

Assessing the Impact of Caring for a Person with Schizophrenia: Development of the Schizophrenia Caregiver Questionnaire

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Abstract

Background The responsibilities of caring for a person with schizophrenia may significantly impact informal caregivers' lives. The Zarit Burden Interview (ZBI) was originally developed to assess burden among caregivers of people with Alzheimer's disease.

Objective This research was conducted to inform the development of a revised version of the ZBI, relevant to caregivers of people with schizophrenia.

Methods Based on published qualitative research, the questionnaire was reviewed and modified in accordance with industry-standard guidelines. The resulting questionnaire [the Schizophrenia Caregiver Questionnaire (SCQ)] was then completed by 19 caregivers during cognitive debriefing interviews to assess understanding, relevance and comprehensiveness.

Results Review of the ZBI resulted in a number of operational changes to improve face validity and potential sensitivity. Further questions were added based on key concepts identified in existing literature and minor phrasing alterations

were made to improve content validity. Findings from caregiver interviews supported the content validity of the SCQ.

Conclusion The SCQ provides a comprehensive view of caregivers' subjective experiences of caregiving and demonstrated strong face and content validity. The questionnaire will be important in both clinical assessment and evaluating the efficacy of interventions designed to reduce or alleviate caregiver burden. Future research will seek to establish the psychometric validity of the questionnaire.

Key Points for Decision Makers

The Zarit Burden Interview (ZBI) is a widely used measure of caregiver burden; however, it has not been validated for use in caregivers of people with schizophrenia.

Following a review of the content of the ZBI and informed by qualitative interviews with caregivers of people with schizophrenia, the ZBI has been modified to develop a new disease-specific measure: the Schizophrenia Caregiver Questionnaire (SCQ).

The SCQ was shown to be comprehensive and relevant to caregivers of people with schizophrenia and has strong face validity.

Future work is ongoing to determine the reliability and validity of the instrument in this population.

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1 Background

Over the past 50 years there has been transition in care provision for schizophrenia patients from formal hospital-based healthcare systems to outpatient and community

services. It is estimated that 50–90 % of people with chronic psychiatric illness live with their families or friends [1, 2]. Informal caregivers (defined as “a person who has significant responsibility for managing the well-being of a person diagnosed with schizophrenia in an unpaid capacity” [3]) therefore provide an important service by reducing the need for formal care and the burden upon healthcare systems [4].

While providing informal care for a person with schizophrenia can be a rewarding experience, fulfilment of this role can have a significant impact upon the life of an informal caregiver, including interpersonal relationships, ability to fulfil other roles and commitments (e.g. work), and financial situation [5, 6]. In addition, high levels of perceived burden among caregivers can lead to increased physical and psychological health problems, which in turn can have considerable consequences on healthcare systems and wider society. Not only do the healthcare needs of overburdened caregivers incur costs, but a loss of productivity due to terminated employment and time off work and an increasing reliance on formal, paid assistance result in substantial costs to society [7, 8]. In the UK in 2007, for instance, it was estimated that 4.8 % of caregivers of people with schizophrenia had terminated employment and 15.5 % took a mean of 12.5 days off work per year as a result of their caregiving role, which translated into a mean economic loss of £517 per caregiver each year [9].

Health technology assessments in many countries, as well as payers and prescribers, now recognise the value of evidence demonstrating alleviation of the impact of providing informal care for someone with a medical condition for facilitating decision making. In order to monitor the subjective impact on caregivers, however, there is a need for an accurate and reliable measure which assesses the impact perceived by caregivers as opposed to the observable impact on their lives. This can only be reported by caregivers themselves.

The Zarit Burden Interview (ZBI) is a 22-item questionnaire developed to assess the level of subjective burden experienced by the principal caregivers of people with dementia and people with disabilities [10]. The ZBI, which was developed in 1980, is arguably the most widely used measure of caregiver burden. The instrument has been adapted for use in a number of languages [11–16] and has been used extensively in clinical studies and published research among caregivers of people with a variety of physical and mental disorders, including schizophrenia [17–19]. Despite this, however, the relevance and meaningfulness of the ZBI for use in schizophrenia is still unknown. Similarly, the validity of the ZBI for monitoring caregiver burden in clinical research or longitudinal studies in schizophrenia has also not been evaluated.

The aims of the present study were to review evidence supporting the validity of the ZBI for assessment of the impact of caring for a person with schizophrenia in accordance with best practice guidelines for the development and evaluation of self-report measures (e.g. US Food and Drug Administration *Guidance for Industry—Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims*) [20]; inform modifications to the ZBI; and explore the relevance and understanding of the resulting questionnaire [the Schizophrenia Caregiver Questionnaire (SCQ)] during qualitative cognitive debriefing interviews with caregivers of people with schizophrenia.

