The item pool for a needs-based measure of quality of life of carers of a family member with dementia

**Development of an item pool for a needs-based measure of quality of life of carers of a family member with dementia**

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Acknowledgements

We would like to acknowledge the input of our co-investigator colleagues: Dr Zoe Hoare, University of Bangor, Professor Paul Kind, University of Leeds, Emeritus Professor Alan Tennant, University of Leeds, as well as advice and help with recruitment from Carers Leeds and the Alzheimer’s Society. We would also like to thank all those carers who participated.

Compliance with ethical standards

Jan Oyebode, Penny Wright, Simon Pini, Mike Horton, each declare that this work was supported by the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). Grant title: HQLC Dementia Carers Instrument Development: DECIDE (MR/M025179/1) and that the grant is registered on the UK Research and Innovation Gateway: http://gtr.ukri.org/projects?ref=MR/M025179/1. They also declare that they have received financial support for travel to meetings for the study, manuscript preparation or other purposes from the grant funder as part of the award only. In addition, Penny Wright has declared that she is the principal investigator and was the main applicant for the funding that was received from the MRC and NIHR, and Jan Oyebode has declared her position as a co-investigator. The following authors have no conflicts of interest to declare: Emma Ingleson, Molly Megson, Linda Clare, Hareth Al-Janabi, Carol Brayne.

All authors contributed to the overall study design and reviewed and approved the paper. MM, EI and SP collected the data and contributed to analysis. JO wrote the paper with help from PW and SP.

Ethical approval was given in November 2015 by a UK National Health Service ethics committee. Informed consent was obtained from all individual participants included in the study.
Abstract

Purpose
This paper describes the development of an item pool for a needs-based self-report outcome measure of the impact of caring for a relative, friend or neighbour with dementia on carer quality of life. The aims are to give a detailed account of the steps involved and describe the resulting item pool.

Methods
Seven steps were followed: generation of an initial item set drawing on 42 needs-led interviews with carers, a content and face validity check, assessment of psychometric potential, testing of response formats, pre-testing through cognitive interviews with 22 carers, administration rehearsal with 2 carers, and final review.

Results
An initial set of 99 items was refined to a pool of 70 to be answered using a binary response format. Items were excluded due to overlap with others, ceiling effects, ambiguity, dependency on function of the person with dementia or two-part phrasing. Items retained covered a breadth of areas of impact of caring and were understandable and acceptable to respondents.

Conclusions
The resulting dementia-carer specific item pool reflects the accounts of a diverse sample of those who provide care for a person with dementia, allowing them to define the nature of the impact on their lives and resulting in a valid acceptable set of items.

Key Points for Decision Makers

- Dementia, and interventions for dementia, affect not only the patient but also family carers and therefore clinical decision-making needs to be informed by impacts on carers’ quality of life as well as that of patients.
- The needs-based approach, used in this study, is a valuable person-centred approach on which to base measures of quality of life. The approach suggests that a person’s quality of life is affected by a condition insofar as that condition affects the person’s ability to fulfil his or her needs.
- Between establishing needs and developing a carer-reported measure of quality of life come several steps that must be rigorously followed if a valid and useful measure is to be developed. This paper describes these steps.
1 Introduction

Despite evidence to suggest decline in the incidence of dementia in Europe, there is a likelihood that overall prevalence will remain relatively static as the population ages [1]. In the UK it is estimated that by 2025 over one million people will be living with dementia [2]. Most are supported by informal carers, those who provide care for a relative, friend or neighbour, who cannot cope without their support [2,3]. Carers are estimated to contribute annually the equivalent of between £1.34 billion [4] and £13.2 billion [5] worth of unpaid hours of care in the UK alone. Therefore, maintaining carer quality of life (QoL) is not only important for individual carers and those cared for, but also for society.

