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# BMJ Open

## A quality improvement approach to cognitive interviewing in questionnaire development

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3 **A quality improvement approach to cognitive interviewing in questionnaire**  
4 **development**  
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3 **1 Abstract:**

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5 **2 Aim:**

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8 **3** Our aim was to pre-test and develop a carers' assistive technology experience questionnaire for a  
9  
10 **4** survey of informal carers of persons with dementia using Plan-Do-Study-Act cycles.

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12  
13 **5 Methods:**

14  
15 **6** The Plan-Do-Study-Act (PDSA) cycle is a commonly used improvement process in health care  
16  
17 **7** settings. We used this method for conducting rapid cycle tests of change through cognitive  
18  
19 **8** interviews to pre-test the questionnaire. The items for the questionnaire were developed based on  
20  
21 **9** an earlier systematic review and qualitative study. PDSA cycles were used incrementally with  
22  
23 **10** learning from each cycle used to inform subsequent changes to the questionnaire prior to testing on  
24  
25 **11** the next participant.

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27  
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29  
30 **12 Results:**

31  
32 **13** Nine participants were recruited based on eligibility criteria and purposive sampling. Cognitive  
33  
34 **14** interviewing using think aloud and concurrent verbal probing was used to test the comprehension,  
35  
36 **15** recall, decision and response choice of participants to the questionnaire. Seven PDSA cycles  
37  
38 **16** involving the participants helped to identify problems with the questionnaire items, instructions,  
39  
40 **17** layout and grouping of items. Participants used a laptop, smart phone and/or tablet computer for  
41  
42 **18** testing the electronic version of the questionnaire and one participant also tested the paper version.  
43  
44 **19** A cumulative process of presenting items in the questionnaire, anticipating problems with specific  
45  
46 **20** items and learning from the unanticipated responses from participants through rapid cycle tests of  
47  
48 **21** change allowed rich learning and reflection to progressively improve the questionnaire.

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52  
53 **22 Conclusion:**

54  
55 **23** Using rapid cycle tests of change in the pre-testing questionnaire phase of research provided a  
56  
57 **24** structure for conducting cognitive interviews. Learning and reflections from the rapid testing and  
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3 25 revisions made to the questionnaire helped improve the process of reaching the final version of the  
4  
5 26 questionnaire, that the authors were confident would measure what was intended, rapidly and with  
6  
7 27 less respondent burden.  
8  
9

10 28 **Key words:**  
11

12 29 Cognitive interview; Plan-Do-Study Act cycles; Questionnaire development  
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For peer review only

### 1 **Strengths and limitations of this study:**

- 2 • This study recruited participants from across the UK, adopting a purposeful sampling  
3 strategy to identify suitable participants with diverse age groups and living arrangements,  
4 who could support interpreting and answering items within the questionnaire.
- 5 • The recruitment and purposeful sampling strategy aimed at providing balance of participants  
6 from different ethnic and gender backgrounds.
- 7 • Use of concurrent think aloud and verbal probing methods during the cognitive interviews  
8 allowed for richer interpretation and in-depth understanding of changes needed to the  
9 questionnaire.
- 10 • The participants were recruited through voluntary participation in research databases and  
11 potentially may not be representative.

### 12 **Introduction:**

13 In survey research, the data collection tool is typically a structured questionnaire and the  
14 measurements obtained are the respondent's answers to survey questions [1]. This type of data  
15 collection assumes that all participants understand the questions in a consistent way; the questions  
16 are asking for information that participants have and can retrieve and the questions are worded in a  
17 way that the participants are able to answer them as intended by the researcher. In order to  
18 provide a valid and reliable instrument, the wording, structure, and layout of the questionnaire must  
19 make allowance for the nature and characteristics of the participating population [2].

### 20 Cognitive interviews:

21 Cognitive interviews are commonly used for pre-testing survey questions [1,3]. They can provide  
22 information on how the questions are understood and answered by typical participants. Cognitive  
23 interviews can help detect problems participants may have in understanding survey instructions and  
24 items, and in formulating answers [4]. Cognitive interviews can identify problems in item  
25 interpretation, memory retrieval, decision processes, and response selection [5]. A draft

26 questionnaire with candidate items is developed and cognitive interviewing with participants  
 27 representing the target population is used to revise the questionnaire. Cognitive interviews also  
 28 afford the opportunity to detect other problems in questionnaire instructions, design, and  
 29 organisation [6]. They consist of one-to-one interviews in which the respondents describe their  
 30 thoughts while answering the survey questions and can be done through different methods such as  
 31 think aloud, verbal probing, confidence rating, card sorting and paraphrasing [2]. Cognitive  
 32 interviews are usually undertaken in rounds, with several participants interviewed in each round,  
 33 their responses analysed and changes to the questionnaire only made after each round, [7,8] this  
 34 process in itself could be burdensome for respondents and researchers and involve higher costs  
 35 during questionnaire development.

#### 36 Plan-Do-Study-Act cycles:

37 The iterative process of learning and revising through cognitive interviews can be viewed as  
 38 following the steps of action-oriented learning such as Plan-Do-Study-Act (PDSA) cycles [9,10]. PDSA  
 39 cycles consist of [9,11]

36 Plan	state the objective of the test, the planned change, make predictions of what will happen and why and develop a plan to test the change
40 Do	carry out the test/intervention, document problems and unexpected observations, begin analysis of the data
44 Study	complete the analysis of the data, compare the data to earlier predictions in the plan phase and summarise and reflect on what was learnt
48 Act	determine what modifications should be made, i.e., deciding that the intervention has achieved the required standard and can therefore be implemented more widely or deciding that an entirely new change is required and the current plan should be changed and prepare a plan for the next test

40 While PDSA cycles are commonly used in clinical care, few clinical research trials have documented  
 41 its use for implementation [12] and none have used PDSA cycles as a framework for cognitive  
 42 interviews for pre-testing questionnaires. The authors present here one way of developing a



1  
2  
3 43 questionnaire, based on using rapid cycle tests for change framed within PDSA cycles for conducting  
4  
5 44 cognitive interviews in pre-testing questionnaire items to develop the Carers' Assistive Technology  
6  
7 45 Experience Questionnaire (CATEQ). This is an alternative way of developing and pre-testing a  
8  
9 46 questionnaire and highlights how rapid cycle tests for change such as PDSA cycles can be used in  
10  
11  
12 47 questionnaire development.

#### 15 48 **Ethics:**

16  
17 49 This study was approved by the University of Oxford Central University Research Ethics Committee  
18  
19 50 (Reference number: R57703/RE001). All volunteers were provided with a participant information  
20  
21 51 sheet (supplementary file 1). All recruited participants provided informed written consent prior to  
22  
23 52 the cognitive interviews. All participants are identified by a participant number within this paper.

#### 26 53 **Methods:**

##### 28 54 **Patient and public involvement:**

29  
30  
31 55 This study is part of a larger research project which has a patient and public advisory group that  
32  
33 56 meets twice a year. The group consists of two carers of persons with dementia and a person with  
34  
35 57 dementia (all living in England). This group gave feedback on the initial items and instructions  
36  
37 58 framed as part of the CATEQ and reviewed the final version of CATEQ submitted for ethical approval.  
38  
39 59 This group has also committed to support dissemination of study results to other patient  
40  
41 60 involvement groups and their wider networks.

##### 45 61 Study Design:

46  
47  
48 62 The authors describe the steps followed in designing the questionnaire and conducting the cognitive  
49  
50 63 interviews using PDSA cycles to arrive at the final version of the CATEQ.

##### 53 64 1. Develop items for the questionnaire:

54  
55 65 The items of CATEQ were developed on the basis of results from a systematic review [13,14] and a  
56  
57 66 qualitative study [15] and are intended to be administered as an electronic survey. The CATEQ  
58  
59 67 explores themes that carers (family, friends and neighbours) described as relevant for use of

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2  
3 68 Assistive Technology (AT) for dementia care in the community. An iterative process of drafting,  
4  
5 69 evaluation, revision and content checking was followed. Attention was taken to draft the items in  
6  
7 70 the questionnaire to: capture the intended concept of experience using AT and their impact on  
8  
9 71 carers; relevance to all members of the target population irrespective of age, living arrangements  
10  
11 72 and relationship with the person with dementia; the response choices were ordered in a meaningful  
12  
13 73 way; ensure the questions were worded in a manner consistent with best practice style guide by  
14  
15 74 Alzheimer's society [16]; each item represented a single concept, rather than a multidimensional  
16  
17 75 concept; the content of the items was appropriate for the recall period of the previous 4 weeks; and  
18  
19 76 the items could be answered in a self-administered questionnaire. The questionnaire items were  
20  
21 77 mainly closed questions with multiple choice answers with some questions being partially closed  
22  
23 78 with "other" as open-ended text options. The questions were a mixture of behavioural (*What input*  
24  
25 79 *is required from you for using the assistive technology?; How often are you able to solve problems*  
26  
27 80 *with the assistive technology by yourself?*), opinion (*How helpful is the assistive technology in*  
28  
29 81 *reducing your stress?; How helpful is the assistive technology in giving you more time for yourself?*)  
30  
31 82 and factual questions (*age; gender; who was involved in the choice of AT?*). The CATEQ included  
32  
33 83 questions to capture demographic information of participants, health-related quality of life and  
34  
35 84 expression of interest in participating in qualitative interviews later. None of the questions except  
36  
37 85 for the consent question at the beginning of the survey had a forced-choice response (i.e.  
38  
39 86 respondents could omit answers to questions). The draft questionnaire had a Likert like rating scale  
40  
41 87 as response choices. For ease of administering cognitive interviews the initial set of interviews did  
42  
43 88 not include demographic and health-related quality of life questions. This questionnaire was labelled  
44  
45 89 draft 0 and minor corrections were made based on comments by the patient and public advisory  
46  
47 90 group for the project and by three clinical and social care experts involved in prescribing AT for use  
48  
49 91 by persons with dementia at home. This modified CATEQ was labelled draft 1 and was used in the  
50  
51 92 first cognitive interview.  
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59 2. Design cognitive interview process:  
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3 94 Cognitive interviews were used to assess participants' comprehension of the items in CATEQ as well  
4  
5 95 as establish that no important items were missing. A semi-structured interview guide with think  
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7 96 aloud questions, and verbal probing questions, was developed to elicit further information from the  
8  
9 97 participants [box1]. All the cognitive interviews were conducted by VS who is an Occupational  
10  
11 98 Therapist and is trained in qualitative interviewing and quality improvement methods. Regular time  
12  
13 99 was made for all the authors to meet to discuss progress with the cognitive interviews and  
14  
15 100 modifications to the drafts of CATEQ.

16  
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18  
19 101 Recruitment: Participants for the cognitive interviews were recruited through the Join Dementia  
20  
21 102 Research website [17]. Participants were carers of persons with dementia based in the United  
22  
23 103 Kingdom willing to be contacted by researchers through this website. The inclusion criteria were:  
24  
25 104 adult carers - family, friends or neighbours - providing at least 10 hours of care (e.g. shopping,  
26  
27 105 leisure, personal care, finance) per week to a person with dementia who lives in their own home,  
28  
29 106 with the carer living together with or away from the person with dementia; carers should have used  
30  
31 107 at least one AT device at home in the previous year and be able to communicate in English.  
32  
33  
34 108 Participants were emailed a copy of the participant information sheet [supplementary file 1] and a  
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36 109 purposive sample of participants reflecting variations in gender, age, ethnicity, living arrangements  
37  
38 110 and relationship with persons with dementia were selected. The recruitment commenced in October  
39  
40 111 2019 and the final interview was completed in February 2020. A target sample size of 7-10  
41  
42 112 participants was deemed enough to complete cognitive interviews for items in the CATEQ. This was  
43  
44 113 based on previous estimates [18,19] but the intention was to continue with cognitive interviews  
45  
46 114 until no further amendments to the CATEQ were necessary [20].

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49  
50 115 3. Conduct cognitive interviews:

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52 116 Data collection: Semi-structured interviews were conducted face to face (at the participant's own  
53  
54 117 home/at the researcher's office) taking into consideration the participant's geographical location  
55  
56 118 and preference. The 'think aloud' and verbal probing methods were used for data collection and  
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58 119 involve an interviewer asking the participant how they went about answering a particular survey  
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3 120 question [6]. In the think aloud method, the participant is asked to speak all thoughts aloud as  
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5 121 he/she answers the question. For verbal probing, the interviewer asks specific questions or probes  
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7 122 which are designed to elicit how the participant went about answering the question, for example,  
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9 123 how the participant made their choice among the response options or how they interpreted an  
10  
11 124 instruction [1,2]. Participants were shown the electronic version of CATEQ developed using Qualtrics  
12  
13 125 software [21] during the interview on a laptop. Participant 8 also tested the questionnaire on a  
14  
15 126 smart mobile phone. The final participant in addition to the electronic version, was also requested to  
16  
17 127 comment on the paper version of CATEQ [18]. The participants were not known to the interviewer  
18  
19 128 or the other authors prior to recruitment. Trust and easing into the think aloud interview was built  
20  
21 129 by establishing rapport with the participants. The interviewer (VS) explained that the purpose was to  
22  
23 130 make the questionnaire better by identifying items that were difficult to answer. Interviews were  
24  
25 131 undertaken using concurrent think aloud and verbal probing questions and lasted between 55-95  
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27 132 minutes; all interviews were audio-recorded along with field notes and a PDSA template  
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29 133 [supplementary file 2]. The field notes noted verbal and nonverbal cues from the participants, as  
30  
31 134 well as their perception of the items in CATEQ. Confidentiality of the participants was maintained  
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33 135 throughout the process by avoiding references to names of the participant or persons with  
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35 136 dementia, cities and other person identifiable information.