2 Methods

2.1 Phase 1: Zarit Burden Interview (ZBI) Endpoint Review

2.1.1 Literature Searches

Targeted literature searches were conducted in MEDLINE, EMBASE and PsycInfo, using a combination of keywords (Table 1). The two main objectives of the literature review were firstly to identify articles outlining the experience of caring for a person with schizophrenia based on qualitative research and secondly to identify articles concerning the development and validation of the ZBI or articles detailing the use of the questionnaire in schizophrenia studies. Articles which met pre-specified inclusion and exclusion criteria were selected for review (Table 1). Searches returned 203 qualitative articles and 16 articles relating to the ZBI. A total of 19 qualitative articles [21–44], 16 articles concerning the development of the ZBI [11–16, 19, 45–53] and eight studies detailing the use of the ZBI in schizophrenia [17, 18, 54–59] met the inclusion criteria and were selected for review.

2.1.2 ZBI Review Criteria

Key criteria from best practice guidelines relating to the content and face validity of self-report questionnaires that were considered during the review of the ZBI are defined in Table 2 [20, 60].

2.1.3 Modifications to the ZBI to Form the Schizophrenia Caregiver Questionnaire (SCQ)

Based on findings from the literature, review of the ZBI and author experience in the development of self-report measures [61–70], changes were made to the ZBI to address concerns regarding relevance and sensitivity of the

Table 1 Search strategy for the Zarit Burden Interview ZBI endpoint review

Qualitative literature review key terms	(“Schizophrenia” OR “Schizoaffective”) AND (“Caregiver” OR “Carer” OR “Care provider” OR “Responsible person” OR “Spouse” OR “Parent” OR “Sibling” OR “Family” OR “Friends” OR “Daughter” OR “Son” OR “Child\$” OR “Healthcare professional” OR “Doctor” OR “Clinician” OR “Nurse” OR “Mental Health Nurse” OR “Mental Health Professional” OR “Nurse Practitioner”) AND (“Qualitative” or “IPA” or “Interpretive phenomenological analysis” or “Thematic analysis” or “Grounded theory” or “Content analysis” or “Discourse” OR “Interviews” OR “Focus Groups”) AND (“Lived experience” or “Quality of life” OR “Burden” OR “Impact”)
Qualitative literature review inclusion criteria	<p>Include:</p> <p>Journal article (excludes conferences, dissertations, books or chapters)</p> <p>Article focuses exclusively on burden among caregivers of schizophrenia patients</p> <p>Article reports use of qualitative techniques of investigation</p> <p>Article focuses on burden among caregivers of patients with mental disorders (including reference to schizophrenia)</p> <p>Exclude:</p> <p>Relevant search terms are mentioned but are not the main focus of article</p>
ZBI review key terms	(“Schizophrenia” OR “Schizoaffective”) AND (“Zarit”)
ZBI review inclusion	<p>Include:</p> <p>Journal article (excludes conferences, dissertations, books or chapters)</p> <p>Article refers explicitly to the evaluation of the psychometric properties of the original ZBI or alternate language versions</p> <p>Exclude:</p> <p>Relevant search terms are mentioned but are not the main focus of article</p>

Searches were conducted in November 2011 and were limited to English articles that concerned humans and contained keywords in the title or abstract

ZBI Zarit Burden Interview

Table 2 Endpoint review criteria assessed

Evidence	Issues for consideration
Content validity	<p>Does the questionnaire adequately capture all concepts that are important to patients and in a way that is easily understood and interpreted consistently by patients?</p> <p>Level of participant involvement in development of questionnaire?</p> <p>Has pilot test/cognitive debriefing been conducted?</p> <p>Confirmation of conceptual model?</p> <p>Evidence of conceptual saturation?</p>
Face validity	<p>Does the questionnaire appear to measure what it intends to measure in a manner appropriate for the context of use?</p> <p>Questionnaire wording:</p> <p>Are questions, response scales and instructions worded in a manner that is clear and will be consistently interpreted by patients?</p> <p>Recall period:</p> <p>Appropriate recall period? (Dependent on variability, duration, frequency and intensity of the concept measured, characteristics of the disease/condition)</p> <p>Response scales and scoring:</p> <p>Response scales represent similar intervals and do not bias the direction of responses?</p> <p>Response options are appropriate for the intended population?</p> <p>Do the scores represent a single concept?</p>

questionnaire in this population. All changes were based on consensus decision among all authors. These changes are further described in the Results section.

2.1.4 Development of Supplementary Measures to Understand Caregiver Impact: Caregiver Global Impression Scales

To aid the interpretation of SCQ scores over time and repeated assessments, a series of Caregiver Global Impression (CaGI) scales were also developed and tested among caregivers (Fig. 1). These scales are similar to Clinical Global Impression (CGI) scales commonly used in psychiatry research [71] but were developed to be suitable for completion by caregivers of people with schizophrenia. Three scales were developed to assess caregivers' perception of the severity of the person with schizophrenia's symptoms over the past 4 weeks ["Please rate the severity of his/her symptoms during the past 4 weeks" scored from symptoms (1) to very severe symptoms (6)]; change in the person with schizophrenia's symptoms since the beginning of the study ["Overall, how have his/her symptoms changed (if at all) since the beginning of the study (before starting treatment)?" scored from "very much improved" (1) to "very much worse" (7)]; and change in the experience of caring since the beginning of the study ["Overall, how much have your experiences of caring for a person with schizophrenia changed (if at all) since the beginning of the study (before starting treatment)?" scored from "very much improved" (1) to "very much worse" (7)].