In this context, an increasing number of interventions are aimed at improving quality of life of dementia carers [6], however there is no single widely accepted measure of dementia carers’ quality of life. Self-reported outcome (SRO) measures for QoL must be ‘fit for purpose’ both in terms of their descriptive system (defining relevant content) and their corresponding valuation system (psychometric and econometric). They may be uni- or multi-dimensional. The advantage of a multi-dimensional measure is that more than one ‘construct’ can be evaluated, thereby offering a ‘profile’ which may be useful in economic evaluation. However, they tend to be longer and therefore more burdensome to complete than uni-dimensional measures. If the final item set is intended to be brief, the precision and responsiveness of a unidimensional measure will be maintained but likely reduced for a multidimensional measure. From the large number of varied SROs available to assess aspects of dementia carer QoL there is no agreement about which, if any, delivers the standards required across both the descriptive and valuation systems [7-10]. A recent review of outcome measures, including of QoL [8], identified 32 QoL measures that had been used in dementia carer research. The four most commonly used were the Short Form-36 [11], the EuroQoL (EQ-5D) [12], the World Health Organisation Quality of Life – Bref (WHOQOL-BREF) [13] and the Health Utilities Index Mark [14], none of which is specific to dementia carers. The authors recommend instruments specific to dementia carers should be used in outcome research alongside generic measures due to their greater sensitivity to specific changes. A systematic review [7] adhering to COSMIN methodology [15] identified ten measures used with dementia carer samples. Three of these measures were developed specifically for dementia carers, but two lacked evidence to recommend use [16,17] The third, Impact of Alzheimer Disease on Caregiver Questionnaire [18], is a unidimensional scale with fair to excellent psychometric qualities. However, further evaluation was advised including extending the sample to an older age group and to include carers of those with dementia other than Alzheimer’s disease.

The CarerQoL [19] was specifically developed to measure care-related, rather than health-related or general, QoL in economic evaluations. It aims to capture a description of the caring situation through the use of seven questions reflecting dimensions found in pre-existing scales of carer burden, as well as providing an index of valuation on a visual analogue scale. The scale’s applicability to dementia carers is untested as it has not been specifically used in dementia care studies. The initial validation sample [19] was heterogeneous, including a substantial proportion (28%) of parents, who would be highly unlikely to be carers for those with dementia. A later study of the scale’s psychometric properties [20] involved carers of older people. However, care recipients’
The item pool for a needs-based measure of quality of life of carers of a family member with dementia conditions were unspecified and generalisability is limited as all were in receipt of care from a single long-term care facility in the Netherlands, 74% being resident there.

In response to the lack of suitable measures, in 2014, the British Medical Research Council (MRC), called for research to design a new measure of quality of life of dementia carers to be developed inductively, within a conceptual framework and using gold standard psychometric techniques. In this paper, we report on development of an item pool for a new SRO measure of dementia carer quality of life, conducted as part of the Dementia Carers Instrument Development (DECIDE) study, which was funded through the MRC call.

The conceptual framework adopted was the needs-based approach. This was identified as suitable for our task, as it is fully inductive, positioning the lived experiences of the target population as central to measure development, rather than generating items from previous research. The needs-based approach sees QoL as being attained to the degree to which a person is able to fulfil his or her human needs [21,22]. Caring for someone with dementia has far-reaching effects and therefore can affect needs fulfilment and QoL. Even though the majority of carers gain satisfaction and many experience a sense of mastery or fulfilment [23], the tasks involved may lead to fatigue and financial consequences, and detract from time for work, sleep, leisure, and other relationships [24]. Almost 75% of carers report grieving for lost aspects of their relationship [25,26], 20-33% report clinically significant depression [27,28] and 61% report their health has suffered [29]. Consistent with needs-based theory, needs-based measures [e.g. 30-32] are concerned with the ways that a person’s life is affected by a condition, that is, they focus on the outcome (QoL) rather than condition-related influences on QoL, as might be the case for health-related quality of life measures [33]. The gold standard steps for development of a needs-based quality of life SRO measure include four phases: qualitative interviews, item generation, formatting (nature of item statements, number of response options) and field testing (for face and content validity) [34]. These are followed by assessment of psychometric properties These steps concur with those generally recommended in modern psychometrics [35]. However, it is noted that, in many papers, little detail is given of the individual development steps. This paper provides an account of the development of the item pool for a new needs-based SRO measure (or measures) of the impact of caring for a relative with dementia on carer QoL. The new scale(s) is named SIDECAR (Scales measuring the Impact of DEmentia on CARers) and this title is used in the text that follows. In focusing on the early stages of development, our aims are two-fold: to describe the development of the item pool and to give insight into the development process.

