PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Using rapid cycle tests of change to develop the Carers Assistive
	Technology Experience Questionnaire: a cognitive interview study
	in the UK.
AUTHORS	Sriram, Vimal; Jenkinson, Crispin; Peters, Michele

VERSION 1 – REVIEW

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REVIEWER	Laetitia Ricci
	CIC 1433 Epidémiologie Clinique
	Inserm, CHRU, Université de Lorraine
REVIEW RETURNED	30-Oct-2020
GENERAL COMMENTS	Thank you for giving me the opportunity to review your manuscript.
	 Thank you for letting me review the work. The aim of the paper is interesting: developing a new methodological perspective to optimize cognitive interview using PDSA cycles in questionnaire development particularly in the step of pretesting items. I have 2 major remarks 1) At the beginning of the paper there is a confusion: the reader does not know if the authors want to highlight a new methodological perspective for cognitive interviews, or if the CATEQ development is the objective of the paper. It would be relevant to requalify the work from a methodological perspective. As a result, the abstract and the strengthens are particularly confused and not understandable. The abstract is not clear. For example, there is no concordance between the title and the aim of the paper. 2) The method is questionable since on the basis of the opinion of one participant, the item is rewritten. Why not?, but we have no visibility on a potential interest of the process proposed because there is no comparison of your alternate method of cognitive interviews with another one (for example, a classical method)
	 Detailed feedback point: The notion of rapid cycle appears unexpectedly at the end of the results explanation. However, it constitutes the heart the
	 conclusion. Strengthens and Limitations. Point 1 and 2 share the same idea. Moreover, the sample with 9 participants is not really a strong point. Point 3 does not describe a strengthen. Think aloud is a well-known method. Point 4 Representativeness is not an endpoint when adopting a purpose sampling. So in this section, there is no strengthen or limitation clearly describe.

REVIEWER	Clayon Hamilton
	Fraser Health Authority, BC, Canada
REVIEW RETURNED	04-Nov-2020
REVIEW RETURNED	04-INOV-2020
GENERAL COMMENTS	INTRODUCTION The authors should provide stronger rationale for the study. The authors should consider introducing readers to the key concept related to carer's assistive technology, their experiences, and dementia. The background information on PDSA and cognitive interviews would be better suited for the methods section.
	METHODS The authors need to make a more compelling argument as to why it was appropriate to use PDSA cycles with cognitive interviews. Was the tool administered as it would in the under a regular implementation or was it more of a research study scenario? Did the respondents complete the entire CATEQ or just the component that was being tested in each specific cycle? It is not clear if the SF-12 is apart of the CATEQ or just use along with the CATEQ. What version of the SF-12 was used? More information could be given on the SF-12.
	No information was provided on sample size estimation and the appropriateness of the sample size.
	DISCUSSIONS Was there a true different between conducting several rounds of cognitive testing and PDSA cycles.
	Authors should clarify if they believe the sample was diverse enough. If the participants tested only portions of the instrument, how many participants tested the full instrument? What is the implication of only a few participants testing the full instrument?
	Do the authors believe that younger (< 40 year) or older participants(>75 year) would have responded differently to CATEQ?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

Comment:

At the beginning of the paper there is a confusion: the reader does not know if the authors want to highlight a new methodological perspective for cognitive interviews, or if the CATEQ development is the objective of the paper. It would be relevant to requalify the work from a methodological perspective.

As a result, the abstract and the strengthens are particularly confused and not understandable. The abstract is not clear. For example, there is no concordance between the title and the aim of the paper. Response:

We thank the reviewer for their comment and have modified the abstract and the title of this manuscript to better describe the process. We want to demonstrate that cognitive interviews can be conducted through rapid cycle tests of change that leads to a quicker process of questionnaire development with subsequent decrease in respondent burden. Changes:

Modified the abstract. The title of the manuscript now reads as "Cognitive interviewing through rapid cycle tests of change for measure development, as applied to the new Carers' Assistive Technology Experience Questionnaire (CATEQ)".