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39 137 4. Make decisions to revise questionnaire:  
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43 138 Data Analysis: The PDSA template [supplementary file 2] was used to document the hypothesis  
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45 139 being tested, results of the cognitive interview process and to make changes to the CATEQ. After  
46  
47 140 discussion among all the authors, the questionnaire items were changed in line with suggestions  
48  
49 141 from the participant and accounting for difficulty encountered by the participant with specific items  
50  
51 142 during the cognitive interview. Changes were made after every cognitive interview instead of waiting  
52  
53 143 for rounds of interviews to finish, thereby narrowing the time between data collection, analysis and  
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55 144 changes made. Subsequent CATEQ questionnaire drafts were numbered draft 2, draft 3 etc. which  
56  
57 145 were used contiguously for the progressive set of cognitive interviews.  
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3 146 5. Final Test:  
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5 147 At the end of questionnaire revision, the final version of CATEQ was tested on three volunteers and  
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7 148 the patient and public advisory group to check for time taken to complete the questionnaire, issues  
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9  
10 149 with formatting, skip logic and ease of understanding of the instructions before it was deemed ready  
11  
12 150 to be used in a quantitative survey.  
13

14 151 **Results:**

15  
16 152 Emails (n=38) for recruitment were sent to potential participants. From the responses received  
17  
18 153 (n=22), 11 carers did not meet the eligibility criteria and 9 carers (5 women and 4 men), with varying  
19  
20 154 types of relationship to a person with dementia, took part in interviews [Table1]. Every participant  
21  
22 155 had used at least one AT device in the last 12 months. Participants were aged between 42 to 75  
23  
24 156 years. The authors used PDSA cycles for the cognitive interviews to make iterative changes to the  
25  
26 157 CATEQ. The changes between draft1 and draft7 of the questionnaire are given in Table 2.  
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29  
30 158 PDSA 1: Testing instructions and questionnaire items:

31  
32 159 CATEQ draft 1 had instructions for participating in the survey, eligibility criteria and a consent  
33  
34 160 statement. In addition, it had 29 items (21 items in matrix format) about carers' current experiences  
35  
36 161 and impact of using AT with a person with dementia at home. During PDSA 1, participant 1 was able  
37  
38 162 to comprehend and understand the instructions and commented on the font and layout of the  
39  
40 163 instructions that could be improved. The eligibility criteria and consent statements were easy to  
41  
42 164 understand and overall participant 1 took less time than anticipated to complete these sections. On  
43  
44 165 verbal probing, participant 1 indicated that most instructions only carried information regarding data  
45  
46 166 protection and use which were standard statements.  
47

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50 167 "...these are what...err...you'll find in a product agreement you know...and who reads these  
51  
52 168 through fully? I always click agree, so I can start using the thing, err...you know...like the  
53  
54 169 cookie thing on websites..."  
55  
56

57 170 Participant 1 answered the items on the questionnaire and commented that the layout was easy to  
58  
59 171 follow, the questions were easy to understand with the option of "other" where extra information  
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3 172 was needed. As part of the think aloud interview for item 1 it was observed that there was some  
4  
5 173 difficulty in sorting through AT devices that participant 1 had used but is no longer currently using  
6  
7 174 and additional instructions and questionnaire items to provide details of these devices might be  
8  
9  
10 175 helpful. At the end of the PDSA cycle, modifications to the layout and instructions were made by  
11  
12 176 adjusting font size and paragraph spacing, instructions for current AT was modified and four  
13  
14 177 additional questions on AT previously used and reason for abandonment were added, as well as  
15  
16 178 adding information on the research website at the end of survey message and the CATEQ draft was  
17  
18  
19 179 labelled draft 2.

20  
21 180 PDSA 2: Testing questionnaire items:

22  
23 181 Cognitive interviews with Participants 2 and 3 were carried out separately using the electronic  
24  
25 182 version of draft 2 of CATEQ. Both participants felt the image at the start of the instructions with  
26  
27 183 common AT devices was helpful. The think aloud interviews for the questionnaire items highlighted  
28  
29 184 confusion regarding the cost of AT. The question was framed as: *“Can you give the approximate cost  
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31  
32 185 (in pounds) associated with the assistive technology currently used, paid for by the person with  
33  
34 186 dementia or by you or another carer (family, friend or neighbour)?”* Participant 2 had difficulty in  
35  
36 187 separating out initial cost in purchasing the AT with that of ongoing costs for maintenance.  
37  
38  
39 188 Participant 3 also had difficulty with the cost of AT question *“Are you concerned about cost of the  
40  
41 189 assistive technology?”* as the AT they were using was provided by the social care services without a  
42  
43 190 cost to them. Both participants were able to differentiate questions on *anxiety* and *stress* presented  
44  
45 191 as separate questions. On verbal probing both participants wanted a *“does not apply”* option to  
46  
47 192 matrix questions such as: *“How helpful is the assistive technology in giving you additional time for  
48  
49 193 tasks that you have to do?”* and *“How helpful is the assistive technology in maintaining dignity of the  
50  
51 194 person with dementia?”*. These cognitive interviews also gave authors the unsolicited confirmation  
52  
53  
54 195 that the CATEQ could be self-administered.

55  
56  
57 196 *“...you’ll get more out of me doing this (answering the questions) on a laptop or on the  
58  
59 197 phone than if I were sat in front of you and answering them...these are personal questions  
60*

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2  
3 198 and (I) might be feeling guilty answering them honestly if you were in the room, you know  
4  
5 199 what I mean..." [Participant 2]  
6

7  
8 200 At the end of this PDSA cycle the questionnaire items were modified to change the wording on items  
9  
10 201 on cost and add a "*does not apply*" option to the Likert type scale choice for the matrix questions  
11  
12 202 and the new draft of the CATEQ was labelled draft 3.

13  
14 203 PDSA 3: Testing questionnaire items and skip logic:

15  
16 204 Cognitive interview with Participant 4 was used to test the questionnaire items including the  
17  
18 205 modified items from draft 2, as well as the layout and format of the electronic version of the  
19  
20 206 questionnaire. The think aloud interview confirmed that the modified questionnaire items on cost  
21  
22 207 was better understood by participant 4. On verbal probing participant 4 appreciated the option of  
23  
24 208 "*does not apply*" as a choice. Participant 4 on verbal probing also commented that the layout of the  
25  
26 209 questionnaire was easy to understand and suggested a change in colour scheme for the button  
27  
28 210 indicating progress to the next page of the questionnaire:

29  
30  
31 211 "...You know this arrow button in the bottom (indicates on screen), it is blue now, but if this  
32  
33 212 were in green, other carers who do your survey would think they are good to go, sort of  
34  
35 213 like...you know...like...like a traffic light system and make good headway with your  
36  
37 214 questionnaire..."

38  
39  
40 215 At the end of this PDSA cycle, the colour scheme for the questionnaire was changed and a new  
41  
42 216 version of the CATEQ was labelled draft 4, this version for the next cognitive interview now  
43  
44 217 contained items for capturing demographic data of participants.

45  
46 218 PDSA 4: Testing questionnaire items and demographic questions:

47  
48 219 Cognitive interview with participant 5 concentrated on questionnaire items with a specific focus on  
49  
50 220 the nine demographic questions in CATEQ. Verbal probing and think aloud interview were used to  
51  
52 221 check comprehension, recall and ease of answering demographic questions in the CATEQ. The  
53  
54 222 participant understood the questions readily enough, participant 5 had some hesitation in answering  
55  
56 223 the question on income and on verbal probing disclosed that the participant and the person with  
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1  
2  
3 224 dementia pooled their income for household expenses and some of the hesitation was in disclosing  
4  
5 225 this in a survey, even if it was anonymous. At the end of this PDSA cycle, it was decided to reframe  
6  
7 226 the question on income to '*family income*' and add an option of "*do not wish to disclose*" as part of  
8  
9  
10 227 the response options of this question. After modifying the questionnaire items, further modifications  
11  
12 228 to the instructions for survey participants were made on the advice of the Ethics committee, this  
13  
14 229 included further detailed instructions on use of data, data protection and contact details of all the  
15  
16 230 study authors. The next version of CATEQ incorporating all these changes was labelled draft 5.

18  
19 231 PDSA 5: Testing modified instructions and questionnaire items:

20  
21 232 Participants 6 and 7 participated in cognitive interviews that tested the modified instructions and  
22  
23 233 questionnaire items. Both participants completed the questionnaire items without difficulty and on  
24  
25 234 verbal probing commented that the instructions were long but easy to understand and in any case  
26  
27  
28 235 were not spending too much time on them. On verbal probing participant 7 also felt the order in  
29  
30 236 which items on stress, anxiety, time for self and effort on caring were presented could be rearranged  
31  
32 237 in the questionnaire and grouped together as they helped the participant think through them better  
33  
34 238 and maintain 'flow of thought'. Participant 6 also recommended testing the questionnaire on  
35  
36  
37 239 participants using a smart phone device, as this might be the way some participants would choose to  
38  
39 240 complete the questionnaire during their commute into work. At the end of this PDSA cycle,  
40  
41 241 questionnaire items were regrouped to facilitate ease of recall; items on health related quality of life  
42  
43 242 based on the validated 12 item Short Form survey (SF-12) [22,23] plus three questions on coping  
44  
45 243 with caring and relationship with person with dementia were added and this version of the  
46  
47  
48 244 questionnaire was labelled draft 6.

49  
50 245 PDSA 6: Testing items on health-related quality of life and completion of questionnaire using a smart  
51  
52 246 phone:

53  
54 247 The next PDSA cycle involved a cognitive interview with participant 8, who tested additional items  
55  
56  
57 248 on the questionnaire from the SF-12. As this is a well validated questionnaire, the cognitive interview  
58  
59 249 was limited to comprehension of the questions and answer choices as well as layout of the  
60



1  
2  
3 250 electronic version of the questionnaire with the health related quality of life question items at the  
4  
5 251 end of the questionnaire. The participant also completed the questionnaire using a smart phone  
6  
7 252 device to check for ease of use and layout of the questionnaire in a smart phone device. The  
8  
9  
10 253 participant completed the questionnaire with ease and had no specific difficulty in comprehension  
11  
12 254 or recall of information required for completion of the questionnaire. The layout of the  
13  
14 255 questionnaire on the smart phone was easy to follow and the questions were presented one after  
15  
16 256 the other and was completed without difficulty. At the end of this cycle, the questionnaire was  
17  
18 257 deemed to be ready for a test to include electronic and paper versions to check ease of completion  
19  
20 258 and minor modifications to instructions such as, to remove references to 'IP address will not be  
21  
22 259 collected' and as skip logic could not be applied for consent to participate in future interviews. The  
23  
24  
25 260 next version of CATEQ was labelled draft 7.

26  
27  
28 261 PDSA 7: Testing electronic and paper version of the questionnaire:

29  
30 262 Participant 9 completed the CATEQ initially on a tablet computer and then as a paper version. Time  
31  
32 263 taken to complete the questionnaire without prompts were 19 minutes and 23 minutes respectively.  
33  
34 264 The additional time taken to complete the paper version was because participant 9 had to flip back  
35  
36 265 and forth between the pages as the matrix questions asked about three AT devices that were  
37  
38 266 currently used and the participant needed to remind themselves in which order they were  
39  
40 267 answering this question.

41  
42  
43 268 At the end of this PDSA cycle the CATEQ was deemed to be ready to be used in a survey and was  
44  
45 269 prepared for final comments by the patient and public advisory group. Figure 1 gives a visual  
46  
47 270 depiction of the PDSAs and stages of tasks presented to subsequent participants.

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49  
50 271 **Discussion:**

51  
52 272 Cognitive interviews have helped researchers develop better questions and survey instruments and  
53  
54 273 are increasingly being used routinely to pre-test questionnaires [24,25]. Our results showed rapid  
55  
56 274 cycle tests of change using PDSA cycles as a format could be used as an alternate way of conducting  
57  
58 275 cognitive interviews. Each cycle tested the changes made to the questionnaire and allowed quick  
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2  
3 276 and easy-to-test changes in subsequent versions of the questionnaire without increasing participant  
4  
5 277 burden within the cognitive interview sessions. Cognitive interviews are usually undertaken in  
6  
7 278 rounds, with several participants interviewed and changes to the questionnaire only made after  
8  
9  
10 279 each round [7,8]. Problems in comprehension, recall or response choices to the questionnaire items  
11  
12 280 emerge from the interviews themselves [19] without the interviewer anticipating or having a  
13  
14 281 hypothesis of which items or layout in the questionnaire may require change. Using small tests for  
15  
16 282 change through PDSA cycles on the other hand, enabled better structuring of questionnaire items  
17  
18 283 with improved ease of comprehension, recall and response choices to items within this  
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20  
21 284 questionnaire. Using PDSA cycles as a learning mechanism for cognitive interviews resulted in  
22  
23 285 predicting potential problems (what are we expecting to happen?) with questionnaire items and  
24  
25 286 layout; this allowed the authors to focus on potentially problematic items such as for example  
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27 287 questions on costs and freeing up carer time. Learning from each cognitive interview was used to  
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29  
30 288 inform the modifications that need to be carried out to the questionnaire and changes to the  
31  
32 289 probing questions [24,26]. Making changes to the questionnaire after every cognitive interview as a  
33  
34 290 result, became easier to manage and learning from each cycle of the PDSA was applied to the next  
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36  
37 291 [27,28]. Also, over the course of seven PDSA cycles, the think aloud interviews indicated potential  
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39 292 problems with a questionnaire item or instruction other than the ones that were considered  
40  
41 293 problematic, this unanticipated learning helped re-frame and retest the questionnaire until it was  
42  
43 294 satisfactory. Focussing on different items in the questionnaire and building up the testing helped  
44  
45 295 reduce fatigue among the participants and better insight into item comprehension, language used  
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47  
48 296 and layout. Using PDSA cycles enabled rapid tests of change to questionnaire items, which not only  
49  
50 297 provided information on problems in a question but also its possible source(s), as well as  
51  
52 298 information toward the problem's solution.

