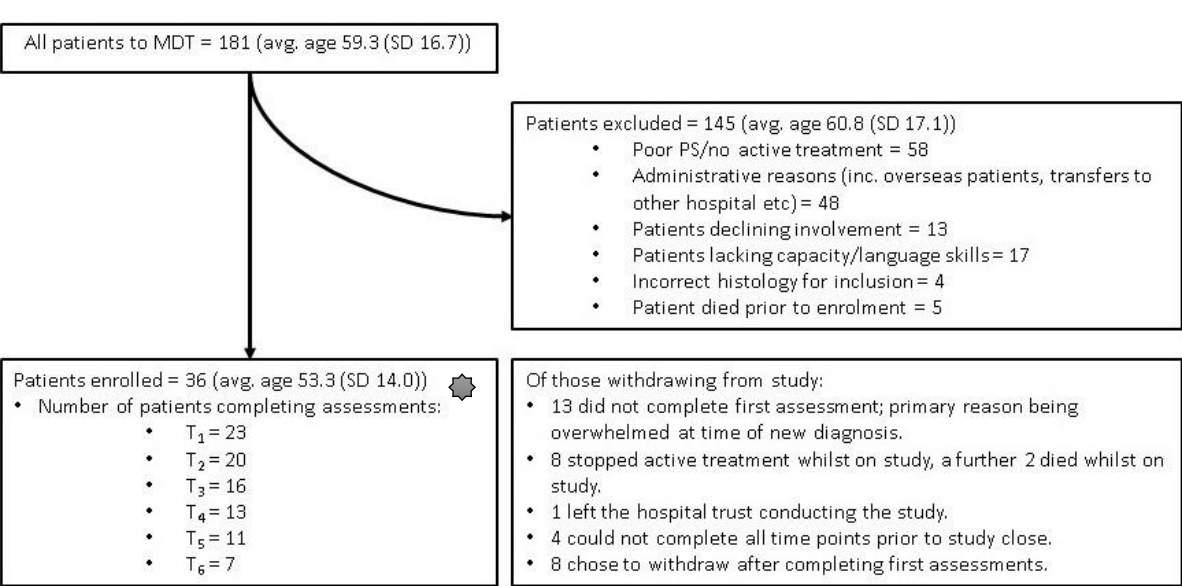


Ref. ISRCTN45555598 IRAS 266261, CPMS 45067 - CAPABLE: Comparing the Patient Generated Index (quality of life tool) in patients and caregivers to standard measures in the high-grade brain tumour population

Participant flow

Overall Study enrolment: 60 participants (36 patients and 24 caregivers)



✱ In addition to the 36 patients enrolled in the study, 24 caregivers consented and actively participated in the trial. Eligible caregivers were those aged 18 years or over who were suggested by the patient. Caregivers had to be able to provide written informed consent and willing to undertake study-specific measures. Caregivers were able to participate in the study independent of patient enrolment, with patient consent for diagnosis and treatment information gathering.

Baseline characteristics

	MALE	FEMALE	TOTAL
OVERALL			
Number of patients	23	13	36
Number of caregivers	6	18	24
PATIENTS			
Age			
Mean age	56.5	46.7	52.9
Median age	61	47	56
Diagnosis			
HGG	20	11	31
Recurrent glioma	3	1	4
Transformed LGG	0	1	1
Baseline PS			
0	6	3	9
1	12	9	21
2	2	0	2
Not completed	3	1	4
End of study PS			
0	0	2	2
1	9	4	13
2	4	2	6
3	0	2	2
4	1	0	1
Not completed	9	3	12
CAREGIVER			
Age			
Mean age	51.7	57	55.6
Median age	51	52.5	51

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Outcome measures

Primary outcome measure

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

<u>Recruitment rate</u>	Patients	Caregiver
	181 patients at MDT	72 met eligibility criteria
	168 screened	24 enrolled
	72 met eligibility criteria	
	36 enrolled	
Recruitment rate	50%	33%

No of completed assessments	Patients	Caregivers	Total
PGI	90	54	145
EORTC	92	59	151
EQ-5D-5L	77	33	110

Completion rates of PGI for patients

No of pts enrolled	36	
	No of patients completing assessments	Percentage Completion
Baseline	27	75
Visit 1	23	64
Visit 2	20	55
Visit 3	16	44
Visit 4	13	36
Visit 5	11	31
Visit 6	7	19

Completion rates of CaGI for Caregivers

No of caregivers enrolled	24	
	No of caregivers completing assessments	Percentage Completion
Baseline	22	92
Visit 1	15	63
Visit 2	13	54
Visit 3	11	46
Visit 4	8	33
Visit 5	6	25
Visit 6	1	4

Our data from the CaPaBLE study has demonstrated feasibility and acceptability of the PGI in patients with brain tumours. In the 15 months that the study was open, 181 patients identified at MDT, 168 patients were screened of which 72 were eligible and 36 recruited (a 50% recruitment rate which is similar findings to previous research in this population).

