

N-O-D-23-00023. Development of a core outcome set for use in adult primary glioma phase III interventional trials – A mixed methods study

Appendix 1

Core Outcome Set-Standards for Reporting: The COS-STAR Statement Checklist

SECTION/TOPIC	ITEM No.	CHECKLIST ITEM	REPORTED ON PAGE NUMBER
TITLE/ABSTRACT			
Title	1a	Identify in the title that the paper reports the development of a COS	1
Abstract	1b	Provide a structured summary	2-3
INTRODUCTION			
Background and Objectives	2a	Describe the background and explain the rationale for developing the COS.	3-4
	2b	Describe the specific objectives with reference to developing a COS.	4
Scope	3a	Describe the health condition(s) and population(s) covered by the COS.	4
	3b	Describe the intervention(s) covered by the COS.	4
	3c	Describe the setting(s) in which the COS is to be applied.	4
METHODS			
Protocol/Registry Entry	4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	4
Participants	5	Describe the rationale for stakeholder groups involved in the COS development process, eligibility criteria for participants from each group, and a description of how the individuals involved were identified.	5-7
Information Sources	6a	Describe the information sources used to identify an initial list of outcomes.	4-6
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable).	6-8
Consensus Process	7	Describe how the consensus process was undertaken.	6-8
Outcome Scoring	8	Describe how outcomes were scored and how scores were summarised.	7
Consensus Definition	9a	Describe the consensus definition.	7
	9b	Describe the procedure for determining how outcomes were included or excluded from consideration during the consensus process.	7-9
Ethics and Consent	10	Provide a statement regarding the ethics and consent issues for the study.	4, 5-6
RESULTS			

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Protocol Deviations	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	10
Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	Table
Outcomes	13a	List all outcomes considered at the start of the consensus process.	
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons, during the consensus process.	
COS	14	List the outcomes in the final COS.	Table
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process.	11
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	10-11
OTHER INFORMATION			
Funding	17	Describe sources of funding/role of funders.	1-2
Conflicts of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	2

From: Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. (2016) Core Outcome Set–STAndards for Reporting: The COS-STAR Statement. *PLoS Med* 13(10): e1002148.
<https://doi.org/10.1371/journal.pmed.1002148>

Appendices

Appendix 2

Guidance for Reporting Involvement of Patients and the Public: GRIPP2 checklist

Section and topic	Item	Reported on page No
1: Aim	Report the aim of PPI in the study	4
2: Methods	Provide a clear description of the methods used for PPI in the study	4
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	9
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	9
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	9

From: Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research BMJ 2017; 358 :j3453 doi:10.1136/bmj.j3453

Appendix 3

Systematic review of qualitative literature search strategy

- 1 exp Glioma/
- 2 exp Brain Neoplasm/
- 3 (("Central-Nervous-System-Neoplasms" or malignant) adj glioma*).ti,ab.
- 4 exp Glioblastoma/
- 5 exp Neuroectodermal Tumors, Primitive, Peripheral/
- 6 neuroectodermal tumo?r*.ti,ab.
- 7 exp Ependymoma/
- 8 ependymoma*.ti,ab.
- 9 (brain adj (tumor* or tumour* or neoplas* or malignan* or cancer*)).ti,ab.
- 10 (glioma* or astrocytoma* or meningioma* or oligodendrogloma* or oligoastrocytoma* or glioblastoma* or GBM* or Glioblastoma multiforme).ti,ab.
- 11 High grade glioma*.ti,ab.

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- 12 Low grade glioma*.ti,ab.
- 13 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
- 14 (("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide) adj3 (interview* or discussion* or questionnaire*)) or (focus group* or qualitative or ethnograph* or fieldwork or "field work" or "key informant").ti,ab. or interviews as topic/ or focus groups/ or narration/ or Qualitative research/
- 15 Interview*.ti,ab.
- 16 (patient reported* or patient-reported* or patient reported outcome* or patient-reported outcome*).ti,ab.
- 17 (mixed methods or mixed-methods).ti,ab.
- 18 14 or 15 or 16 or 17
- 19 13 and 18
- 20 limit 19 to english language

Appendix 4

Semi-structured topic guide

Main questions (questions to be aimed at both patient and caregiver – be sure to check both have had the opportunity to answer to gain perspectives from both sides of the dyad).