55 299 Using rapid cycle tests for change:

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58 300 Unlike usual cognitive interviews, the use of rapid cycle tests of change in this questionnaire  
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60 301 development allowed the authors to test on as small a scale as possible before building confidence

1  
2  
3 302 and scaling up to test additional items in the questionnaire and with different devices and a paper  
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5 303 version. The authors decided to divide questionnaire items for cognitive interviews during the  
6  
7 304 planning phase into parts – instructions, questionnaire items, demographic data, and health related  
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10 305 quality of life questions for pragmatic reasons. Planning to anticipate problems with questionnaire  
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12 306 items this way and splitting the tasks into small manageable tests of change and increasing its  
13  
14 307 complexity over the course of the PDSA cycles helped maximise learning opportunities, decrease  
15  
16 308 costs and time taken to complete cognitive interviews and reduce participant fatigue and burden.  
17  
18 309 The PDSA cycles allowed the ability to break things down and focus on making small, measurable  
19  
20 310 changes [9,28]. Testing using a paper version, a laptop and a smart phone helped identify if question  
21  
22 311 wording communicates the objective of the question; and quickly identify problems such as  
23  
24 312 redundancy, missing skip instructions and awkward wording with only a few interviews, instead of  
25  
26 313 waiting for multiple participants in each round of interviews in the typical way cognitive interviews  
27  
28 314 are conducted. PDSAs are a clever learning methodology whose “simplicity belies its sophistication”  
29  
30 315 [10]; the use of iterative (PDSA) cycles for cognitive interviews provided information that would  
31  
32 316 otherwise have been unseen by the interviewer before launch of the survey - for example questions  
33  
34 317 on AT devices that are no longer being used by carers. The PDSA cycles also helped our learning  
35  
36 318 from unsolicited information such as the questionnaire could be self-administered instead of  
37  
38 319 interviewer administered.  
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44 320 Cognitive interview is one component from a multitude of ways for pre-testing a questionnaire, to  
45  
46 321 assess it does collect the information that it is supposed to. Using rapid cycle tests for change  
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48 322 through PDSA cycles included planning and a researcher hypothesis of the difficulty of the various  
49  
50 323 questions in the questionnaire; this allowed rapid and iterative pre-testing of the questionnaire  
51  
52 324 without having to wait for multiple rounds of cognitive interviews before changes to the  
53  
54 325 questionnaire could be made and re-tested again. The use of PDSA cycles to inform cognitive  
55  
56 326 interviews in questionnaire development is another use for PDSAs and could be one way of pre-  
57  
58 327 testing questionnaires in the future.  
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3 328 **Strengths and limitations of this study:**  
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6 329 The authors acknowledge that whilst cognitive interview methods can be used to evaluate existing  
7  
8 330 questions, and to test proposed revisions to the original questions, they cannot provide quantitative  
9  
10 331 evidence on whether the revised version of the question is better than the original, however the  
11  
12 332 action in each PDSA cycle built on the learning from the previous cycle and we are confident that the  
13  
14 333 final version of the CATEQ is better than the first draft. The authors also acknowledge that some  
15  
16 334 participants were less articulate than others and could not adequately verbalise their thought  
17  
18 335 processes, however a combination of think aloud and verbal probing interviews helped achieve the  
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20 336 intended aim for each PDSA cycle of improving instructions and comprehension, recall and  
21  
22 337 answering of items within the questionnaire.  
23  
24  
25

26 338 **Conclusion:**  
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28 339 The addition of cognitive interviews as an extra step in the survey development process assures data  
29  
30 340 that are more likely to reflect the actual circumstances being examined. The use of PDSA cycles to  
31  
32 341 frame the process of cognitive interviews would be an alternative way to pre-testing questionnaires  
33  
34 342 that minimises risks by using rapid small-scale tests of the changes introduced to layout and items in  
35  
36 343 the questionnaire as well as potentially helping reduce fatigue and burden to researchers and  
37  
38 344 participants. The PDSA process is widely used and familiar to many involved in health care and  
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40 345 appears to be an appropriate mechanism for pre-testing questionnaires before deploying them in  
41  
42 346 large scale surveys in healthcare.  
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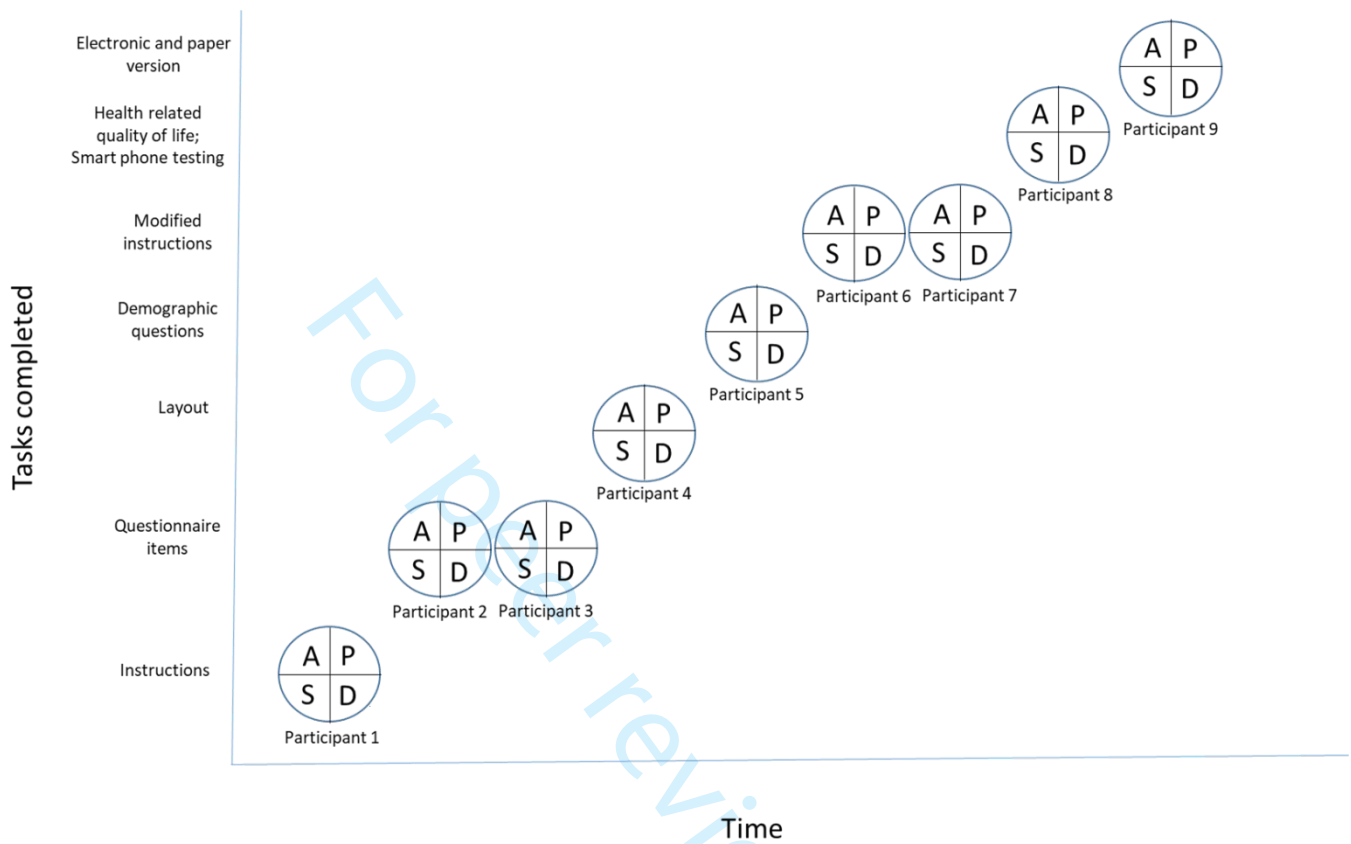
46  
47 347 **List of abbreviations:**  
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50 348 AT – Assistive Technology

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52 349 CATEQ – Carers Assistive Technology Experience Questionnaire

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54 350 PDSA – Plan Do Study Act cycles  
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Figure 1: PDSA cycles and tasks involved in the cognitive interviews



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Table 1: Participant characteristics

ID	Age Range	Gender	Ethnicity
1	56-70	Female	White British
2	56-70	Male	White British
3	40-55	Female	White British
4	40-55	Male	Asian British
5	71-85	Male	White British
6	56-70	Female	Caribbean British
7	40-55	Male	White British
8	40-55	Female	Mixed White British
9	40-55	Female	Asian British

Table 2: Table of changes to CATEQ from draft version 1 to draft version 7

	Questionnaire structure	Draft 1 of CATEQ	Draft 7 of CATEQ
1.	Instructions Line numbers: Paragraphs:	16 12	41 12
2.	Questions on Assistive Technology Questions on Previous Assistive Technology	9 0	10 5
3.	Matrix questions on experience and impact	21	20
4.	Demographic questions	0	9
5.	Health-related quality of life questions	0	15
6.	End of survey response line number	1	1 + research website details
7.	Layout and structure of questionnaire Colour scheme: Font Size:	Blue progress bar 12	Green progress bar 15

## Box 1: Cognitive interview guide

## Pre-interview:

Participant to re-receive the information sheet and asked to read it through. Participant will be given a brief introduction to the research that includes a description of Assistive Technology.

- Show University Card for ID of Researcher and introduce self
- Participant to be told what will happen during the interview process and reminded that the interview will also be audio recorded.
- Participant to be told that a transcript will be made from the audio recording.
- Participant to be told the method of analysis and reminded that they will remain anonymous, and that their data will be confidential.
- Participant given time to ask questions
- Participant will be asked to sign two copies of the consent form, one of which is to be retained by the researcher.

Instructions:

Based on our research, we have the following questions as part of the Carers Assistive Technology Experience Questionnaire. Please look at each page and the questions in this survey. During the interview, we will ask you to speak aloud about what you are thinking as you respond to questions. I am also going to ask you additional questions about individual items in this questionnaire. Remember, the purpose of this interview is to test the questionnaire and not to test you. Are you ready to begin?

We will start with the instructions for the survey:

Example verbal probes used to test the questions:

For Question abc....

1. What to you, is "....."?
2. Tell me more about "....."?
3. Can you repeat this question in your own words?
4. What does "....." mean to you?
5. Would you mind providing some examples about "...."?
6. When you think about "....." what comes to your mind?

Overall for the survey....

7. Are there additional questions you believe should be asked?
8. Are there questions you believe should be deleted?
9. Are there questions you believe should be modified?
10. Are there words used in the questions that you think could be changed to make it more understandable to others who help/look after those with dementia?

Do you have any questions for me?

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3 **1 Declarations:**  
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5  
6 **2 Ethics approval:**  
7

8  
9 **3** This study was granted ethical approval by the University of Oxford Central University Research  
10  
11 **4** Ethics Committee (Reference number: R57703/RE001).  
12

13  
14  
15 **5 Patient consent for publication:**

16  
17 **6** Not required  
18

19  
20  
21 **7 Competing interests:**  
22

23  
24 **8** The authors declare that they do not have any competing interests.  
25

26  
27 **9 Funding:**  
28

29  
30 **10** This research is part of a DPhil in Population Health at the University of Oxford and received no  
31  
32 **11** specific grant from any funding agency in the public, commercial or not-for-profit sectors.  
33

34  
35 **12 Authors' contributions:**  
36

37  
38 **13** VS, CJ and MP conceived the design of the study. VS completed the cognitive interviews and PDSA  
39  
40 **14** cycles templates. VS, MP and CJ discussed emerging issues and agreed final changes to each version  
41  
42 **15** of the questionnaire. VS drafted this version of the manuscript with critical revision and input from  
43  
44 **16** MP and CJ. All authors have read and given approval for this version. VS is the guarantor of the  
45  
46 **17** manuscript.  
47

48  
49  
50 **18 Acknowledgements:**  
51

52  
53 **19** Authors would like to acknowledge support from the three members of the patient and public  
54  
55 **20** engagement and involvement group set up as part of the carers' experience of assistive technology  
56  
57 **21** use in dementia study, for their comments on the questionnaire. We also acknowledge the  
58  
59 **22** contributions of all the participants in this study for their time and invaluable insight into developing  
60



1  
2  
3 23 this questionnaire. The authors acknowledge the constructive comments from Dr Sushmitha  
4  
5 24 Mohapatra and Mr Wayne Scott for their initial comments on the items in the questionnaire.  
6  
7  
8 25 Authors' information:  
9  
10  
11 26 VS is a postgraduate student registered for his DPhil at the University of Oxford exploring informal  
12  
13 27 carers' experience of assistive technology use in dementia. VS is an Occupational Therapist and is  
14  
15 28 trained in interviews and qualitative research methods as part of his clinical training and Masters in  
16  
17 29 Evidence Based Healthcare course from the University of Oxford. VS is also a quality improvement  
18  
19 30 expert and teaches and develops training packages including PDSA methodology for improving  
20  
21 31 quality of care for patient benefit. MP is an Associate Professor within the Health Services Research  
22  
23 32 Unit (HSRU), Nuffield Department of Population Health, University of Oxford. CJ is Professor of  
24  
25 33 Health Services Research and Director of the HSRU, Nuffield Department of Population Health,  
26  
27 34 University of Oxford. MP and CJ have extensive experience in qualitative research methods and are  
28  
29 35 joint supervisors of VS for the DPhil.  
30  
31  
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34 36 Data sharing statement:  
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36 37 The datasets generated during the study are available from the corresponding author on reasonable  
37  
38 38 request.  
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## Developing the Carers Assistive Technology Experience Questionnaire

### PARTICIPANT INFORMATION SHEET

Ethics Approval Reference: R57703/RE001

#### 1. **What is the purpose of this study?**

Dementia describes a set of symptoms that may include memory loss and difficulties with thinking, problem solving or language. Caring for a person with dementia can be demanding for informal carers (family, friends and neighbours) and can affect their mental and physical health and their social lives. **Assistive Technology (AT)** devices are often electronic. They include talking clocks, electronic medication dispensers, smart gas meters, falls and motion detectors and door exit alarms. While Assistive Technology is usually aimed at helping the person with dementia, these may also have an impact on carers. Due to the thinking and problem-solving difficulties of the person with dementia, the carer may need to be an active user of the Assistive Technology. It is not yet clear what positive or negative effects such technology may have on carers and there is little information on their experience with its use.