2 Method

2.1 Procedure

Ethical approval for the study was given in November 2015 by a UK National Health Service ethics committee. Following this, a number of developmental steps were followed, consistent with the four steps described by Hunt and McKenna [34], outlined above. The process was adapted in three ways: (i) to include two iterations of validity testing, (ii) to separate item generation into item generation and item reduction, (iii) to add a step of field-testing for acceptability and feasibility. Each step, its purpose and the method used are outlined in figure 1.
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and more detail is given below. Informed consent was obtained from all participants in the study. The grant is registered on the UK Research and Innovation Gateway: http://gtr.ukri.org/projects?ref=MR/M025179/1

2.2 Qualitative interviews
Semi-structured interviews, designed to elicit ways that caring impacted upon carers’ lives, were conducted with carers supporting a relative with dementia in the community. Carers needed to be aged 16 years or older, have capacity to consent and be able to understand English. Purposive sampling was used to ensure variation in age, ethnicity, gender, relationship to person with dementia, rurality, and co-residence with person cared-for. Participants were recruited from an NHS organisation (Bradford District Care NHS Foundation Trust), two charitable organisations (Carers Leeds: a local organisation supporting carers; the Alzheimer’s Society: the major UK national charity for dementia) and through participants passing on the project details to other carers known to them. An initial approach was made by a person from a recruiting organisation involved in potential participants’ support, or they responded directly to the research team using contact details displayed on fliers. A member of the research team then contacted the prospective participant to check eligibility, provide further information, answer questions and arrange a time to visit, take consent and interview. Interviewees could be seen at home or in a service-based setting. The interviews, which were audio-recorded, focused on finding out about the ways that caring impacted on quality of life by asking about rewarding and challenging experiences of caring and related thoughts, feelings and experiences. (The semi-structured interview schedule can be seen in openly available material supplementary to Pini et al. [36]). Recordings were professionally transcribed, then safely deleted and personal details in transcripts were changed to protect confidentiality.

2.3 Generation of initial item set
Anonymised transcripts from the qualitative interviews were used to generate the initial item set. Each transcript was examined by one of the research team (SP, EI, MM), who extracted all phrases used by carers to describe the impact of caring on their lives, with a view to comprehensively capturing key areas. A second member of the team checked this process for reliability across 10 transcripts. To enable the process of linking from key phrases to items, the researchers (SP, JO, PW, EI) grouped those with similar content together, using N-Vivo software [37] to manage the data. This provided an easy overview of excerpts that reflected similar impacts. Phrases were then embedded in first person and current tense, to create draft items which drew on the words and expressions used by the participants (see table 1). Pros and cons of including both positively and negatively worded items were discussed within the wider research team and project advisory board. There were measurement advantages, from psychometric and valuation perspectives, from all items being posed in the same direction but from a clinical and carer perspective it was felt important to include positively as well as negatively directed items should these appear in the interview scripts. The trade-off of direct carer experience, against potential impact on the measurement properties, was considered worthwhile, in order to accentuate the truest reflection of carer experience and ensure that carers could relate to the items.
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2.4 Initial content and face validity check
Suggestions to improve comprehension, ambiguity and relevance of the items were put forward by the core research team (SP, PW, JO, EI), the wider research team (MH, LC, HA-J), two carer consultants to the project and a project partner (Carers Leeds: a local organisation supporting carers). The two carer consultants had been invited to become study consultants by Carers Leeds in recognition of their potential to contribute an ‘expert-by-experience’ perspective. Suggestions were reviewed and discussed by the core research team and consensus reached on any changes.

