

CAPABLE: Comparing the Patient Generated Index (quality of life tool) in patients and caregivers to standard measures in the high-grade brain tumour population

Submission date 20/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and Study Aims:

Brain tumours are the leading cause of cancer death in the under-40s. Even with all the current treatment opportunities available, survival from this illness is still poor. With this in mind, a patient's quality of life - their overall function and well-being - should be a focus in treatment decision making, as quality of life has been shown to play an important role in overall outcome. There are specific 'tools' in the form of questionnaires to measure quality of life, however, those currently available are time consuming and burdensome. Moreover, "quality of life" is a difficult concept to measure as its meaning may be different to different people. Furthermore, the impact on caregivers' quality of life - notably in time, financial concerns and personal health consequences should not be forgotten about.

The purpose of this study is to identify whether the patient generated index (PGI) - a tool designed to document quality of life concerns in a more personalised manner as they are stated by the individual - is feasible in the brain tumour population (patients and caregivers). We will ask patients to complete both standard validated questionnaires as well as the patient generated index (PGI) and we will use the same process to assess quality of life of their main caregiver - a method we are terming the Caregiver Generated Index (CaGI). The intention is then to compare the results of PGI and CaGI to the existing standard quality of life questionnaires to get an understanding of how well they capture the impact of living with this new diagnosis.

Who can participate?

Adults who have been diagnosed with a brain tumour and are undergoing active treatment and /or their caregiver.

What does the study involve?

Participants will be required to visit the hospital and complete some questionnaires on 6 occasions over 6 months.

What are the possible benefits and risks of participating?

There will be no direct benefit but ultimately, we hope that we will be able to validate the Patient Generated Index so that it can be utilised in routine clinical practice to help deliver more personalised care. We anticipate that the process of using the PGI and other questionnaires may highlight some areas of concern which may not have been discussed in normal clinic visits. We would anticipate that this process would itself be beneficial; however, if required, we will be able (with the participants' permission) to discuss these areas of concern with their wider treating team and access other support services if necessary.

Where is the study run from?

1. Imperial College Healthcare NHS Trust
2. Barts Health NHS Trust
3. Guys & St Thomas NHS Foundation Trust

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

October 2019 to March 2022

Who is funding the study?

1. Imperial Health Charity
2. NIHR Imperial Biomedical Research Centre
3. Royal Marsden Cancer Charity (RM Partners)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

266261

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 266261, CPMS 45067

Study information

Scientific Title

CaPaBLE: Caregiver and Patient less-Burden Life Evaluation - A Phase II observational study comparing the Patient Generated Index (Quality of life tool) in patients and caregivers to conventional QoL measures in the high-grade brain tumour population

Acronym

CaPaBLE

Study objectives

The CaPaBLE study intends to assess the feasibility of using the PGI process with patients diagnosed with brain tumours, additionally we will use the same process to assess QoL of their main caregiver - a method we are terming the Caregiver Generated Index (CaGI). The results of PGI and CaGI will be compared to existing standard QoL questionnaires to get an understanding how well they capture the impact of living with this new diagnosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/04/2020, London - Bloomsbury Research Ethics Committee (3rd Floor 4 Minshull Street Manchester M1 3DZ, UK; +44 (0)207 104 8375; bloomsbury.rec@hra.nhs.uk), ref: 20/LO/0338

Study design

Phase II non-randomized pragmatic cohort study of patients and caregivers

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Quality of life in newly diagnosed/ recurrent high-grade primary brain tumour patients and their caregivers

Interventions

This is an observational study; patients will therefore receive treatment as clinically indicated, in line with standard guidelines. Potential participants will include any patient that is referred to the Brain Tumour MDT and/or neuro-oncology clinic with a suspected new, or recurrent, high grade brain tumour and plan is for:

- neurosurgical biopsy or resection
- start a course of radical radiotherapy (≥ 45 Gy)
- course of chemoradiotherapy
- stereotactic radiotherapy
- or for re-treat for relapsed disease

Participants will be divided into three cohorts for eligibility/ recruitment into the study:

1. Patient and caregiver both consent for study
2. Patient consents for study and the caregiver does not consent to take part in study
3. Patient does not consent to being part of study but gives consent for research team to have access to medical records. Caregiver consents to being enrolled into study.

Participants will then take part in an observational, longitudinal study of HRQoL from diagnosis to six months or discontinuation of treatment or death. Patients will undergo standard follow up procedures (both clinical and imaging assessment) as part of their routine clinical care (monthly if on chemo-radiotherapy and 3-6 monthly during the follow up), and for this study will be followed from enrolment until 6 months. We intend to complete both patient and caregiver assessments at the same clinic visits. At all visits, the PGI/CaGI will be completed prior to any other assessment (EORTC QLQ30, BN20, CarGOQoL and EQ-5D-5L). At each visit the PGI/CaGI is

completed anew, this will allow assessment of change in domains highlighted and the weighting ascribed to them. To assess their previous medical history and concurrent medical conditions, the attending medical professional or researcher will complete the Adult Co-Morbidity Evaluation 27 with the patient and caregiver at enrolment.

The initial assessment for patients consists of taking a full medical history and gathering background information (gender, age, ethnicity etc) and a brief assessment of your memory and concentration (MoCA) which normally takes 5-10 minutes. Once this is completed, the Patient Generated Index will be completed which is a three step process. After this two standard questionnaires, totaling 50 questions, (QLQ-C30 and BN20) will need to be completed. This typically takes less than 15 minutes. Further assessments will take place at 2 and 6 weeks and then at 3, 4, and 6 months (end of study). At study visits 3 and 5 we will also ask participants to do an additional questionnaire which consists of 5 questions (EQ-5D) - which is the same for caregivers.