#### Purpose of this research:

Using themes from existing research studies and interviews with carers, researchers from the Nuffield Department of Population Health, University of Oxford, have developed a Carers' Assistive Technology Experience Questionnaire for use with informal carers (family, friends and neighbours) who support and help persons with dementia at home.

To refine and understand, if the questions in this questionnaire measure what it is intended for and if carers understand and correctly interpret the questions, we want to carry out *cognitive interviews* with a sample of carers of persons with dementia who have used assistive technology.

The cognitive interviews will explore your interpretation and understanding of the survey questions within this questionnaire to identify errors and problems with the questionnaire before it is used in a survey.

#### 2. **Why have I been invited to take part?**

You have been invited because you are over 18 years of age and a family member/friend/neighbour of a person with dementia.

To participate in the study, you need to be

- Looking after or supporting a person with dementia who has used at least one electronic AT device (such as those described above) at home within the past year.

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2  
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4  
5 **3. Do I have to take part?**

6 No, your participation is voluntary. You can ask questions about the study before deciding whether  
7 to take part. If you agree to take part, you may withdraw from the study at any time, without any  
8 penalty and without giving a reason. If you choose to withdraw after the interview, the research  
9 team will delete any data including personal information and interview recordings and transcripts,  
10 and it will not be used in the analysis.  
11  
12

13  
14 **4. What will happen if I take part in the study?**

15 By taking part in this interview, you are helping us evaluate how easy or difficult the questions in the  
16 Carers Assistive Technology Experience Questionnaire are to understand and answer. If you are  
17 happy to take part, you will be asked to answer questions in an informal interview, like a  
18 conversation. The interview questions will ask you about your understanding of the survey  
19 questions, your views on any missing information from the questionnaire and if the questionnaire is  
20 user-friendly and comments on the visual appearance and layout of the questionnaire.  
21  
22

23  
24 The interview will be audio recorded to allow for us to type up your answers. You will never be  
25 identified by any of your personal information.

26 The interview will take approximately 60-90 minutes and will take place at your home, your place of  
27 work, by telephone or at the University of Oxford. The interview location and time will be arranged  
28 in discussion with you, to suit your convenience and preference. The interviews will be conducted by  
29 Mr Vimal Sriram, a doctoral student at the University of Oxford.  
30  
31

32  
33 **5. Are there any potential risks in taking part?**

34 The questions asked during the interview may be personal and occasionally some people feel upset  
35 when asked to think about their experiences of looking after a person with dementia. You do not  
36 have to answer any question that you would prefer not to answer. If you become upset at any point,  
37 the researcher will ask you if you wish to pause or stop the interview. You could then: stop and  
38 withdraw your data (the interview recording would be deleted), end the interview and allow the  
39 interview recording until that point to be used in the research, or carry on with the interview when  
40 you are ready.  
41  
42

43 The researcher can also provide you with an information sheet which contains a list of organisations  
44 who you can get in touch with if you feel the need for further support.  
45  
46

47 **6. Are there any benefits in taking part?**

48 You will not receive any direct benefit by taking part in this study. However, the information gained  
49 in this research study will improve the survey questionnaire and subsequently provide a better  
50 understanding and insight of carers' experiences of using assistive technology.  
51  
52

53 **7. What happens to my data?**

54 The **research data** will be stored and examined using University approved software.

55 Any information that you may have given in the interview that could identify you will be removed  
56 from the interview before it is analysed. Confidentiality will be maintained throughout this research  
57 study. If you consent to take part in this study, you will be required to sign an informed consent  
58 form. To protect your identity, your name will be replaced by a pseudonym in any research reports.  
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3 Any identifying information like your name, details or other personal information will not be used or  
4 disclosed to anyone outside, to any third party or appear on any transcripts, thesis, publications or  
5 on any academic paper.  
6  
7

8 However, there might be certain circumstances in which it may be necessary to breach this  
9 confidentiality and disclose information to a third party. This includes situations when someone  
10 provides information during the study that raises serious concern about:

- 11 - Intention to harm themselves or other people
  - 12 - Risk to the health, welfare or safety of vulnerable adults such as someone with dementia
  - 13 - Disclosure of a criminal offence
- 14  
15  
16

17 The researcher will discuss this issue with you before telling anyone else. The researcher will be  
18 obliged to share this evidence with his supervisors, who may advise that further action is taken.  
19

20 Personal / sensitive information such as your name, age, gender, marital status, employment status,  
21 telephone number or address details in case of face-face interviews will be stored confidentially  
22 using computer software that does not allow anyone else except the researcher and his supervisors  
23 access to your data. All paper forms will be stored in a locked cupboard within the Department of  
24 Population Health, University of Oxford. Your personal/sensitive data, including your signed consent  
25 forms will be kept separately from audio recordings and transcripts from your interviews. Your  
26 answers may be quoted directly in the research publication with information suitably anonymised.  
27 All audio recordings will be erased permanently once they have been transcribed.

28 All research data and records will be stored for a minimum retention period of 3 years after  
29 publication or public release of the work of the research.  
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#### 34 **8. Will the research be published?**

35 The research will be written up as a doctoral thesis. On successful submission of the thesis, it will be  
36 deposited both in print and online in the University archives, to facilitate its use in future research.  
37 The thesis will be published open access.  
38

39 Additionally, the research may be published in academic journals and presented in national and  
40 international conferences. The University of Oxford is committed to the dissemination of its  
41 research for the benefit of society and the economy and, in support of this commitment, has  
42 established an online archive of research materials. This archive includes digital copies of student  
43 theses successfully submitted as part of a University of Oxford postgraduate degree programme.  
44 Holding the archive online gives easy access for researchers to the full text of freely available theses,  
45 thereby increasing the likely impact and use of that research.  
46  
47  
48

#### 49 **9. Who is organising and funding the research?**

50 This study is being carried out as part of the DPhil (PhD) Programme in Population Health at the  
51 Nuffield Department of Population Health, University of Oxford.  
52

#### 53 **10. Who has reviewed this study?**

54 This study has been reviewed by, and received ethics clearance through, the University of Oxford  
55 Central University Research Ethics Committee (Reference number: R57703/RE001).  
56  
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#### 58 **11. Data Protection:**

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1  
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3 The University of Oxford is the data controller with respect to your personal data, and as such will  
4 determine how your personal data is used in the study. The University will process your personal  
5 data for the purpose of the research outlined above. Research is a task that we perform in the  
6 public interest. Further information about your rights with respect to your personal data is available  
7 from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.”  
8  
9

10  
11 **12. Who do I contact if I have a concern about the study or I wish to complain?**

12 If you have a concern about any aspect of this study, you can contact me through an email at  
13 [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk) or by telephone on 01865 743762 or my supervisors Dr Michele Peters  
14 ([michele.peters@dph.ox.ac.uk](mailto:michele.peters@dph.ox.ac.uk)) or by telephone on 01865 289428 or Professor Crispin Jenkinson  
15 ([crispin.jenkinson@dph.ox.ac.uk](mailto:crispin.jenkinson@dph.ox.ac.uk)) or by telephone on 01865 289441, who will do their best to  
16 answer your query. We will acknowledge your concern within 10 working days and give you an  
17 indication of how we intend to deal with it. If you remain unhappy or wish to make a formal  
18 complaint, please contact the chair of the Research Ethics Committee at the University of Oxford  
19 who will seek to resolve the matter in a reasonably expeditious manner:  
20 Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk);  
21 Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD  
22  
23  
24  
25

26 **13. Further Information and Contact Details**

27 The interviews for this researcher study will be carried out by Mr. Vimal Sriram (Doctoral student)  
28 from the Nuffield Department of Population Health, University of Oxford. The researcher will  
29 identify himself to you using a University of Oxford student card.  
30  
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41 If you would like to discuss the research with someone beforehand (or if you have questions  
42 afterwards), please contact:  
43  
44

45 Mr. Vimal Sriram  
46 Nuffield Department of Population Health  
47 Health Services Research Unit  
48 Richard Doll Building, Old Road Campus, Oxford OX3 7LF  
49 Telephone number: 01865 743762  
50 E-mail: [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk)  
51  
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53

54 **Thank you for taking the time to read this information sheet.**  
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## CATEQ Cognitive Interview

## Worksheet for Testing Change- PDSA Cycle 1

**Aim:** To test items in the CATEQ for understandability, response choice and layout

Every goal will require multiple small tests of change

Describe your first (or next) test of change	Person Responsible	When to be done	Where to be done
Complete cognitive interview with participant 1	VS	14.11.2019	Participant 1's home

List the task needed to set up this test of change	Person Responsible	When to be done	Where to be done
<ol style="list-style-type: none"> <li>1. Test comprehension of initial instructions</li> <li>2. Test eligibility criteria listed</li> <li>3. Test layout and format for informed consent statement</li> <li>4. Test layout and instructions of willingness to participate in part 3 interviews</li> <li>5. Test layout and instructions of end of survey statement</li> <li>6. Test items 1-29</li> </ol>	VS	14.11.2019	Participant 1's home.

Predict what will happen when the next test is carried out	Measures to determine if predictions accurate
<ol style="list-style-type: none"> <li>1. Participant 1 will be able to comprehend all initial instructions in the CATEQ (time: 3 minutes) and will agree with layout.</li> <li>2. Participant 1 will agree with the eligibility criteria as listed out (time: 1 minute)</li> <li>3. Participant 1 will agree with layout and format of informed consent statement</li> <li>4. Participant 1 will agree with layout and instructions for the willingness to participate in part 3 interviews</li> </ol>	<ol style="list-style-type: none"> <li>1. Time taken to read through the instructions; Able to understand the instructions on verbal probing.</li> <li>2. Time taken to read through the eligibility criteria; On verbal probing able to answer that the eligibility criteria listed is comprehensible.</li> <li>3. On verbal probing, able to inform layout and format of informed consent statement is simple and easy to answer.</li> <li>4. On verbal probing, able to inform that the layout and instructions for the willingness to participate in part 3 interviews is simple and easy to</li> </ol>



CATEQ Cognitive Interview

<p>5. Participant 1 will agree with layout and instructions at the end of the survey.</p> <p>6. Participant 1 will be able to comprehend, retrieve and answer questionnaire items 1-23</p>	<p>answer.</p> <p>5. On verbal probing, able to inform that the layout and instructions for the end of survey message is simple and easy to answer.</p> <p>6. On concurrent think-aloud exercise, able answer questions as comprehensible, easy to retrieve answers to. On verbal probing able to inform if response choices of the items are adequate.</p>
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**Do** Describe what actually happened when you ran the test

Completed cognitive interview with audio recording at participant’s home with informed consent. Used concurrent verbal probing for instructions, eligibility criteria, consent statement, participation in further interviews and the end of survey statement. Think aloud method used for items 1-29 to record understanding, retrieval of information and answering questions plus verbal probing about response choice for these items.

Time taken to complete each section was noted and verbal prompting and their responses were also noted in field notes using a paper copy of the CATEQ to concurrently record comprehension, retrieval and use of information.

**Study** Describe the measured results and how they compared to the predictions

Total time taken for the interview was 70 minutes.

1. Time taken to complete reading instructions was 90 seconds. Participant 1 indicated that the instructions about the questionnaire and approximate time that it would take to complete the questionnaire was useful. Commented that the font size could be slightly bigger and the instructions could be further spaced to allow for easier reading.
2. Participant 1 understood the eligibility criteria and took 30 seconds to read this through and did not recommend any changes.
3. Participant 1 understood the informed consent statement and did not recommend any changes.
4. Participant 1 understood the instructions for willingness to participate in further interviews section of the CATEQ, recommended using email address and/or telephone number to be added to the instructions.

## CATEQ Cognitive Interview

5. Participant 1 understood and agreed with the layout and final instructions at the end of survey and did not recommend any changes.

6. Think aloud exercise for questions 1-29 – easy to understand instructions and liked the “other” option for free text questions. Participant 1 had difficulty sorting through AT devices no longer being used.

**Act** Describe what modifications to the plan will be made for the next cycle

Make changes to the font and layout of the initial instructions. Add questions and clarify in instructions about AT used in the past and no longer in current use. Test entire CATEQ item list on participant 2.

## COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
<b>Domain 1: Research team and reflexivity</b>			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
<b>Domain 2: Study design</b>			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
<b>Domain 3: analysis and findings</b>			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

**Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.**

# BMJ Open

## Using rapid cycle tests of change to develop the Carers Assistive Technology Experience Questionnaire: a cognitive interview study in the UK.

