Development of a Core Outcome Set and Identification of Patient-Reported Outcomes for Primary Glioma Trials: Protocol for the COBra Study

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COBra Study
Patient Reported Core Outcomes in Brain Tumour Trials

BACKGROUND:

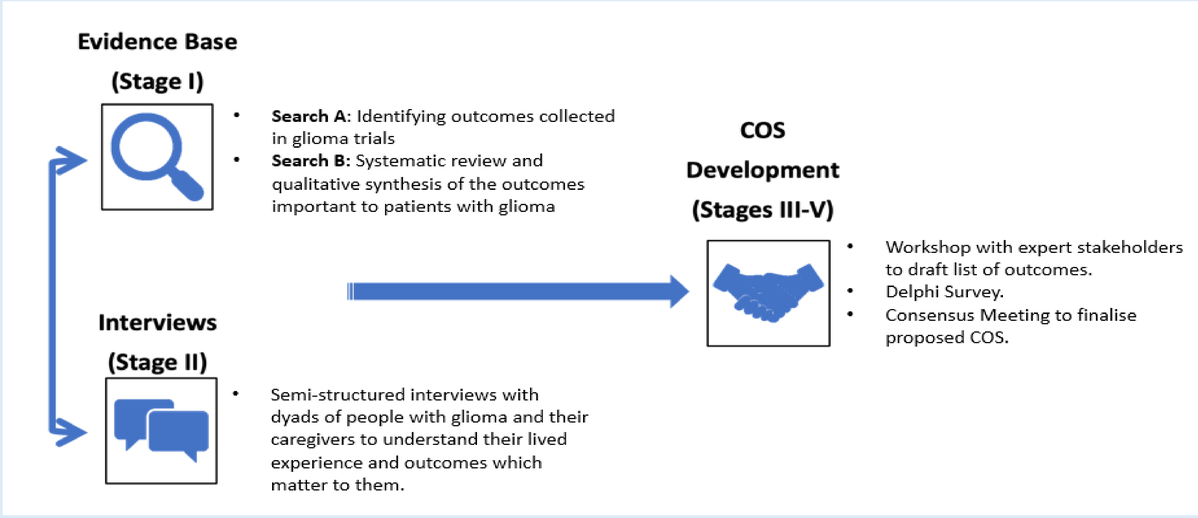
- Gliomas and their treatment have negative impacts on patients and those close to them.
- High rates of physical and cognitive morbidity differ from other cancers and reduced health-related quality of life.
- Poor prognosis of some glioma patients and the high symptom burden has resulted in growing emphasis on quality of survival – the quality of prolonged life in cancer.
- Patient-reported outcomes (PROs) enable assessment of outcomes including symptoms, functional health, well-being and psychological impacts from the patients' perspective, without interpretation by a clinician or anyone else.
- PROs enable insight into the impact of treatment on a patients' perceived wellbeing where other outcome data may indicate minimal differences in disease control and survival, potentially influencing patients' treatment choices.
- Glioma trials using outcomes that allow holistic analysis of treatment benefits and risks enable informed care decisions.
- Currently, outcome assessment in glioma trials is inconsistent, hindering evidence synthesis.
- There is a growing acknowledgement of the value of PRO data in relation to glioma

A core outcome set (COS) is an agreed minimum set of outcomes to be measured and reported in all trials within a specific area.

AIMS:

1. Develop a COS for use in glioma trials, applicable across glioma types.
2. Identify outcomes from the final COS that can be patient-reported.

METHODS: The COS will be developed in **5 stages**. Outcome lists will be generated in **Stages I and II**. **Stage III** will include removal of duplicates and formulation of accessible terminology for inclusion in the **Stage IV** Delphi survey - a two-round process, whereby the outcomes will be rated by key stakeholders. Participants will finalise the COS in the **Stage V** consensus meeting. The study team will identify PROs from the COS outcomes. Further research is needed to match PROs to available measures.



***DISCUSSION*:** A COS facilitates consistent outcome collection, analysis, and reporting, enables data synthesis and meta-analyses, reduces research waste, and informs patient-centred care. Identifying PROs may enable their efficient implementation in practice. For people with glioma, the process ensures their perspective is captured and reflected in research practice

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