity, quality of life and disease response/progression

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
CORNWALL-PLYMOUTH, NRESCommittee.SouthWest- (HEALTH RESEARCH AUTHORITY), 27/06/2018, IRAS Project ID: 236115

### Study design
Observational single-centre phase II open-label non-randomised feasibility cohort study in primary and secondary brain tumour patients

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Community

## Study type(s)
Other

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Primary and secondary brain tumours

## Interventions
The study idea originated from a patient undergoing treatment for a brain tumour, and has undergone structured patient and public involvement (PPI) with feedback incorporated into the protocol. Expert patients within the study management group have been consulted and reviewed the study design.

We will use the Axivity AX3 accelerometer device, purchased directly from Axivity. We will recruit patients and conduct the study for 46 months in all. We will aim to recruit 70 patients in total, with follow-up (standard follow up with radiological and clinical assessment as clinically required) of at least 6 months in all patients. We aim to recruit a minimum of the first 10 patients in each of the major treatment groups (high-grade tumour, chemo-radiotherapy; low-grade tumour for surgery alone; brain metastasis for surgery and/ or SRS) with matched healthy volunteers (main caregiver)). Within a 1 year period we typically treat > 50 patients with primary brain tumours having chemo-radiotherapy, and > 50 patients with metastatic disease having SRS. However, we expect that patient-worn monitoring will only be acceptable to a proportion of patients in clinic. We therefore intend to run the trial for 48 months to allow for recruitment and follow-up.

Steps
1. Screening of patients from Brain MDT and Neuro-Oncology clinics
2. Patient comes to clinic (as clinically indicated)
3. Patient given PIS to read (either contacted in advance and mailed, or asked to re-attend clinic to allow minimum of 24 hours), agrees to the study and provides informed consent
4. Patient enrolment into the study
5. Training by the research nurse to wear wrist band devices; Review of patient telephone and installation of Moves Application. The Moves App will be correlated with the AX3 device data to assess for similarities in data collection in a mobile versus wrist worn tracker device.
6. Patient wears wrist band device continuously
7. At each visit data is sampled, and device replaced with recharged version
8. At each visit, patient completes standard HRQoL and toxicity questionnaires
9. Patients will be given the opportunity to use the Hospital Trust’s existing secure care information exchange (CIE) portal available online to fill in the required questionnaires, if they

have access to home computing. Participants can also opt to swap devices at 1 monthly intervals (battery charging required) by using provided stamped, addressed envelopes, or charging themselves using the charging cable provided. These measures are to try and avoid extra visits by the patient, though if required will be reimbursed.
10. On completion of the study, or if the participant withdraws, the device will need to be returned via a provided stamped, addressed envelope.
11. Patients will be followed from their first hospital appointment until either they reach PS 3 for more than 2 weeks, until they have been off-treatment with stable disease for 6 months, or they chose to withdraw from the study.
12. For normal healthy volunteer participants, they will be approached to take part in the study if they attend of one the initial outpatient appointments of the patient participant, and will be given a separate participant information sheet and consent form to sign. They will be asked to wear the AX3 accelerometer device as per the patient participant, but will not be required to fill in questionnaires on HRQoL and fatigue. They will instead be given the CareGiver Oncology Quality of Life questionnaire (CarGOQoL), a specific questionnaire for caregivers of cancer patients.

## Intervention Type
Device

## Phase
Phase II

## Primary outcome measure
1. Compliance and acceptability in patient use of devices, measured as >=50% data completeness in patients at 3 months post enrolment.
2. Patient physical activity, monitored over the period of time in which the participant is enrolled into the trial. Patients will be followed from their first hospital appointment until either they reach PS 3 for more than 2 weeks, until they have been off-treatment with stable disease for 6 months, or they choose to withdraw from the study.

## Secondary outcome measures
The following will be measured at enrolment, week 2 (+/- 7 days), week 6 (+/- 14 days), week 8 (+/- 7 days), week 10 (+/- 7 days), week 14 (+/- 14 days), week 18 (+/- 14 days), week 22 (+/- 14 days), and then 3 monthly until either patient becomes PS 3, until they have been off-treatment with stable disease for 6 months, or withdraws from study, along with at any unexpected visits:
1. Quality of life scores (EORTC QLQ C-30 and BN-20)
2. Performance status (PS), measured using ECOG scale
3. Imaging (standard imaging as clinically indicated) measured with 3 MRI and Contrast Head scans, reported using RANO criteria
4. Self reported fatigue and activity (MFI) measured using the MFI scale
5. Medication and steroid dose, monitored through documentation by the study team of any changes in medication since the last study review

6. Disease progression will be measured using MRI head imaging every 3 months until the patient becomes PS 3, until they have been off-treatment with stable disease for 6 months, or until they withdraw from the study, along with any unexpected visits.

## Overall study start date
02/09/2017

### Completion date
01/12/2023

# Eligibility

### Key inclusion criteria
1. Primary or secondary brain tumours recently diagnosed and about to start treatment (unless matched healthy volunteers)
2. Patients with histology or clinically proven primary or secondary tumours who are fit to have radical treatment including surgery, radiotherapy or chemotherapy (unless matched healthy volunteers)
3. If being treated for recurrent tumour then at least 6 months must have elapsed since the completion of previous treatment (unless matched healthy volunteers)
4. Able to provide written informed consent
5. Fluent in English
6. Willing to undertake trial-specific measures, including wearing of and upload of data from wristband.
7. Aged over 18 years and 90 years or under

Patients do not need a smart phone to be eligible for this study

### Participant type(s)
Mixed

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
70

### Key exclusion criteria
1. Patient undergoing WBRT
2. Patients with poor PS (PS3, 4) undergoing palliative treatments
3. Patients who have recently completed treatment (within 6 months) for primary or metastatic brain tumour

### Date of first enrolment
02/07/2018

### Date of final enrolment
01/07/2022

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Charing Cross Hospital**
Fulham Palace Road
London
United Kingdom
W6 8RF

## Sponsor information

### Organisation
Imperial College NHS Healthcare Trust

### Sponsor details
Becky Ward
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/056ffv270

## Funder(s)

### Funder type
Not defined

### Funder Name
Brain Tumour Research Campaign (BTRC)

## Results and Publications

## Publication and dissemination plan
Results will be published and disseminated at local, national and international meetings (EANO, ESTRO, ECAI) and in peer-reviewed journals (Neuro-oncology, BJC, AI in Medicine).
We will work with two expert patients in BrainWear (both treated for HGG) and wider PPI groups to develop lay summaries and improve recruitment for the study, along with using our strong existing links with several brain tumour charities to disseminate the trial and results.
We will host a one day conference on the 'Clinical Applications of Wearables and IoT', aimed at junior researchers and industry.

## Intention to publish date
02/07/2023

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Matthew Williams (matt.williams3@nhs.net). The data made available will be the study protocol and anonymised raw accelerometer data from the AX3 device which will be made available for a period of up to 10 years after the study has closed, to allow for further data analysis. The data will be available to those working in within the biosensors network for further data analysis using machine learning techniques. This has been explicitly stated in the consent form which participants will be asked to sign at enrolment, and the data will be completely anonymised.

## IPD sharing plan summary
Available on request