In parallel with generation of the item pool, the researchers also conducted a separate thematic analysis [38] of the qualitative interviews to derive a needs-led framework of the impact of dementia care upon fulfilment of carers’ needs. This was not conducted to inform scale development, but was a separate piece of work, fully described elsewhere [36]. The framework was iteratively developed with the final version capturing the way caring impacted on the fulfilment of nine needs: Being a carer impacts on fulfilling my need to feel in control of my life; to feel close to the person I care for; to be my own person; to feel connected to the people around me; to take care of myself; for freedom; to protect the person I care for; to get things done and to share/express my thoughts and feelings. There were two useful points of connection between the thematic analysis and the item development (see here and 2.8 below). At this stage we checked the items for spread against the themes of the needs-led framework. This enabled us to be more confident that the item pool comprehensively reflected all key areas of impact of caring on quality of life (see table 1).

2.5 Item reduction 1
In order to maximise the measurement range of the item set, we aimed for the item pool to include some items that were likely to be endorsed by almost every carer, some that very few carers would endorse and some likely to fall at each step between these extremes. To do this, we placed each item on a hypothetical ‘ruler’ of carers’ needs-based quality of life. Placement was informed by (i) the frequency with which content of an item had been mentioned across the qualitative interviews, (ii) whether the item content had been mentioned across the diversity of carers who had been interviewed and (iii) the comments made by the carer consultants.

2.6 Field-testing for content and face validity and response format
2.6.1 Participants for cognitive interviews
Cognitive interviews [39] were used to field test the items. Participants were purposively recruited to ensure variation by age and education, known to affect test performance [40], and ethnicity (white British, black British, South Asian) to reflect major ethnic groups in the UK population since this affects language use and acceptability. To meet the requirements of the purposive sampling strategy we aimed to recruit up to 24 participants. It has been found that the chance of identifying significant problems with items decreases with the
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sample size [41]. Our anticipated sample size was larger than the number of 5-15 recently recommended [42] giving confidence that we would have sufficient to identify any major issues. We aimed for roughly equal numbers of participants new to the study and participants who had taken part in the earlier qualitative interviews. Inclusion of the latter group allowed some cognitive interviewees to comment on whether or not the item pool reflected issues they had spoken about at interview, a strategy that adds to content validity [43]. Carers were eligible if they were aged over 16 years and cared for a relative with a diagnosis of dementia and were recruited through the three organisations described in 2.2 above.

2.6.2 Procedure for cognitive interviews
The cognitive interviews involved each participant reading out each item and describing aloud the thought process leading to their answer. The aim was to give the researchers insight into the way each item was understood [39], considering four issues related to each question (ease of understanding, clarity of meaning, perceived usefulness, ability to use a Yes/No response format). A sheet was used for the interviewer to enter a tick or cross for each of these four attributes for each question, as well as offering space to note participants’ comments or suggestions for re-wording. While these potential sources of confusion were predefined, probes were spontaneous dependent on the reaction of the participant rather than scripted [42]. We anticipated that the full set of items drawn from the interviews might be considerable and therefore adopted a strategy to keep burden manageable: Items would be divided into three groups reflecting those judged to be most straightforward, intermediate and most contentious in terms of comprehension and sensitivity of subject matter. All cognitive interviewees would complete the most problematic items, as it was important to have full feedback on these. The ‘straightforward’ items would be divided into sub-sets with half the interviewees completing one sub-set and the other half completing the alternative sub-set. The medium complexity items would be divided into three subsets, with a third of the cognitive interviewees completing each subset. In summary, items anticipated as more straightforward or of medium complexity would be completed by fewer participants.

In addition, at this stage, response formats were considered. Binary and Likert formats were considered by the research team: a 4-option Likert scale (Strongly Agree – Strongly Disagree) would produce more information since these contain more measurement points than a dichotomous format. On the other hand, a binary format (Yes/No) would produce scores that would be more reliable, as they would be less susceptible to variable interpretation by the respondents of the boundaries between the response options. A binary format would also maintain consistency with disease-specific quality of life scales that have followed the needs-led approach [30-33] and would transfer more readily for valuation aspects of the study. As there were pros and cons to each format and as it was crucial for carers to be able and willing to respond to items, it was decided to make a final decision based on user preferences. Each participant in the cognitive interviews was therefore invited to answer 12 items using both a binary format and a Likert scale and was asked which format they preferred. Sequence of presentation of the formats was alternated between participants to minimise any order effects.