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Secondary outcome measures included:

Patient quality of life measured at baseline, 2 weeks, 6 weeks, 3 months, 4 months, 6 months using the following: Patient Generated Index; Cancer quality of life questionnaire (QLQ-C30); Quality of Life Questionnaire - Brain Cancer Module (BN20); EQ-5D (at 6 weeks and 4 months only)

Caregiver quality of life measured at baseline, 2 weeks, 6 weeks, 3 months, 4 months, 6 months using the following: Caregiver Generated Index; CareGiver Oncology Quality of Life questionnaire (CarGoQoL); EQ-5D (at 6 weeks and 4 months only)

PGI/CaGI vs Comparator Standard Measure

We have associated participant raised topics with the domains of their comparator standard measures. This has been an iterative process through collaboration within our group. For the topics that we have recorded as matching their comparators standard measure domains these were either fit or partial fits:

- “fit” meaning the topics match the wording of domain items.
- “Partial fit” which are those topics which pair with the wider theme of the domain and the items contained within them.

PATIENT SECONDARY OUTCOME MEASURES

PGI Topics vs Standard Measures; Descriptive Analysis

Table showing the number of PGI topics raised that aligned with the EORTC domains.

EORTC Domain	Patient topics matching domain
RF - Role functioning	58
BNFU - Future Uncertainty	47
SF - Social functioning	35
PF - Physical functioning	29
QL - Global health status/QoL	16
EF - Emotional functioning	15
CF - Cognitive functioning	10
BNCD - Communication Deficit	10

Table showing topics raised via PGI not picked up in standard measure and the number of times raised:

Topics not matching EORTC domains	Topic Count
Driving	9
Independence	8
Intimacy	7
Impact on relationships	6
COVID	4
Identity	4
Impact of treatment	4
Loss of fulfilment	2

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CAREGIVER SECONDARY OUTCOME MEASURES

CaGI Topics vs Standard Measures; Descriptive Analysis

Table showing the number of CaGI topics raised that aligned with the CarGOQOL domains.

CarGOQOL Domain	Caregiver topics matching domain
PsWB - Psychological Well Being	35
BD - Burden	27
AF - Admin and Finance	21
LT - Leisure Time	20
PhWB – Physical Well Being	7
CP – Coping	6
PL – Private Life	5
RHC - Relationship with Healthcare	2

Table showing topics raised via CaGI not picked up in standard measure and the number of time raised

Topics not matching CarGOQOL domain	Topic Count
Future uncertainty	27
Impact on relationships	23
Employment	7
COVID	2
Global health	1
Travel	1

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.

Summary of key findings when comparing PGI/CaGI topics to their comparators standard measures:

- 97% of topics raised by patients and 77% of topics raised by caregivers could be mapped to the domains of their respective standard QoL measure.
- Over half of topics raised by patients and caregivers mapped to 3 most common domains of relevant standard measure;
- Several commonly raised topic clusters (driving, independence and intimacy for patients; future uncertainty and impact on relationships for caregivers) do not map to standard measures.

Adverse events

We have no adverse events to report for this study.

Publication

We have published multiple abstracts/ posters at conferences including at British Neuro-Oncology Society (oral presentation) and the European Association of Neuro-Oncology and we plan to publish in a peer-reviewed journal.

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BNOS 2021 and 2022

Lillie Pakzad-Shahabi, James Tallant, Mary Wells, Matthew Williams, CaPaBLE: Comparing the Patient Generated Index to standard quality of life measures in patients and caregivers affected by high-grade brain tumours - Preliminary analysis, *Neuro-Oncology*, Volume 23, Issue Supplement_4, October 2021, Page iv2, <https://doi.org/10.1093/neuonc/noab195.003>

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