This initial assessment for caregivers consists of gathering information about their background (gender, age, ethnicity etc) and any underlying health condition which they feel is relevant for us to know about. Once this is completed, the Caregiver Generated Index will be completed which is a three-step process. After this participants will be asked to complete a standard questionnaire totalling 41 questions (CarGoQoL). This should take approximately 5 to 10 minutes. Further assessments will take place at 2 and 6 weeks and then at 3, 4, and 6 months (end of study). At study visits 3 and 5 we will also ask for you to do an additional questionnaire which consists of 5 questions (EQ-5D) - which is the same for patients.

Intervention Type

Other

Primary outcome measure

1. Feasibility and acceptability of novel, personalised measures of HRQoL in patients with brain tumours and their caregivers, which will be assessed using completion rates at the end of the study
2. Patient quality of life measured at baseline, 2 weeks, 6 weeks, 3 months, 4 months, 6 months using the following:
 - 2.1. Patient Generated Index
 - 2.2. Cancer quality of life questionnaire (QLQ-C30)
 - 2.3. Quality of Life Questionnaire - Brain Cancer Module (BN20)
 - 2.4. EQ-5D (at 6 weeks and 4 months only)
3. Caregiver quality of life measured at baseline, 2 weeks, 6 weeks, 3 months, 4 months, 6 months using the following:
 - 3.1. Caregiver Generated Index
 - 3.2. CareGiver Oncology Quality of Life questionnaire (CarGoQoL)
 - 3.3. EQ-5D (at 6 weeks and 4 months only)

Secondary outcome measures

Patient, caregiver and professional views on the comparative benefits and drawbacks of standard approaches and PGI/CaGI measured using two focus groups (midway through and end of study) where patients, caregivers and multi-disciplinary staff will be invited to have open discussions in regards to the PGI/ CaGI vs standard methods. In each session we will ask participants to express their views and thoughts, and then reflect emerging themes to the group to stimulate further discussion.

Overall study start date

01/10/2019

Completion date

07/03/2022

Eligibility

Key inclusion criteria

Patient:

1. Newly diagnosed, or recurrent, high-grade primary brain tumour. We define a high-grade tumour as any grade 3 or 4 primary brain tumour (including meningioma)
2. Newly diagnosed patients intending to undergo neurosurgical biopsy or resection, or to start a course of radical (≥ 45 Gy) radiotherapy or a course of chemoradiotherapy or stereotactic radiotherapy.
3. Recurrent brain tumours patients undergoing further treatment including surgery, chemotherapy or re-irradiation.
4. Performance status 0, 1, or 2
5. Able to provide written informed consent
6. Intention to attend at least 5 clinic visits over a 6-month period to the study site
7. Age 18 years and above
8. Willing to undertake study-specific measures

Caregiver:

1. Main caregiver of patient with newly diagnosed or recurrent high-grade primary brain tumour
2. Caregiver of patient receiving treatment (surgery and/or radiotherapy/ chemotherapy) expected to last ≥ 3 weeks in total
3. Aged 18 years and above
4. Intention to attend at least 5 clinic visits over a 6-month period to the study site
5. Willing to undertake study-specific measures
6. Able to provide written informed consent

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

130

Total final enrolment

60

Key exclusion criteria

Patient:

1. Diagnosed with a low-grade brain tumour (including grade 1 and 2 meningiomas)
2. Poor performance status (PS 3,4) or rapidly deteriorating fitness and for best supportive care and/or symptom control only
3. Diagnosed with a high-grade brain tumour but not planned for any intervention
4. Language barriers
5. Poor cognition status based on clinical assessment/ Montreal Cognitive Assessment (MoCA)/ MDT)
6. Refusal to participate

Caregiver:

1. Severe cognitive problems based on the doctor's opinion
2. Language barrier
3. Ongoing active treatment for own medical condition expected to significantly limit attendance for study assessments (missing 2 or more clinic visits). To be assessed by attending clinical or research team

Date of first enrolment

15/06/2020

Date of final enrolment

31/07/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Charing Cross Hospital

Imperial College Healthcare NHS Trust
Fulham Palace Rd
Hammersmith
London
United Kingdom
W6 8RF

Study participating centre

The Royal London Hospital

Barts Health NHS Trust
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre**Guy's Hospital**

Guys and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information**Organisation**

Imperial College London

Sponsor details

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Sponsor type

University/education

Website

<http://www3.imperial.ac.uk/>

ROR

<https://ror.org/041kmwe10>

Funder(s)**Funder type**

Charity

Funder Name

Imperial Health Charity

Alternative Name(s)

Imperial Charity, IHC

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

NIHR Imperial Biomedical Research Centre

Alternative Name(s)

NIHR Imperial BRC, Imperial Biomedical Research Centre, BRC

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Funder Name

Royal Marsden Cancer Charity (RM Partners)

Alternative Name(s)

The Royal Marsden Cancer Charity

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

We intend to publish and disseminate our finding through peer reviewed scientific journals , conference presentations and updates/ publication on websites (i.e Brain Tumour Research; Imperial College London)

Intention to publish date

01/10/2021

Individual participant data (IPD) sharing plan

All data generated or analysed 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?
Participant information sheet	version v1.5		04/01/2021	No	Yes
Participant information sheet	version v1.5		04/01/2021	No	Yes
Protocol file	version v3.3	14/04/2020	04/01/2021	No	No
HRA research summary			28/06/2023	No	No
Abstract results		15/10/2021	30/11/2023	No	No
Abstract results		05/09/2022	30/11/2023	No	No
Abstract results		01/10/2022	30/11/2023	No	No
Basic results		29/11/2023	30/11/2023	No	No