2.7 Administration, acceptability and feasibility testing
Instructions for administration were drafted by two researchers (SP, JO) and agreed across the core research team and with the carer consultants. Following this, two rehearsal interviews were conducted in which two new
The item pool for a needs-based measure of quality of life of carers of a family member with dementia participants completed the entire item pool, reading the instructions and completing the items without interruption to test for overall coherence and timing.

2.8 Item reduction 2
A final review by the research team was undertaken with the aim of reducing the item pool to a maximum of 70; a number considered by our carer advisors and carer consultants as an acceptable length for larger scale testing. To inform item removal, the team considered: (i) cognitive interview feedback (to remove any items with persisting ambiguity and those where responses appeared heavily dependent on external factors); (ii) spread of items (to retain items related to all nine themes of the thematic analysis); (iii) inter-item correlations (to reduce redundancy from overlap); (iv) ceiling and floor effects (where all respondents endorsed/or did not endorse the item); and (v) removal of any two-part items.

3 Results
Key demographic characteristics of the qualitative interview sample are shown in table 2. In addition, the sample had been caring an average of 54 months (range 5-180), 33 were co-resident with the person cared for, diagnoses of those cared for were Alzheimer’s disease (18), vascular dementia (13), other dementia (9), type not known (2). Twelve of the people with dementia could not be left alone, 24 could be alone for up to half a day and seven for a whole day. Forty-one carers were interviewed at home and one at their place of work. Interviews lasted on average 77 minutes (range 23-150).

Ninety-nine potential items were generated from the transcripts, with every aspect of the thematic framework represented. In addition to embedding expressions used by carers themselves in the items, as intended, words were paraphrased where an expression was colloquial and might not be widely understood. In addition, Some items were added which voiced implied but unsaid issues that may have been taboo to be mentioned more openly by interviewees. As a result of the initial content and face validity check, 15 items were reworded to improve general clarity, for example, paraphrasing participants’ words to circumvent colloquialisms; one two-part question was split into its two component parts; three items were collapsed into one (“I have been given clear information about support available to me as a carer”); and 5 items were added reflecting implied but unsaid issues (e.g. “I fear what might happen if I am honest with services.” “I often lose my temper with the person I care for.”). The revised item pool now had 103 items. Placing the 103 potential items on the hypothetical ‘ruler’ resulted in 11 items being removed (item pool now 92). Checking the distribution across the nine themes of the needs-led framework revealed that there was still at least one item in the pool linked with each theme.

Following this initial preparation, the items were tested across twenty-two carers who participated in cognitive interviews. Ten were new to the study and twelve had taken part in the initial qualitative interviews. (See table 2 for sociodemographic details).
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Following the strategy outlined in 2.6.2, two of the research team (JO, SP) met to assign items to the problematic, straightforward or intermediate categories. Judgements were informed by subject matter (e.g. “The stresses of caring make me think about harming myself”), possible difficulty in comprehension (e.g. “Receiving help is more hassle than it is worth”) and items where it had been difficult to capture a particular experience succinctly (e.g. “Having to trick the person I care for into doing things makes me feel bad”). Twenty-eight of the items were judged ‘straightforward’, 16 likely to be problematic and 48 as intermediate. All 22 cognitive interviewees were presented with 46 of the 92 items (16 problematic, 14 straightforward, 16 intermediate). Every item was responded to by at least 7 interviewees and items anticipated as more straightforward or intermediate were completed by fewer participants.

Following the first eight cognitive interviews the research team reviewed the feedback. It was noted that the “Yes/No” response format was creating ambiguity in responses to some questions. For example, both Yes and No appeared to endorse the item “I am not in control of my emotions” (“Yes, I am not in control” and “No, I am not in control”). To solve this, the response wording was changed to “Agree/Disagree”. (“I agree with ‘I am not in control’ ” vs “I disagree with ‘I am not in control’ ”). Changes to wording were also considered if more than one respondent highlighted a similar problem with an item. This resulted in three items being reworded.