1. Can you tell me more about your diagnosis of LGG/HGG?
 - What happened and how did they manage to get a diagnosis
2. Can you tell me what you understand about your LGG/HGG?
 - What is happening in your body right now, can you explain what LGG/HGG means for you, how is LGG/HGG affecting you
3. What symptoms have you experienced?
 - Probe for any differences in symptoms pre and post diagnosis and treatment.
4. What treatment have you received? Do you have any treatment planned?
 - 'Treatment' may include surgery, radiotherapy, chemotherapy
5. What impact do you think the treatment has had on you/your family/friends?
6. What impact do your symptoms have on your day to day life?
 - Probe for impact on relationship with others, including caregiver, social activities, work and any other day to day activities
7. Is there anything you do which helps you manage your symptoms?

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- This is other than formal treatments and consider formal rehabilitation sessions or more informal activities which may help

8. What care have you received from your doctor or nurse, or any other health care professionals to help you manage your symptoms?

9. In your opinion, what do you think are the most important symptoms to address? What is it that makes them the most important? How will addressing these symptoms improve your day to day life?

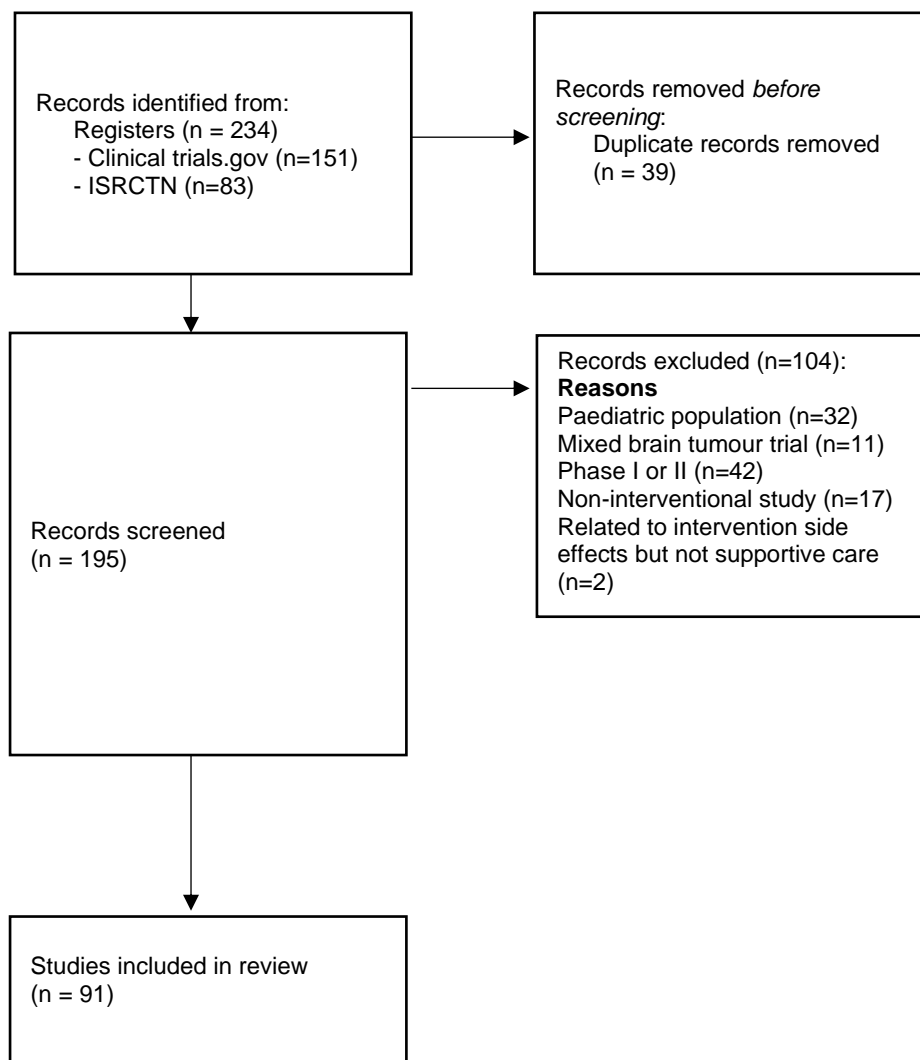
10. Thinking of all that we have discussed today, in regard to the treatment you have received, (either current, past or future treatment – dependent on what the patient has experienced) what are the most important aspects following treatment that you were/are hoping will/were addressed, or are there any aspects that you were expecting to be addressed following treatment but were not? (If any, what aspects following treatment improved or did not improve?)

11. Overall, what are your overall experiences of living with LGG/HGG?

- Probe for both positive and negative

12. Is there anything else you would like to say which has not been mentioned during this interview which we need to know?

Appendix 5 - PRISMA FLOW DIAGRAM – Registry Review



Appendices

Appendix 6 - PRISMA FLOW DIAGRAM – Systematic review of qualitative literature