Comment:

The method is questionable since on the basis of the opinion of one participant, the item is rewritten. Why not?, but we have no visibility on a potential interest of the process proposed because there is no comparison of your alternate method of cognitive interviews with another one (for example, a classical method)

Response:

We thank the reviewer for this comment. However, as we have explained in the introduction, we present using rapid cycle tests for change as an alternative to the established way of conducting cognitive interviews – i.e. doing cognitive interviews in rounds with multiple participants. The intention is to simplify this process and not compromise on the process of interviewing itself – using think aloud and verbal probing. We have also clarified to avoid confusion that the iterative changes were tested with subsequent participants in each round and only when there was no modification required were those sections of the questionnaire finalised.

Changes:

Added lines 148 – 152 ". The authors also ensured each subsequent participant, in addition to "thinking-aloud" on a focused section of the questionnaire, also commented on the latest iteration of the full questionnaire to determine if the modified version then functioned as intended, without introducing further difficulties in comprehension or changes needed to the questionnaire".

Comment:

The notion of rapid cycle appears unexpectedly at the end of the results explanation. However, it constitutes the heart the conclusion.

Response:

We thank the reviewer for this comment, however, we are not in agreement with the reviewer, as we have made clear in the introduction lines 48-50 that we "present here one way of developing a questionnaire, based on using rapid cycle tests for change framed within PDSA cycles for conducting cognitive interviews in pre-testing questionnaire items to develop the CATEQ".

In addition, we describe the characteristics of PDSA cycles in the introduction, the use of PDSA templates in data collection and iterative revision of the questionnaire in the methods and results section.

Comment:

Strengthens and Limitations. Point 1 and 2 share the same idea. Moreover, the sample with 9 participants is not really a strong point. Point 3 does not describe a strengthen. Think aloud is a well-known method. Point 4 Representativeness is not an end-point when adopting a purpose sampling. So in this section, there is no strengthen or limitation clearly describe. Response:

We thank the reviewer for their comments. We agree that points 1 and 2 share the same strength of purposive sampling and have combined them together.

We do not however agree with their comment on - 9 participants not being a suitable sample size – as other researchers such as Coons, Klingshirn state that around 7-15 participants are sufficient and Willis also adds that "as few as 5 or 6 subjects may provide useful information to improve survey items".

Our point 4 was meant to highlight the weakness that our sample was drawn from voluntary participants already registered in a research database as opposed to general carers in the community. For example, as reviewer 2 points out and we have clarified - we did not have participants who were aged less than 40 years in this study, this could simply be because, this particular population group is not well represented within the research database.

Changes:

In the strengths and limitations section, we have combined participant characteristics in points 1 and 2 into one point. Which now reads as "This study recruited participants from across the UK, adopting a purposeful sampling strategy to identify suitable participants with diverse age groups, gender, ethnicity and living arrangements, who could support interpreting and answering items within the questionnaire" and deleted point 2.

Reviewer: 2

Comment:

INTRODUCTION

The authors should provide stronger rationale for the study. The authors should consider introducing readers to the key concept related to carer's assistive technology, their experiences, and dementia. The background information on PDSA and cognitive interviews would be better suited for the methods section.

Response:

We thank the reviewer for their comment and have added to the introduction section. This combined with the modification to the abstract and title, we hope meets the suggestion made by the reviewer. We want to introduce the reader to the concept of pre-testing in survey development and cognitive interviews as a mechanism for doing this and how rapid cycle tests for change through PDSA cycles can help this process. We believe this is best achieved by retaining this in the introduction section, with additional details on cognitive interviewing and the process of using PDSA cycles in the methods section.

Changes:

Abstract and title changed.

Lines 12 – 18 added "Dementia describes a set of symptoms that may include memory loss and difficulties with thinking, problem solving or language [1]. Caring for a person with dementia can be demanding for carers (family, friends and neighbours) and can affect their mental and physical health and their social lives [2]. Assistive Technology (AT) may support carers in caring for persons with dementia in the community; however, very little is known about their experience and use of AT [3,4]. To better understand the use and impact of AT on carers, we developed a survey instrument – Carers' Assistive Technology Experience Questionnaire (CATEQ)".

Comment:

METHODS

- The authors need to make a more compelling argument as to why it was appropriate to use PDSA cycles with cognitive interviews.