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<b>Primary Subject Heading</b>:	Geriatric medicine
Secondary Subject Heading:	Health services research
Keywords:	QUALITATIVE RESEARCH, GERIATRIC MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Dementia < NEUROLOGY

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3 **Using rapid cycle tests of change to develop the Carers Assistive Technology Experience**  
4 **Questionnaire: a cognitive interview study in the UK.**  
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8  
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**Abstract:**

We describe the use of rapid cycle tests of change to pre-test and develop a carers' assistive technology experience questionnaire for a survey of informal carers of persons with dementia. The Plan-Do-Study-Act (PDSA) cycle is a commonly used improvement process in health care settings. We used this method for conducting rapid cycle tests of change through cognitive interviews to pre-test the questionnaire. The items for the questionnaire were developed based on an earlier systematic review and qualitative study. PDSA cycles were used incrementally with learning from each cycle used to inform subsequent changes to the questionnaire prior to testing on the next participant.

Design: Qualitative with use of cognitive interviews through rapid cycle tests of change.

Setting: United Kingdom

**Results:**

Nine participants were recruited based on eligibility criteria and purposive sampling. Cognitive interviewing using think aloud and concurrent verbal probing was used to test the comprehension, recall, decision and response choice of participants to the questionnaire. Seven PDSA cycles involving the participants helped to identify problems with the questionnaire items, instructions, layout and grouping of items. Participants used a laptop, smart phone and/or tablet computer for testing the electronic version of the questionnaire and one participant also tested the paper version. A cumulative process of presenting items in the questionnaire, anticipating problems with specific items and learning from the unanticipated responses from participants through rapid cycle tests of change allowed rich learning and reflection to progressively improve the questionnaire.

**Conclusion:**

Using rapid cycle tests of change in the pre-testing questionnaire phase of research provided a structure for conducting cognitive interviews. Learning and reflections from the rapid testing and revisions made to the questionnaire helped improve the process of reaching the final version of the



1  
2  
3 26 questionnaire, that the authors were confident would measure what was intended, rapidly and with  
4  
5 27 less respondent burden.  
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8 **Key words:**  
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10 29 Cognitive interview; Plan-Do-Study Act cycles; Questionnaire development  
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For peer review only

### 1 **Strengths and limitations of this study:**

- 2 • This study recruited participants from across the UK, adopting a purposeful sampling  
3 strategy to identify suitable participants with diverse age groups, gender, ethnicity and living  
4 arrangements, who could support interpreting and answering items within the  
5 questionnaire.
- 6 • Use of concurrent think aloud and verbal probing methods during the cognitive interviews  
7 allowed for richer interpretation and in-depth understanding of changes needed to the  
8 questionnaire.
- 9 • The participants were recruited through voluntary participation in research databases and  
10 potentially may not be representative.

### 11 **Introduction:**

12 Dementia describes a set of symptoms that may include memory loss and difficulties with thinking,  
13 problem solving or language [1]. Caring for a person with dementia can be demanding for carers  
14 (family, friends and neighbours) and can affect their mental and physical health and their social lives  
15 [2]. Assistive Technology (AT) may support carers in caring for persons with dementia in the  
16 community; however, very little is known about their experience and use of AT [3,4]. To better  
17 understand the use and impact of AT on carers, we developed a survey instrument – Carers'  
18 Assistive Technology Experience Questionnaire (CATEQ).

19 In survey research, the data collection tool is typically a structured questionnaire and the  
20 measurements obtained are the respondent's answers to survey questions [5]. This type of data  
21 collection assumes that all participants understand the questions in a consistent way; the questions  
22 are asking for information that participants have and can retrieve and the questions are worded in a  
23 way that the participants are able to answer them as intended by the researcher. In order to provide  
24 a valid and reliable instrument, the wording, structure, and layout of the questionnaire must make  
25 allowance for the nature and characteristics of the participating population [6].

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3 26 Cognitive interviews:  
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6 27 Cognitive interviews are commonly used for pre-testing survey questions [5,7]. They can provide  
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8 28 information on how the questions are understood and answered by typical participants. Cognitive  
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10 29 interviews can help detect problems participants may have in understanding survey instructions and  
11  
12 30 items, and in formulating answers [8]. Cognitive interviews can identify problems in item  
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14 31 interpretation, memory retrieval, decision processes, and response selection [9]. A draft  
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16 32 questionnaire with candidate items is developed and cognitive interviewing with participants  
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18 33 representing the target population is used to revise the questionnaire. Cognitive interviews also  
19  
20 34 afford the opportunity to detect other problems in questionnaire instructions, design, and  
21  
22 35 organisation [10]. They consist of one-to-one interviews in which the respondents describe their  
23  
24 36 thoughts while answering the survey questions and can be done through different methods such as  
25  
26 37 think aloud, verbal probing, confidence rating, card sorting and paraphrasing [6]. Cognitive  
27  
28 38 interviews are usually undertaken in rounds, with several participants interviewed in each round,  
29  
30 39 their responses analysed and changes to the questionnaire only made after each round [11–13]. This  
31  
32 40 process could be burdensome for respondents and researchers and involve higher costs during  
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34 41 questionnaire development.

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40 42 Plan-Do-Study-Act cycles:  
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42 43 The iterative process of learning and revising through cognitive interviews can be viewed as  
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44 44 following the steps of action-oriented learning such as Plan-Do-Study-Act (PDSA) cycles [14,15].  
45  
46 45 PDSA cycles consist of [14,16]

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50 Plan state the objective of the test, the planned change, make predictions of what will  
51 happen and why and develop a plan to test the change  
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53 Do carry out the test/intervention, document problems and unexpected  
54 observations, begin analysis of the data  
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3 Study complete the analysis of the data, compare the data to earlier predictions in the  
4 plan phase and summarise and reflect on what was learnt  
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7 Act determine what modifications should be made, i.e., deciding that the  
8 intervention has achieved the required standard and can therefore be  
9 implemented more widely or deciding that an entirely new change is required  
10 and the current plan should be changed and prepare a plan for the next test  
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14 46 While PDSA cycles are commonly used in clinical care, few clinical research trials have documented  
15  
16 47 its use for implementation [17] and none have used PDSA cycles as a framework for cognitive  
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18 48 interviews for pre-testing questionnaires. The authors present here one way of developing a  
19  
20 49 questionnaire, based on using rapid cycle tests for change framed within PDSA cycles for conducting  
21  
22 50 cognitive interviews in pre-testing questionnaire items to develop the CATEQ. This is an alternative  
23  
24 51 way of developing and pre-testing a questionnaire and highlights how rapid cycle tests for change  
25  
26 52 such as PDSA cycles can be used in questionnaire development.  
27  
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29

### 30 **Ethics:**

31  
32 54 This study was approved by the University of Oxford Central University Research Ethics Committee  
33  
34 55 (Reference number: R57703/RE001). All volunteers were provided with a participant information  
35  
36 56 sheet (supplementary file 1). All recruited participants provided informed written consent prior to  
37  
38 57 the cognitive interviews. All participants are identified by a participant number within this paper.  
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41

### 42 **Methods:**

#### 43 **Patient and public involvement:**

44  
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46 60 This study is part of a larger research project which has a patient and public advisory group that  
47  
48 61 meets twice a year. The group consists of two carers of persons with dementia and a person with  
49  
50 62 dementia (all living in England). This group gave feedback on the initial items and instructions  
51  
52 63 framed as part of the CATEQ and reviewed the final version of CATEQ submitted for ethical approval.  
53  
54 64 This group has also committed to support dissemination of study results to other patient  
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56 65 involvement groups and their wider networks.  
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3 66 Study Design:  
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6 67 The authors describe the steps followed in designing the questionnaire and conducting the cognitive  
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8 68 interviews using PDSA cycles to arrive at the final version of the CATEQ.  
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10  
11 69 1. Develop items for the questionnaire:  
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13 70 The items of CATEQ were developed on the basis of results from a systematic review [3,18] and a  
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15 71 qualitative study [4] and are intended to be administered as an electronic survey. The CATEQ  
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17 72 explores themes that carers (family, friends and neighbours) described as relevant for use of  
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19 73 Assistive Technology (AT) for dementia care in the community. An iterative process of drafting,  
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21 74 evaluation, revision and content checking was followed. Attention was taken to draft the items in  
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23 75 the questionnaire to: capture the intended concept of experience using AT and their impact on  
24  
25 76 carers; relevance to all members of the target population irrespective of age, living arrangements  
26  
27 77 and relationship with the person with dementia; the response choices were ordered in a meaningful  
28  
29 78 way; ensure the questions were worded in a manner consistent with best practice style guide by  
30  
31 79 Alzheimer's society [19]; each item represented a single concept, rather than a multidimensional  
32  
33 80 concept; the content of the items was appropriate for the recall period of the previous 4 weeks; and  
34  
35 81 the items could be answered in a self-administered questionnaire. The questionnaire items were  
36  
37 82 mainly closed questions with multiple choice answers with some questions being partially closed  
38  
39 83 with "other" as open-ended text options. The questions were a mixture of behavioural (*What input*  
40  
41 84 *is required from you for using the assistive technology?; How often are you able to solve problems*  
42  
43 85 *with the assistive technology by yourself?*), opinion (*How helpful is the assistive technology in*  
44  
45 86 *reducing your stress?; How helpful is the assistive technology in giving you more time for yourself?*)  
46  
47 87 and factual questions (*age; gender; who was involved in the choice of AT?*). The CATEQ included  
48  
49 88 questions to capture demographic information of participants, health-related quality of life and  
50  
51 89 expression of interest in participating in qualitative interviews later. None of the questions except  
52  
53 90 for the consent question at the beginning of the survey had a forced-choice response (i.e.  
54  
55 91 respondents could omit answers to questions). The draft questionnaire had a Likert like rating scale  
56  
57  
58  
59  
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1  
2  
3 92 as response choices. For ease of administering cognitive interviews the initial set of interviews did  
4  
5 93 not include demographic (for participants 1-4) and health-related quality of life (participants 1-6)  
6  
7 94 questions. This questionnaire was labelled draft 0 and minor corrections were made based on  
8  
9  
10 95 comments by the patient and public advisory group for the project and by three clinical and social  
11  
12 96 care experts involved in prescribing AT for use by persons with dementia at home. This modified  
13  
14 97 CATEQ was labelled draft 1 and was used in the first cognitive interview.

16 98 2. Design cognitive interview process:

18  
19 99 Cognitive interviews were used to assess participants' comprehension of the items in CATEQ as well  
20  
21 100 as establish that no important items were missing. A semi-structured interview guide with think  
22  
23 101 aloud questions, and verbal probing questions, was developed to elicit further information from the  
24  
25 102 participants [box1]. All the cognitive interviews were conducted by VS who is an Occupational  
26  
27  
28 103 Therapist and is trained in qualitative interviewing and quality improvement methods. Regular time  
29  
30 104 was made for all the authors to meet to discuss progress with the cognitive interviews and  
31  
32 105 modifications to the drafts of CATEQ.

34 106 Recruitment: Participants for the cognitive interviews were recruited through the Join Dementia  
35  
36 107 Research website [20]. Participants were carers of persons with dementia based in the United  
37  
38 108 Kingdom willing to be contacted by researchers through this website. The inclusion criteria were:  
39  
40 109 adult carers - family, friends or neighbours - providing at least 10 hours of care (e.g. shopping,  
41  
42 110 leisure, personal care, finance) per week to a person with dementia who lives in their own home,  
43  
44 111 with the carer living together with or away from the person with dementia; carers should have used  
45  
46 112 at least one AT device at home in the previous year and be able to communicate in English.  
47  
48 113 Participants were emailed a copy of the participant information sheet [supplementary file 1] and a  
49  
50 114 purposive sample of participants reflecting variations in gender, age, ethnicity, living arrangements  
51  
52 115 and relationship with persons with dementia were selected. The recruitment commenced in October  
53  
54 116 2019 and the final interview was completed in February 2020. A target sample size of 7-10  
55  
56 117 participants was deemed enough to complete cognitive interviews for items in the CATEQ. This was  
57  
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1  
2  
3 118 based on previous estimates [13,21,22] but the intention was to continue with cognitive interviews  
4  
5 119 until no further amendments to the CATEQ were necessary [23].  
6

7  
8 120 3. Conduct cognitive interviews:  
9

10 121 Data collection: Semi-structured interviews were conducted face to face (at the participant's own  
11  
12 122 home/at the researcher's office) taking into consideration the participant's geographical location  
13  
14 123 and preference. The 'think aloud' and verbal probing methods were used for data collection and  
15  
16 124 involve an interviewer asking the participant how they went about answering a particular survey  
17  
18 125 question [10]. In the think aloud method, the participant is asked to speak all thoughts aloud as  
19  
20 126 he/she answers the question. For verbal probing, the interviewer asks specific questions or probes  
21  
22 127 which are designed to elicit how the participant went about answering the question, for example,  
23  
24 128 how the participant made their choice among the response options or how they interpreted an  
25  
26 129 instruction [5,6]. Participants were shown the electronic version of CATEQ developed using Qualtrics  
27  
28 130 software [24] during the interview on a laptop. Participant 8 also tested the questionnaire on a  
29  
30 131 smart mobile phone. The final participant in addition to the electronic version, was also requested to  
31  
32 132 comment on the paper version of CATEQ [21]. The participants were not known to the interviewer  
33  
34 133 or the other authors prior to recruitment. Trust and easing into the think aloud interview was built  
35  
36 134 by establishing rapport with the participants. The interviewer (VS) explained that the purpose was to  
37  
38 135 make the questionnaire better by identifying items that were difficult to answer. Interviews were  
39  
40 136 undertaken using concurrent think aloud and verbal probing questions and lasted between 55-95  
41  
42 137 minutes; all interviews were audio-recorded along with field notes and a PDSA template  
43  
44 138 [supplementary file 2]. The field notes noted verbal and nonverbal cues from the participants, as  
45  
46 139 well as their perception of the items in CATEQ. Confidentiality of the participants was maintained  
47  
48 140 throughout the process by avoiding references to names of the participant or persons with  
49  
50 141 dementia, cities and other person identifiable information.  
51  
52  
53  
54  
55

56  
57 142 4. Make decisions to revise questionnaire:  
58  
59  
60

1  
2  
3 143 Data Analysis: The PDSA template [supplementary file 2] was used to document the hypothesis  
4  
5 144 being tested, results of the cognitive interview process and to make changes to the CATEQ. After  
6  
7 145 discussion among all the authors, the questionnaire items were changed in line with suggestions  
8  
9  
10 146 from the participant and accounting for difficulty encountered by the participant with specific items  
11  
12 147 during the cognitive interview. Changes were made after every cognitive interview instead of waiting  
13  
14 148 for rounds of interviews to finish, which is the process in traditional cognitive interview  
15  
16 149 methods[13], thereby narrowing the time between data collection, analysis and changes made. The  
17  
18 150 authors also ensured each subsequent participant, in addition to “thinking-aloud” on a focused  
19  
20 151 section of the questionnaire, also commented on the latest iteration of the full questionnaire to  
21  
22 152 determine if the modified version then functioned as intended, without introducing further  
23  
24 153 difficulties in comprehension or changes needed to the questionnaire. Subsequent CATEQ  
25  
26 154 questionnaire drafts were numbered draft 2, draft 3 etc. which were used contiguously for the  
27  
28 155 progressive set of cognitive interviews.