Following a further eight interviews the research team again reviewed the responses. One item was removed because it caused confusion and could not be adequately reworded; six items were reworded; and two were changed from single items for friends/family into separate items for friends and family respectively. Finally, six further interviews were conducted, resulting in one more item being removed and another reworded. As we had covered key attributes outlined in the purposive sampling strategy and no new issues were raised in interviews 21 and 22, recruitment ceased at this point.

This resulted in an item pool of 92 items, all of which were acceptable to the participants. The binary response format was adopted in accordance with the majority view (14/22 respondent), in keeping with other needs-based QoL measures [19-21], and maximising fit with later aspects of the study.

Two rehearsal interviews were conducted with two new participants (white British female spousal carers, aged 65 years +, who had left school at the minimum leaving age, one from an urban and one from a rural area). Neither participant found it difficult or distressing to complete the entire item pool. Both completed the vast majority of items without asking for extra information or clarification (2 and 4 queries respectively). Finally, twenty-two items were removed to reduce the item pool from 92 to 70 items. Reasons for removal of items were: redundancy due to overlap (7), ceiling effects (2), floor effects (0), two-part questions (13, ambiguity (4), dependent on the function of the person with dementia (2), not carer specific (1) (some items were removed for more than one reason, see supplementary material for details). Table 3 shows the 70 items included in the final pool.
4. Discussion

The primary aim of this report was to describe the nature and development of a needs-based PRO item pool to take forward into a larger-scale psychometric study. This will provide data for Rasch analysis and allow development of one or more short uni-dimensional carer-reported outcome measure(s) of dementia carers’ quality of life. In the next stages, the SIDECAR item pool will undergo psychometric testing including Rasch analysis to derive an item bank and a short SRO measure, which will be subject to valuation studies. Additionally, the pool has potential to provide items for parallel forms and provides a set of acceptably worded items on carer quality of life that could be used as a basis for comprehensive assessment of carers’ needs to inform support or interventions.

In line with the needs-based approach, the items were grounded in the experience of a diverse sample of UK-based family carers of people with dementia and were not based on prior theory or research. The generation of the items directly from the interview transcripts complies with FDA guidelines for scale generation [44] while preserving the lived experience of carers, as well as, where possible, their words. The face validity and cognitive interview processes enhanced acceptability and understandability. The checks for content validity and psychometric suitability ensured relevance to carers and usefulness to researchers. The process of development followed widely used steps, with expansion of the stages of item generation and reduction, and testing of face and content validity, to ensure rigour of the item pool and new measures to be developed from it.

Many questionnaires of QoL in dementia carers are generic rather than specific, or are multi-domain scales [9], whereas the item pool described here is specific to dementia carers and reflects a wide range of impacts but without explicit division into domains. Two of the seven carer QoL scales reviewed by Dow et al [9] were dementia specific but only one of these [17] was grounded in carer accounts from focus groups, conducted with diverse groups in the USA. The approach taken to development of that scale was multi-trait scaling, whereas we took a needs-based approach. One strength of the SIDECAR item pool is its derivation from interviews with a purposively sample of diverse dementia carers with different caring contexts. The item pool gains validity from this sampling strategy.

The work has a number of limitations. We were unable to include friends and neighbours as carers in the participant samples, had few carers from rural settings, and all participants were UK based, so limiting generalisability.

5. Conclusion

In this paper, we have described the development of a 70-item pool for a needs-based SRO measure of carer quality of life, giving a degree of detail that may be of interest to researchers interested in developing needs-based SRO scales. The dementia-carer specific item pool reflects the accounts of a diverse sample of those who provide care for a person with dementia, allowing them to define the nature of the impact on their lives and resulting in a valid acceptable set of items.
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Data Availability Statement
The University of Leeds will make a link to the published study available through the White Rose repository. The datasets generated and/or analysed during the current study are available from https://doi.org/10.5518/375
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