Author’s response to reviews

Title: Research involving adults lacking capacity to consent: a content analysis of participant information sheets for consultees and legal representatives in England and Wales

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Author’s response to reviews:

We would like to thank the reviewers for once again giving their time to review our manuscript. We have revised the manuscript to address their very helpful comments in full, and believe that this strengthens the manuscript ready for publication.

Reviewer reports:

Reviewer #1: Dear Authors,

Thank you very much for taking the time to carefully revise your manuscript in response to my recommendations. I think the Discussion section is now much improved and overall the clarity of writing has increased considerably. I have some comments to make about certain revisions. The page and line references below refer to the revised document which shows tracked changes.

p6 lines 81-85: I am still concerned about the categories you have used to classify studies you identified from the UKCTG. I understand that the condition-specific search terms are those used by the UKCTG. However, if I understand correctly, the study team created the classification system relating to "capacity status". I think this needs to be made more explicit in your manuscript. I am also confused by the terminology you use - you appear to be using "capacity" to refer both to decision-making capacity and the ability to "hold relevant views"; I think these are two different things. Therefore, I think this needs clarification / justification. I would also still
argue that it is discriminatory and inconsistent with the Mental Capacity Act (2005) to associate specific health conditions with mental capacity status. I think you could remedy these limitations by explicitly stating that you have created this classification system and by providing a clear rationale for this which includes some acknowledgement of the limitations of your system. I think it would be helpful for the reader for you to acknowledge that not everybody with a diagnosis of stroke or TBI or in receipt of critical care will experience "sudden loss of capacity", that not everybody with Down's syndrome or PMLD will have had "no capacity to hold relevant views", etc..

Thank you for your helpful comments on this issue. The section has been amended (p5 line 71 - p6 line 43) to read:

‘Whilst capacity is considered decision-specific rather than global and is not a static construct [5], the circumstances under which a proxy decision-maker is required, and their prior experience of acting as decision-maker, are relevant factors in this context. The UKCTG is primarily intended for patients to find relevant clinical trials to participate in and so the database primarily uses condition-specific search terms, in addition to filters such as trial status. Therefore studies which included adults who lacked capacity were identified by searching the database for appropriate medical conditions or populations which are more likely to be associated with cognitive impairment. Studies which involved emergency research, and therefore a consent waiver, were excluded.

A search strategy was designed to include trials conducted in different decisional contexts through classifying the circumstances under which proxy involvement is required as either: as part of a progressive process, following a sudden or acute event, or to reflect long-term circumstances. This necessitated a pragmatic search strategy which identified condition-specific search terms (as required by UKCTG) that would capture trials across these three areas. It is recognised that a lack of capacity cannot be established by reference to a condition [5], and only some individuals living with these conditions will experience any cognitive impairment, or impaired capacity specific to the particular enrolment decision. Searches were conducted in June and July 2017 by one researcher (VS) using search terms agreed by three researchers (VS, FW, KH). Search terms to identify eligible studies were divided between three groups of decisional contexts:
• progressive process – search terms ‘dementia’ (all types), ‘Huntingdon’s Disease’

• sudden or acute event — search terms ‘stroke’, ‘traumatic brain injury’, ‘critical care’

• long-term circumstances — search terms ‘Down’s syndrome’, ‘intellectual disability’, ‘learning disability’

The headings and terms used in Table 1 (page 9 and 10) have been amended accordingly.

p10 line 164: "7-67%" - apologies, but I am still not clear how the percentages were derived!

This has been clarified and amended to:

‘the area of interest that related to the proxy’s role (area of interest/total length of document) comprised 7-68% of the total length of the document.’ (p10 line 173) and the numerators and denominators added to Table 2 (p11).

p18 line 341: instead of "were", do you mean "where"?

Thank you for highlighting this, it has been amended (p19 line 344)

p20 lines 368-370: I think this sentence needs revising to make its meaning clearer. At present, I do not really understand the links you are making between being a care home resident, having a dementia diagnosis, having cognitive impairment and lacking capacity to consent to research.

This has been amended to:

‘People living with dementia, which affects around 69% of care home residents [31], may particularly experience greater fluctuation and variation in decision-making capacity [33] compared to the populations included in other studies, although all adults lacking capacity should
be supported and involved in decisions that concern them as far as is possible [23, 34].' (p20 lines 366-370)

p20 line 375: "according to his or her capacity" - I am not sure what you mean by this phrase; it would be helpful if you could revise the sentence to make its meaning clearer.

This has been amended, including using the phrase verbatim from the Medicines for Human Use (Clinical Trials) Regulations to:

‘Under the CTR, the person lacking capacity must have ‘received information according to his capacity of understanding regarding the trial, its risks and its benefits’ [6]. Although arguably this might form part of the researcher’s obligation, in general the study documents do not identify the need to inform the person lacking capacity about the trial or to include them in the decision.’ (p20 lines 371-375)

p21 lines 401-406: I still find this sentence difficult to read and understand. Perhaps it would be clearer if you wrote "both in terms of differences in scope....and because the negative orientation...."?

Thank you. This has been amended accordingly (p21 lines 397-398)

p22 line 425: I think it would be helpful if you changed "were not" back to "not being".

This has been amended (p22 line 416)

P24 line 488: I think it would be helpful to the reader if you could include brief information to explain what the "layered or tiered approach" involves.

Details about a layered approach has been added (p24 lines 473-477)
P25 line 512: I think it would be easier for the reader if you changed "and therefore comply with..." to "and thereby ensure compliance with...".

Thank you. This has been amended (p25 line 498)

p30 Additional file 1: Please explain the acronym "CNS".

An explanation of the term has been added to the key (p37)

If these concerns can be addressed, I would be happy to recommend that the manuscript be published. I look forward to reading your revised manuscript!

Best wishes

Thank you for your helpful comments.

Reviewer #2: I am happy that the suggestions made in the previous review round have been adequately addressed.

Thank you for your encouraging comment.