31  
32  
33 156 5. Final Test:

34  
35 157 At the end of questionnaire revision, the final version of CATEQ was tested on three volunteers and  
36  
37 158 the patient and public advisory group to check for time taken to complete the questionnaire, issues  
38  
39 159 with formatting, skip logic and ease of understanding of the instructions before it was deemed ready  
40  
41 160 to be used in a quantitative survey.

42  
43  
44 161 **Results:**

45  
46 162 Emails (n=38) for recruitment were sent to potential participants. From the responses received  
47  
48 163 (n=22), 11 carers did not meet the eligibility criteria and 9 carers (5 women and 4 men), with varying  
49  
50 164 types of relationship to a person with dementia, took part in interviews [Table1]. Every participant  
51  
52 165 had used at least one AT device in the last 12 months. Participants were aged between 42 to 75  
53  
54 166 years. The authors used PDSA cycles for the cognitive interviews to make iterative changes to the  
55  
56 167 CATEQ. The changes between draft1 and draft7 of the questionnaire are given in Table 2.

57  
58  
59 168 PDSA 1: Testing instructions and questionnaire items:  
60



1  
2  
3 169 CATEQ draft 1 had instructions for participating in the survey, eligibility criteria and a consent  
4  
5 170 statement. In addition, it had 29 items (21 items in matrix format) about carers' current experiences  
6  
7 171 and impact of using AT with a person with dementia at home. During PDSA 1, participant 1 was able  
8  
9 172 to comprehend and understand the instructions and commented on the font and layout of the  
10  
11 173 instructions that could be improved. The eligibility criteria and consent statements were easy to  
12  
13 174 understand and overall participant 1 took less time than anticipated to complete these sections. On  
14  
15 175 verbal probing, participant 1 indicated that most instructions only carried information regarding data  
16  
17 176 protection and use which were standard statements.

18  
19  
20  
21 177 "...these are what...err...you'll find in a product agreement you know...and who reads these  
22  
23 178 through fully? I always click agree, so I can start using the thing, err...you know...like the  
24  
25 179 cookie thing on websites..."

26  
27  
28 180 Participant 1 answered the items on the questionnaire and commented that the layout was easy to  
29  
30 181 follow, the questions were easy to understand with the option of "other" where extra information  
31  
32 182 was needed. As part of the think aloud interview for item 1 it was observed that there was some  
33  
34 183 difficulty in sorting through AT devices that participant 1 had used but is no longer currently using  
35  
36 184 and additional instructions and questionnaire items to provide details of these devices might be  
37  
38 185 helpful. At the end of the PDSA cycle, modifications to the layout and instructions were made by  
39  
40 186 adjusting font size and paragraph spacing, instructions for current AT was modified and four  
41  
42 187 additional questions on AT previously used and reason for abandonment were added, as well as  
43  
44 188 adding information on the research website at the end of survey message and the CATEQ draft was  
45  
46 189 labelled draft 2.

47  
48  
49  
50 190 PDSA 2: Testing questionnaire items:

51  
52 191 Cognitive interviews with Participants 2 and 3 were carried out separately using the electronic  
53  
54 192 version of draft 2 of CATEQ. Both participants felt the image at the start of the instructions with  
55  
56 193 common AT devices was helpful. The think aloud interviews for the questionnaire items highlighted  
57  
58 194 confusion regarding the cost of AT. The question was framed as: "*Can you give the approximate cost*  
59  
60

1  
2  
3 195 (*in pounds*) associated with the assistive technology currently used, paid for by the person with  
4  
5 196 dementia or by you or another carer (family, friend or neighbour)?” Participant 2 had difficulty in  
6  
7 197 separating out initial cost in purchasing the AT with that of ongoing costs for maintenance.  
8  
9  
10 198 Participant 3 also had difficulty with the cost of AT question “Are you concerned about cost of the  
11  
12 199 assistive technology?” as the AT they were using was provided by the social care services without a  
13  
14 200 cost to them. Both participants were able to differentiate questions on *anxiety* and *stress* presented  
15  
16 201 as separate questions. On verbal probing both participants wanted a “does not apply” option to  
17  
18 202 matrix questions such as: “How helpful is the assistive technology in giving you additional time for  
19  
20 203 tasks that you have to do?” and “How helpful is the assistive technology in maintaining dignity of the  
21  
22 204 person with dementia?”. These cognitive interviews also gave authors the unsolicited confirmation  
23  
24 205 that the CATEQ could be self-administered.

26  
27  
28 206 “...you’ll get more out of me doing this (answering the questions) on a laptop or on the  
29  
30 207 phone than if I were sat in front of you and answering them...these are personal questions  
31  
32 208 and (I) might be feeling guilty answering them honestly if you were in the room, you know  
33  
34 209 what I mean...” [Participant 2]

35  
36  
37 210 At the end of this PDSA cycle the questionnaire items were modified to change the wording on items  
38  
39 211 on cost and add a “does not apply” option to the Likert type scale choice for the matrix questions  
40  
41 212 and the new draft of the CATEQ was labelled draft 3.

42  
43 213 PDSA 3: Testing questionnaire items and skip logic:

44  
45 214 Cognitive interview with Participant 4 was used to test the questionnaire items including the  
46  
47 215 modified items from draft 2, as well as the layout and format of the electronic version of the  
48  
49 216 questionnaire. The think aloud interview confirmed that the modified questionnaire items on cost  
50  
51 217 was better understood by participant 4. On verbal probing participant 4 appreciated the option of  
52  
53 218 “does not apply” as a choice. Participant 4 on verbal probing also commented that the layout of the  
54  
55 219 questionnaire was easy to understand and suggested a change in colour scheme for the button  
56  
57 220 indicating progress to the next page of the questionnaire:

1  
2  
3 221 “...You know this arrow button in the bottom (indicates on screen), it is blue now, but if this  
4  
5 222 were in green, other carers who do your survey would think they are good to go, sort of  
6  
7 223 like...you know...like...like a traffic light system and make good headway with your  
8  
9 224 questionnaire...”.

10 225 At the end of this PDSA cycle, the colour scheme for the questionnaire was changed and a new  
11  
12 226 version of the CATEQ was labelled draft 4, this version for the next cognitive interview now  
13  
14  
15  
16 227 contained items for capturing demographic data of participants.

17  
18  
19 228 PDSA 4: Testing questionnaire items and demographic questions:

20  
21 229 Cognitive interview with participant 5 concentrated on questionnaire items with a specific focus on  
22  
23 230 the nine demographic questions in CATEQ. Verbal probing and think aloud interview were used to  
24  
25 231 check comprehension, recall and ease of answering demographic questions in the CATEQ. The  
26  
27 232 participant understood the questions readily enough, participant 5 had some hesitation in answering  
28  
29 233 the question on income and on verbal probing disclosed that the participant and the person with  
30  
31 234 dementia pooled their income for household expenses and some of the hesitation was in disclosing  
32  
33 235 this in a survey, even if it was anonymous. At the end of this PDSA cycle, it was decided to reframe  
34  
35 236 the question on income to ‘*family income*’ and add an option of “*do not wish to disclose*” as part of  
36  
37 237 the response options of this question. After modifying the questionnaire items, further modifications  
38  
39 238 to the instructions for survey participants were made on the advice of the Ethics committee, this  
40  
41 239 included further detailed instructions on use of data, data protection and contact details of all the  
42  
43 240 study authors. The next version of CATEQ incorporating all these changes was labelled draft 5.

44  
45  
46 241 PDSA 5: Testing modified instructions and questionnaire items:

47  
48 242 Participants 6 and 7 participated in cognitive interviews that tested the modified instructions and  
49  
50 243 questionnaire items. Both participants completed the questionnaire items without difficulty and on  
51  
52 244 verbal probing commented that the instructions were long but easy to understand and in any case  
53  
54 245 were not spending too much time on them. On verbal probing participant 7 also felt the order in  
55  
56 246 which items on stress, anxiety, time for self and effort on caring were presented could be rearranged  
57  
58  
59  
60

1  
2  
3 247 in the questionnaire and grouped together as they helped the participant think through them better  
4  
5 248 and maintain 'flow of thought'. Participant 6 also recommended testing the questionnaire on  
6  
7 249 participants using a smart phone device, as this might be the way some participants would choose to  
8  
9  
10 250 complete the questionnaire during their commute into work. At the end of this PDSA cycle,  
11  
12 251 questionnaire items were regrouped to facilitate ease of recall; items on health related quality of life  
13  
14 252 based on the validated 12 item Short Form survey (SF-12) version 1 [25,26] plus three questions on  
15  
16 253 coping with caring and relationship with person with dementia were added to the CATEQ and this  
17  
18 254 version of the questionnaire was labelled draft 6.

20  
21 255 PDSA 6: Testing items on health-related quality of life and completion of questionnaire using a smart  
22  
23 256 phone:

24  
25 257 The next PDSA cycle involved a cognitive interview with participant 8, who tested additional items  
26  
27 258 on the questionnaire from the SF-12. The SF-12 contains items covering physical functioning, social  
28  
29 259 functioning, role functioning (physical and mental), vitality, bodily pain, mental health and general  
30  
31 260 health. The SF-12 generates two summary scores: The Physical Component Score and the Mental  
32  
33 261 Component Scores. A higher score indicates better quality of life. As the SF-12 is well validated the  
34  
35 262 cognitive interview was limited to comprehension of the questions and answer choices as well as  
36  
37 263 layout of the electronic version of the questionnaire with the health related quality of life question  
38  
39 264 items at the end of the questionnaire. The participant also completed the questionnaire using a  
40  
41 265 smart phone device to check for ease of use and layout of the questionnaire in a smart phone  
42  
43 266 device. The participant completed the questionnaire with ease and had no specific difficulty in  
44  
45 267 comprehension or recall of information required for completion of the questionnaire. The layout of  
46  
47 268 the questionnaire on the smart phone was easy to follow and the questions were presented one  
48  
49 269 after the other and was completed without difficulty. At the end of this cycle, the questionnaire was  
50  
51 270 deemed to be ready for a test to include electronic and paper versions to check ease of completion  
52  
53 271 and minor modifications to instructions such as, to remove references to 'IP address will not be  
54  
55  
56  
57  
58  
59  
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1  
2  
3 272 collected' and as skip logic could not be applied for consent to participate in future interviews. The  
4  
5 273 next version of CATEQ was labelled draft 7.  
6  
7 274 PDSA 7: Testing electronic and paper version of the questionnaire:  
8  
9  
10 275 Participant 9 completed the CATEQ initially on a tablet computer and then as a paper version. Time  
11  
12 276 taken to complete the questionnaire without prompts were 19 minutes and 23 minutes respectively.  
13  
14 277 The additional time taken to complete the paper version was because participant 9 had to flip back  
15  
16 278 and forth between the pages as the matrix questions asked about three AT devices that were  
17  
18 279 currently used and the participant needed to remind themselves in which order they were  
19  
20 280 answering this question.  
21  
22  
23 281 At the end of this PDSA cycle the CATEQ was deemed to be ready to be used in a survey and was  
24  
25 282 prepared for final comments by the patient and public advisory group. Figure 1 gives a visual  
26  
27 283 depiction of the PDSAs and stages of tasks presented to subsequent participants.