- Was the tool administered as it would in the under a regular implementation or was it more of a research study scenario? Did the respondents complete the entire CATEQ or just the component that was being tested in each specific cycle?

- It is not clear if the SF-12 is apart of the CATEQ or just use along with the CATEQ. What version of the SF-12 was used? More information could be given on the SF-12.

- No information was provided on sample size estimation and the appropriateness of the sample size. Response:

- We thank the reviewer for this comment. We have mentioned the usual process of cognitive interviews -i.e. being done in rounds and why this may be burdensome in lines 37-41 "Cognitive interviews are usually undertaken in rounds, with several participants interviewed in each round, their responses analysed and changes to the questionnaire only made after each round" and how the use of rapid cycle tests for change through PDSA cycles – lines 50-52 "This is an alternative way of developing and pre-testing a questionnaire and highlights how rapid cycle tests for change such as PDSA cycles can be used in questionnaire development".

- We thank the reviewer for seeking clarification on how the questionnaire was administered. We have described this in lines 128-131 and in lines 92-94. We have also further added lines 148-152 to clarify that even if the participants focused on particular aspects of the questionnaire, they did comment on the latest iteration of the full questionnaire.

- We thank the reviewer for pointing out this omission on the SF-12. We have added in line 251 "SF-12 version" and lines 257 -260 to clarify this.

- We are not in agreement with the reviewer comment on sample size estimation, as this is a qualitative methodology, we did not estimate sample size. We wish to clarify that for cognitive interviews sample size often consist of 8-12 individuals (Willis, Garcia, Murphy). Although these numbers are small by normal standards of empirical research, the major objectives concern the attainment of insights and generation of hypotheses, as opposed to statistical power. Large samples are often unnecessary because it often becomes quickly evident if an evaluated question is flawed. We have highlighted this in lines 116 -119.

Changes:

Corrected line 92-94 which now reads as "For ease of administering cognitive interviews the initial set of interviews did not include demographic (for participants 1-4) and health-related quality of life (participants 1-6) questions".

Added lines 148-152 "The authors also ensured each subsequent participant, in addition to "thinkingaloud" on a focused section of the questionnaire, also commented on the latest iteration of the full questionnaire to determine if the modified version then functioned as intended, without introducing further difficulties in comprehension or changes needed to the questionnaire"

Added lines 257-260 "The SF-12 contains items covering physical functioning, social functioning, role functioning (physical and mental), vitality, bodily pain, mental health and general health. The SF-12 generates two summary scores: The Physical Component Score and the Mental Component Scores. A higher score indicates better quality of life".

Comment:

DISCUSSIONS

Was there a true different between conducting several rounds of cognitive testing and PDSA cycles.

Response:

We thank the reviewer for this question. We believe using rapid cycle tests for change helped us arrive at the final version of the questionnaire more rapidly and with less respondent burden. We have clarified that the learning, prediction of potential problems with the questionnaire and the unanticipated learning did make a difference in conducting the cognitive interviews through the lens of PDSA cycles.

Comment:

Authors should clarify if they believe the sample was diverse enough.

Response:

We thank the reviewer for this comment. We have clarified this in the recruitment subsection of Methods in lines 113 – 115 and give an overview of the participant characteristics in Table 1.

Comment:

If the participants tested only portions of the instrument, how many participants tested the full instrument? What is the implication of only a few participants testing the full instrument? Response:

We thank the reviewer for seeking this clarification. We have clarified this by adding to lines 92-94 and in lines 149-153.

Changes:

Lines 92-94 now reads as "For ease of administering cognitive interviews the initial set of interviews did not include demographic (for participants 1-4) and health-related quality of life (participants 1-6) questions.

Comment:

Do the authors believe that younger (< 40 year) or older participants (>75 year) would have responded differently to CATEQ?

Response:

We are not entirely sure how to interpret this question. We deliberately chose a wide age range, but the purpose of that was to test the comprehension of questionnaire items and not their responses to the questions themselves.

We did not have any <40-year-old participants. This reflects the demographic of carers of persons with dementia who wish to participate in research and are registered on the research database. We do acknowledge that this might not be representative of the "true" population of carers and list this as a weakness in our strengths and limitations section.