28  
29  
30 284 **Discussion:**

31  
32 285 Cognitive interviews have helped researchers develop better questions and survey instruments and  
33  
34 286 are increasingly being used routinely to pre-test questionnaires [27,28]. Our results showed rapid  
35  
36 287 cycle tests of change using PDSA cycles as a format could be used as an alternate way of conducting  
37  
38 288 cognitive interviews. Each cycle tested the changes made to the questionnaire and allowed quick  
39  
40 289 and easy-to-test changes in subsequent versions of the questionnaire without increasing participant  
41  
42 290 burden within the cognitive interview sessions. Cognitive interviews are usually undertaken in  
43  
44 291 rounds, with several participants interviewed and changes to the questionnaire only made after  
45  
46 292 each round [11,12]. Problems in comprehension, recall or response choices to the questionnaire  
47  
48 293 items emerge from the interviews themselves [22] without the interviewer anticipating or having a  
49  
50 294 hypothesis of which items or layout in the questionnaire may require change. Using small tests for  
51  
52 295 change through PDSA cycles on the other hand, enabled better structuring of questionnaire items  
53  
54 296 with improved ease of comprehension, recall and response choices to items within this  
55  
56 297 questionnaire. Using PDSA cycles as a learning mechanism for cognitive interviews resulted in

1  
2  
3 298 predicting potential problems (what are we expecting to happen?) with questionnaire items and  
4  
5 299 layout; this allowed the authors to focus on potentially problematic items such as for example  
6  
7 300 questions on costs and freeing up carer time. Learning from each cognitive interview was used to  
8  
9 301 inform the modifications that need to be carried out to the questionnaire and changes to the  
10  
11 302 probing questions [27,29]. Making changes to the questionnaire after every cognitive interview as a  
12  
13 303 result, became easier to manage and learning from each cycle of the PDSA was applied to the next  
14  
15 304 [30,31]. Also, over the course of seven PDSA cycles, the think aloud interviews indicated potential  
16  
17 305 problems with a questionnaire item or instruction other than the ones that were considered  
18  
19 306 problematic, this unanticipated learning helped re-frame and retest the questionnaire until it was  
20  
21 307 satisfactory. Focussing on different items in the questionnaire and building up the testing helped  
22  
23 308 reduce fatigue among the participants and better insight into item comprehension, language used  
24  
25 309 and layout. Using PDSA cycles enabled rapid tests of change to questionnaire items, which not only  
26  
27 310 provided information on problems in a question but also its possible source(s), as well as  
28  
29 311 information toward the problem's solution.  
30  
31  
32  
33

34  
35 312 Advantage of using rapid cycle tests for change:  
36

37  
38 313 Unlike usual cognitive interviews, the use of rapid cycle tests of change in this questionnaire  
39  
40 314 development allowed the authors to test on as small a scale as possible before building confidence  
41  
42 315 and scaling up to test additional items in the questionnaire and with different devices and a paper  
43  
44 316 version. The authors decided to divide questionnaire items for cognitive interviews during the  
45  
46 317 planning phase into parts – instructions, questionnaire items, demographic data, and health related  
47  
48 318 quality of life questions for pragmatic reasons. Planning to anticipate problems with questionnaire  
49  
50 319 items this way and splitting the tasks into small manageable tests of change and increasing its  
51  
52 320 complexity over the course of the PDSA cycles helped maximise learning opportunities, decrease  
53  
54 321 costs and time taken to complete cognitive interviews and reduce participant fatigue and burden.  
55  
56 322 The PDSA cycles allowed the ability to break things down and focus on making small, measurable  
57  
58 323 changes [14,31]. Testing using a paper version, a laptop and a smart phone helped identify if  
59  
60

1  
2  
3 324 question wording communicates the objective of the question; and quickly identify problems such as  
4  
5 325 redundancy, missing skip instructions and awkward wording with only a few interviews, instead of  
6  
7 326 waiting for multiple participants in each round of interviews in the typical way cognitive interviews  
8  
9 327 are conducted. PDSAs are a clever learning methodology whose “simplicity belies its sophistication”  
10  
11 328 [15]; the use of iterative (PDSA) cycles for cognitive interviews provided information that would  
12  
13 329 otherwise have been unseen by the interviewer before launch of the survey - for example questions  
14  
15 330 on AT devices that are no longer being used by carers. The PDSA cycles also helped our learning  
16  
17 331 from unsolicited information such as the questionnaire could be self-administered instead of  
18  
19 332 interviewer administered.

20  
21  
22  
23 333 Cognitive interview is one component from a multitude of ways for pre-testing a questionnaire, to  
24  
25 334 assess it does collect the information that it is supposed to. Using rapid cycle tests for change  
26  
27 335 through PDSA cycles included planning and a researcher hypothesis of the difficulty of the various  
28  
29 336 questions in the questionnaire; this allowed rapid and iterative pre-testing of the questionnaire  
30  
31 337 without having to wait for multiple rounds of cognitive interviews before changes to the  
32  
33 338 questionnaire could be made and re-tested again. The use of PDSA cycles to inform cognitive  
34  
35 339 interviews in questionnaire development is another use for PDSAs and could be one way of pre-  
36  
37 340 testing questionnaires in the future.

#### 341 **Strengths and limitations of this study:**

342 The authors acknowledge that whilst cognitive interview methods can be used to evaluate existing  
343 questions, and to test proposed revisions to the original questions, they cannot provide quantitative  
344 evidence on whether the revised version of the question is better than the original, however the  
345 action in each PDSA cycle built on the learning from the previous cycle and we are confident that the  
346 final version of the CATEQ is better than the first draft. The authors also acknowledge that some  
347 participants were less articulate than others and could not adequately verbalise their thought  
348 processes, however a combination of think aloud and verbal probing interviews helped achieve the

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2  
3 349 intended aim for each PDSA cycle of improving instructions and comprehension, recall and  
4  
5 350 answering of items within the questionnaire.  
6  
7

8 351 **Conclusion:**  
9

10 352 The addition of cognitive interviews as an extra step in the survey development process assures data  
11  
12 353 that are more likely to reflect the actual circumstances being examined. The use of PDSA cycles to  
13  
14 354 frame the process of cognitive interviews would be an alternative way to pre-testing questionnaires  
15  
16 355 that minimises risks by using rapid small-scale tests of the changes introduced to layout and items in  
17  
18 356 the questionnaire as well as potentially helping reduce fatigue and burden to researchers and  
19  
20 357 participants. The PDSA process is widely used and familiar to many involved in health care and  
21  
22 358 appears to be an appropriate mechanism for pre-testing questionnaires before deploying them in  
23  
24 359 large scale surveys in healthcare.  
25  
26  
27

28 360 **List of abbreviations:**  
29

30  
31 361 AT – Assistive Technology  
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33 362 CATEQ – Carers Assistive Technology Experience Questionnaire  
34

35 363 PDSA – Plan Do Study Act cycles  
36  
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38 364  
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40 365 **Figures:**  
41

42 366 Figure 1: PDSA cycles and tasks involved in the cognitive interviews  
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Table 1: Participant characteristics

ID	Age Range	Gender	Ethnicity
1	56-70	Female	White British
2	56-70	Male	White British
3	40-55	Female	White British
4	40-55	Male	Asian British
5	71-85	Male	White British
6	56-70	Female	Caribbean British
7	40-55	Male	White British
8	40-55	Female	Mixed White British
9	40-55	Female	Asian British

Table 2: Table of changes to CATEQ from draft version 1 to draft version 7

	Questionnaire structure	Draft 1 of CATEQ	Draft 7 of CATEQ
1.	Instructions Line numbers: Paragraphs:	16 12	41 12
2.	Questions on Assistive Technology Questions on Previous Assistive Technology	9 0	10 5
3.	Matrix questions on experience and impact	21	20
4.	Demographic questions	0	9
5.	Health-related quality of life questions	0	15
6.	End of survey response line number	1	1 + research website details
7.	Layout and structure of questionnaire Colour scheme: Font Size:	Blue progress bar 12	Green progress bar 15

## Box 1: Cognitive interview guide

## Pre-interview:

Participant to re-receive the information sheet and asked to read it through. Participant will be given a brief introduction to the research that includes a description of Assistive Technology.

- Show University Card for ID of Researcher and introduce self
- Participant to be told what will happen during the interview process and reminded that the interview will also be audio recorded.
- Participant to be told that a transcript will be made from the audio recording.
- Participant to be told the method of analysis and reminded that they will remain anonymous, and that their data will be confidential.
- Participant given time to ask questions
- Participant will be asked to sign two copies of the consent form, one of which is to be retained by the researcher.

Instructions:

Based on our research, we have the following questions as part of the Carers Assistive Technology Experience Questionnaire. Please look at each page and the questions in this survey. During the interview, we will ask you to speak aloud about what you are thinking as you respond to questions. I am also going to ask you additional questions about individual items in this questionnaire. Remember, the purpose of this interview is to test the questionnaire and not to test you. Are you ready to begin?

We will start with the instructions for the survey:

Example verbal probes used to test the questions:

For Question abc....

1. What to you, is "....."?
2. Tell me more about "....."?
3. Can you repeat this question in your own words?
4. What does "....." mean to you?
5. Would you mind providing some examples about "...."?
6. When you think about "....." what comes to your mind?

Overall for the survey....

7. Are there additional questions you believe should be asked?
8. Are there questions you believe should be deleted?
9. Are there questions you believe should be modified?
10. Are there words used in the questions that you think could be changed to make it more understandable to others who help/look after those with dementia?

Do you have any questions for me?

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3 **1 Declarations:**  
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6 **2 Ethics approval:**  
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8  
9 **3** This study was granted ethical approval by the University of Oxford Central University Research  
10  
11 **4** Ethics Committee (Reference number: R57703/RE001).  
12

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15 **5 Patient consent for publication:**  
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18 **6** Not required  
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21 **7 Competing interests:**  
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23  
24 **8** The authors declare that they do not have any competing interests.  
25

26  
27 **9 Funding:**  
28

29  
30 **10** This research is part of a DPhil in Population Health at the University of Oxford and received no  
31  
32 **11** specific grant from any funding agency in the public, commercial or not-for-profit sectors.  
33

34  
35 **12 Authors' contributions:**  
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37  
38 **13** VS, CJ and MP conceived the design of the study. VS completed the cognitive interviews and PDSA  
39  
40 **14** cycles templates. VS, MP and CJ discussed emerging issues and agreed final changes to each version  
41  
42 **15** of the questionnaire. VS drafted this version of the manuscript with critical revision and input from  
43  
44 **16** MP and CJ. All authors have read and given approval for this version. VS is the guarantor of the  
45  
46 **17** manuscript.  
47

48  
49  
50 **18 Acknowledgements:**  
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52  
53 **19** Authors would like to acknowledge support from the three members of the patient and public  
54  
55 **20** engagement and involvement group set up as part of the carers' experience of assistive technology  
56  
57 **21** use in dementia study, for their comments on the questionnaire. We also acknowledge the  
58  
59 **22** contributions of all the participants in this study for their time and invaluable insight into developing  
60

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2  
3 23 this questionnaire. The authors acknowledge the constructive comments from Dr Sushmitha

4  
5 24 Mohapatra and Mr Wayne Scott for their initial comments on the items in the questionnaire.

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8 25 Authors' information:

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10  
11 26 VS is a postgraduate student registered for his DPhil at the University of Oxford exploring informal

12  
13 27 carers' experience of assistive technology use in dementia. VS is an Occupational Therapist and is

14  
15 28 trained in interviews and qualitative research methods as part of his clinical training and Masters in

16  
17 29 Evidence Based Healthcare course from the University of Oxford. VS is also a quality improvement

18  
19 30 expert and teaches and develops training packages including PDSA methodology for improving

20  
21 31 quality of care for patient benefit. MP is an Associate Professor within the Health Services Research

22  
23 32 Unit (HSRU), Nuffield Department of Population Health, University of Oxford. CJ is Professor of

24  
25 33 Health Services Research and Director of the HSRU, Nuffield Department of Population Health,

26  
27 34 University of Oxford. MP and CJ have extensive experience in qualitative research methods and are

28  
29 35 joint supervisors of VS for the DPhil.

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34 36 Data sharing statement:

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36 37 The datasets generated during the study are available from the corresponding author on reasonable

37  
38 38 request.

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For peer review only

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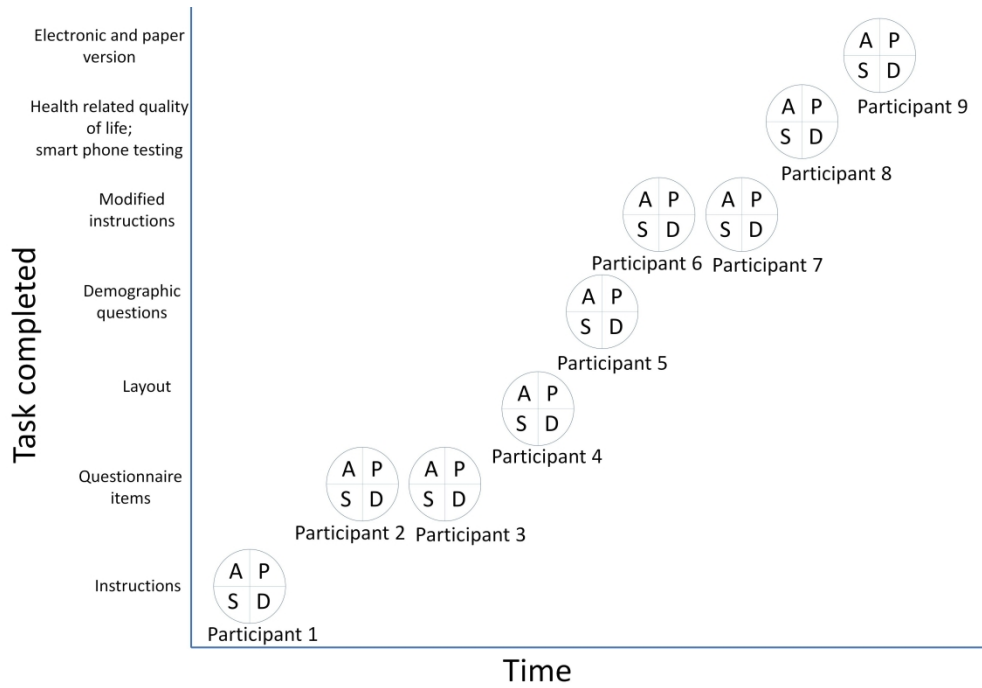


Figure 1: PDSA cycles and tasks involved in the cognitive interviews

PDSA cycles and tasks involved in the cognitive interviews. Each cycle shows the focused section of the questionnaire that participants were asked to comment on.

1172x834mm (96 x 96 DPI)



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## Developing the Carers Assistive Technology Experience Questionnaire

### PARTICIPANT INFORMATION SHEET

Ethics Approval Reference: R57703/RE001

#### 1. **What is the purpose of this study?**

Dementia describes a set of symptoms that may include memory loss and difficulties with thinking, problem solving or language. Caring for a person with dementia can be demanding for informal carers (family, friends and neighbours) and can affect their mental and physical health and their social lives. **Assistive Technology (AT)** devices are often electronic. They include talking clocks, electronic medication dispensers, smart gas meters, falls and motion detectors and door exit alarms. While Assistive Technology is usually aimed at helping the person with dementia, these may also have an impact on carers. Due to the thinking and problem-solving difficulties of the person with dementia, the carer may need to be an active user of the Assistive Technology. It is not yet clear what positive or negative effects such technology may have on carers and there is little information on their experience with its use.

#### Purpose of this research:

Using themes from existing research studies and interviews with carers, researchers from the Nuffield Department of Population Health, University of Oxford, have developed a Carers' Assistive Technology Experience Questionnaire for use with informal carers (family, friends and neighbours) who support and help persons with dementia at home.

To refine and understand, if the questions in this questionnaire measure what it is intended for and if carers understand and correctly interpret the questions, we want to carry out *cognitive interviews* with a sample of carers of persons with dementia who have used assistive technology.

The cognitive interviews will explore your interpretation and understanding of the survey questions within this questionnaire to identify errors and problems with the questionnaire before it is used in a survey.

#### 2. **Why have I been invited to take part?**

You have been invited because you are over 18 years of age and a family member/friend/neighbour of a person with dementia.

To participate in the study, you need to be

- Looking after or supporting a person with dementia who has used at least one electronic AT device (such as those described above) at home within the past year.

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5 **3. Do I have to take part?**

6 No, your participation is voluntary. You can ask questions about the study before deciding whether  
7 to take part. If you agree to take part, you may withdraw from the study at any time, without any  
8 penalty and without giving a reason. If you choose to withdraw after the interview, the research  
9 team will delete any data including personal information and interview recordings and transcripts,  
10 and it will not be used in the analysis.  
11

12  
13  
14 **4. What will happen if I take part in the study?**

15 By taking part in this interview, you are helping us evaluate how easy or difficult the questions in the  
16 Carers Assistive Technology Experience Questionnaire are to understand and answer. If you are  
17 happy to take part, you will be asked to answer questions in an informal interview, like a  
18 conversation. The interview questions will ask you about your understanding of the survey  
19 questions, your views on any missing information from the questionnaire and if the questionnaire is  
20 user-friendly and comments on the visual appearance and layout of the questionnaire.  
21

22  
23 The interview will be audio recorded to allow for us to type up your answers. You will never be  
24 identified by any of your personal information.

25 The interview will take approximately 60-90 minutes and will take place at your home, your place of  
26 work, by telephone or at the University of Oxford. The interview location and time will be arranged  
27 in discussion with you, to suit your convenience and preference. The interviews will be conducted by  
28 Mr Vimal Sriram, a doctoral student at the University of Oxford.  
29

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33 **5. Are there any potential risks in taking part?**

34 The questions asked during the interview may be personal and occasionally some people feel upset  
35 when asked to think about their experiences of looking after a person with dementia. You do not  
36 have to answer any question that you would prefer not to answer. If you become upset at any point,  
37 the researcher will ask you if you wish to pause or stop the interview. You could then: stop and  
38 withdraw your data (the interview recording would be deleted), end the interview and allow the  
39 interview recording until that point to be used in the research, or carry on with the interview when  
40 you are ready.  
41

42 The researcher can also provide you with an information sheet which contains a list of organisations  
43 who you can get in touch with if you feel the need for further support.  
44

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46  
47 **6. Are there any benefits in taking part?**

48 You will not receive any direct benefit by taking part in this study. However, the information gained  
49 in this research study will improve the survey questionnaire and subsequently provide a better  
50 understanding and insight of carers' experiences of using assistive technology.  
51

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54 **7. What happens to my data?**

55 The **research data** will be stored and examined using University approved software.

56 Any information that you may have given in the interview that could identify you will be removed  
57 from the interview before it is analysed. Confidentiality will be maintained throughout this research  
58 study. If you consent to take part in this study, you will be required to sign an informed consent  
59 form. To protect your identity, your name will be replaced by a pseudonym in any research reports.  
60

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2  
3 Any identifying information like your name, details or other personal information will not be used or  
4 disclosed to anyone outside, to any third party or appear on any transcripts, thesis, publications or  
5 on any academic paper.  
6  
7

8 However, there might be certain circumstances in which it may be necessary to breach this  
9 confidentiality and disclose information to a third party. This includes situations when someone  
10 provides information during the study that raises serious concern about:

- 11 - Intention to harm themselves or other people
  - 12 - Risk to the health, welfare or safety of vulnerable adults such as someone with dementia
  - 13 - Disclosure of a criminal offence
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17 The researcher will discuss this issue with you before telling anyone else. The researcher will be  
18 obliged to share this evidence with his supervisors, who may advise that further action is taken.  
19

20 Personal / sensitive information such as your name, age, gender, marital status, employment status,  
21 telephone number or address details in case of face-face interviews will be stored confidentially  
22 using computer software that does not allow anyone else except the researcher and his supervisors  
23 access to your data. All paper forms will be stored in a locked cupboard within the Department of  
24 Population Health, University of Oxford. Your personal/sensitive data, including your signed consent  
25 forms will be kept separately from audio recordings and transcripts from your interviews. Your  
26 answers may be quoted directly in the research publication with information suitably anonymised.  
27 All audio recordings will be erased permanently once they have been transcribed.

28 All research data and records will be stored for a minimum retention period of 3 years after  
29 publication or public release of the work of the research.  
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#### 34 **8. Will the research be published?**

35 The research will be written up as a doctoral thesis. On successful submission of the thesis, it will be  
36 deposited both in print and online in the University archives, to facilitate its use in future research.  
37 The thesis will be published open access.  
38

39 Additionally, the research may be published in academic journals and presented in national and  
40 international conferences. The University of Oxford is committed to the dissemination of its  
41 research for the benefit of society and the economy and, in support of this commitment, has  
42 established an online archive of research materials. This archive includes digital copies of student  
43 theses successfully submitted as part of a University of Oxford postgraduate degree programme.  
44 Holding the archive online gives easy access for researchers to the full text of freely available theses,  
45 thereby increasing the likely impact and use of that research.  
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#### 49 **9. Who is organising and funding the research?**

50 This study is being carried out as part of the DPhil (PhD) Programme in Population Health at the  
51 Nuffield Department of Population Health, University of Oxford.  
52

#### 53 **10. Who has reviewed this study?**

54 This study has been reviewed by, and received ethics clearance through, the University of Oxford  
55 Central University Research Ethics Committee (Reference number: R57703/RE001).  
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#### 58 **11. Data Protection:**

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3 The University of Oxford is the data controller with respect to your personal data, and as such will  
4 determine how your personal data is used in the study. The University will process your personal  
5 data for the purpose of the research outlined above. Research is a task that we perform in the  
6 public interest. Further information about your rights with respect to your personal data is available  
7 from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.”  
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10  
11 **12. Who do I contact if I have a concern about the study or I wish to complain?**

12 If you have a concern about any aspect of this study, you can contact me through an email at  
13 [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk) or by telephone on 01865 743762 or my supervisors Dr Michele Peters  
14 ([michele.peters@dph.ox.ac.uk](mailto:michele.peters@dph.ox.ac.uk)) or by telephone on 01865 289428 or Professor Crispin Jenkinson  
15 ([crispin.jenkinson@dph.ox.ac.uk](mailto:crispin.jenkinson@dph.ox.ac.uk)) or by telephone on 01865 289441, who will do their best to  
16 answer your query. We will acknowledge your concern within 10 working days and give you an  
17 indication of how we intend to deal with it. If you remain unhappy or wish to make a formal  
18 complaint, please contact the chair of the Research Ethics Committee at the University of Oxford  
19 who will seek to resolve the matter in a reasonably expeditious manner:  
20 Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk);  
21 Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD  
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26 **13. Further Information and Contact Details**

27 The interviews for this researcher study will be carried out by Mr. Vimal Sriram (Doctoral student)  
28 from the Nuffield Department of Population Health, University of Oxford. The researcher will  
29 identify himself to you using a University of Oxford student card.  
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41 If you would like to discuss the research with someone beforehand (or if you have questions  
42 afterwards), please contact:  
43  
44

45 Mr. Vimal Sriram  
46 Nuffield Department of Population Health  
47 Health Services Research Unit  
48 Richard Doll Building, Old Road Campus, Oxford OX3 7LF  
49 Telephone number: 01865 743762  
50 E-mail: [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk)  
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54 **Thank you for taking the time to read this information sheet.**  
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## CATEQ Cognitive Interview

## Worksheet for Testing Change- PDSA Cycle 1

**Aim:** To test items in the CATEQ for understandability, response choice and layout

Every goal will require multiple small tests of change

Describe your first (or next) test of change	Person Responsible	When to be done	Where to be done
Complete cognitive interview with participant 1	VS	14.11.2019	Participant 1's home

List the task needed to set up this test of change	Person Responsible	When to be done	Where to be done
<ol style="list-style-type: none"> <li>1. Test comprehension of initial instructions</li> <li>2. Test eligibility criteria listed</li> <li>3. Test layout and format for informed consent statement</li> <li>4. Test layout and instructions of willingness to participate in part 3 interviews</li> <li>5. Test layout and instructions of end of survey statement</li> <li>6. Test items 1-29</li> </ol>	VS	14.11.2019	Participant 1's home.

Predict what will happen when the next test is carried out	Measures to determine if predictions accurate
<ol style="list-style-type: none"> <li>1. Participant 1 will be able to comprehend all initial instructions in the CATEQ (time: 3 minutes) and will agree with layout.</li> <li>2. Participant 1 will agree with the eligibility criteria as listed out (time: 1 minute)</li> <li>3. Participant 1 will agree with layout and format of informed consent statement</li> <li>4. Participant 1 will agree with layout and instructions for the willingness to participate in part 3 interviews</li> </ol>	<ol style="list-style-type: none"> <li>1. Time taken to read through the instructions; Able to understand the instructions on verbal probing.</li> <li>2. Time taken to read through the eligibility criteria; On verbal probing able to answer that the eligibility criteria listed is comprehensible.</li> <li>3. On verbal probing, able to inform layout and format of informed consent statement is simple and easy to answer.</li> <li>4. On verbal probing, able to inform that the layout and instructions for the willingness to participate in part 3 interviews is simple and easy to</li> </ol>

## CATEQ Cognitive Interview

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<p>5. Participant 1 will agree with layout and instructions at the end of the survey.</p> <p>6. Participant 1 will be able to comprehend, retrieve and answer questionnaire items 1-23</p>	<p>answer.</p> <p>5. On verbal probing, able to inform that the layout and instructions for the end of survey message is simple and easy to answer.</p> <p>6. On concurrent think-aloud exercise, able answer questions as comprehensible, easy to retrieve answers to. On verbal probing able to inform if response choices of the items are adequate.</p>
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**Do** Describe what actually happened when you ran the test

Completed cognitive interview with audio recording at participant's home with informed consent. Used concurrent verbal probing for instructions, eligibility criteria, consent statement, participation in further interviews and the end of survey statement. Think aloud method used for items 1-29 to record understanding, retrieval of information and answering questions plus verbal probing about response choice for these items.

Time taken to complete each section was noted and verbal prompting and their responses were also noted in field notes using a paper copy of the CATEQ to concurrently record comprehension, retrieval and use of information.

**Study** Describe the measured results and how they compared to the predictions

Total time taken for the interview was 70 minutes.

1. Time taken to complete reading instructions was 90 seconds. Participant 1 indicated that the instructions about the questionnaire and approximate time that it would take to complete the questionnaire was useful. Commented that the font size could be slightly bigger and the instructions could be further spaced to allow for easier reading.
2. Participant 1 understood the eligibility criteria and took 30 seconds to read this through and did not recommend any changes.
3. Participant 1 understood the informed consent statement and did not recommend any changes.
4. Participant 1 understood the instructions for willingness to participate in further interviews section of the CATEQ, recommended using email address and/or telephone number to be added to the instructions.

## CATEQ Cognitive Interview

5. Participant 1 understood and agreed with the layout and final instructions at the end of survey and did not recommend any changes.

6. Think aloud exercise for questions 1-29 – easy to understand instructions and liked the “other” option for free text questions. Participant 1 had difficulty sorting through AT devices no longer being used.

**Act** Describe what modifications to the plan will be made for the next cycle

Make changes to the font and layout of the initial instructions. Add questions and clarify in instructions about AT used in the past and no longer in current use. Test entire CATEQ item list on participant 2.

## COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
<b>Domain 1: Research team and reflexivity</b>			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
<b>Domain 2: Study design</b>			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	



Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
<b>Domain 3: analysis and findings</b>			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

**Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.**