2.2 Phase 2: Cognitive Debriefing Interviews Among Caregivers of People with Schizophrenia

The first step in the development or modification of self-report questionnaires is to confirm content validity in the target population. In accordance, face-to-face, semi-structured, cognitive debriefing interviews were performed with 19 US English-speaking caregivers of people with schizophrenia. In a cognitive debriefing interview, respondents are asked to complete a questionnaire whilst talking through their thought processes (i.e. thinking out loud); the interviewer then questions the respondent on the relevance of items and their understanding of the questionnaire. Respondents' answers during cognitive debriefing of the SCQ and CaGI scales were reviewed to ensure that: (1) the content of the instruments captures the most important aspects of the concept(s) relevant to caregivers; and (2) caregivers understand how to complete the instruments, how to reference the correct recall periods, the meaning of the items, how to use the response scales, and any other features of the instruments that may influence

caregiver responses in the intended mode of administration [72].

2.2.1 Caregiver Recruitment

No definitive guidelines exist regarding the recommended sample sizes for qualitative studies; however, past studies suggest that sample sizes of approximately 12 participants are sufficient for determination of issues of importance to a particular population and for confirmation of user understanding of self-report measures via cognitive debriefing [73, 74]. Evidence suggests the number of interviews is less important than the quality of interviews, with completeness of elicited information strongly influencing sample size [20].

In order to avoid geographical bias, participants were recruited from three sites in the USA (central, eastern and southern states). Caregivers of people with schizophrenia who met predefined eligibility criteria were referred to the study by private physicians. To be eligible for participation, caregivers had to be aged at least 18 years of age and currently providing care for at least 4 h per week to a person with a *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR)* [91] diagnosis of schizophrenia who was currently receiving a marketed atypical or typical antipsychotic, and was defined by their physician on a CGI scale as being at least moderately ill.

A number of external factors were considered in developing recruitment quotas for the current study. These included care recipient subtype [75–77] and severity of schizophrenia [78–81]. The ethnicity [82], sex [78, 83], age [34], education [84] and relationship of the caregiver to person with schizophrenia [85] were also considered as existing research had indicated that these variables may influence the type and extent of the impact of caring for a person with schizophrenia.

2.2.2 Cognitive Debriefing Interview Procedure

Interviews were conducted by an experienced qualitative interviewer using a semi-structured interview guide. The SCQ and CaGI scales were debriefed using a 'think aloud' technique whereby caregivers were asked to read each question or instruction out loud and then vocalise their thoughts as they read and as they selected their responses. Non-leading, open-ended interview questions (e.g. "How would you describe this question in your own words?") were used to ensure that all items were explored thoroughly. Probes were used where necessary, specifically to establish the caregiver's understanding and interpretation of questions and instructions (e.g. "What does feeling

Fig. 1 Caregiver Global Impression (CaGI) scales

Caregiver Global Impression (CaGI)

Please answer the following questions which ask about your experiences of caring for a person with schizophrenia.

I. Severity of symptoms

Please rate the severity of his/her symptoms during the past 4 weeks.

No symptoms	Very mild symptoms	Mild symptoms	Moderate symptoms	Severe symptoms	Very severe symptoms
1	2	3	4	5	6
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

II. Degree of change in symptoms

Overall, how have his/her symptoms changed (if at all) since the beginning of the study (before starting treatment)?

Very much improved since treatment started	Much improved	Minimally improved	No change since treatment started	Minimally worse	Much worse	Very much worse since treatment started
1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

III. Degree of change in experiences of caring

Overall, how much have your experiences of caring for a person with schizophrenia changed (if at all) since the beginning of the study (before the person started treatment)?

Very much improved since treatment started	Much improved	Minimally improved	No change since treatment started	Minimally worse	Much worse	Very much worse since treatment started
1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

‘angry’ mean to you? How is that different to feeling ‘frustrated?’”).

2.2.3 Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by Copernicus Group, a centralized Institutional Review Board (IRB) in the USA (IRB number: ADE2-12-035). Study procedures ensured that written informed consent was obtained from both

people with schizophrenia and their caregivers prior to the collection of any data.

2.2.4 Qualitative Analysis of Interview Transcripts

Qualitative analysis during ‘cognitive debriefing’ focused specifically on whether SCQ and CaGI concepts and questions were relevant and consistently understood by participants. A qualitative software package (Atlas.ti; ATLAS.ti Scientific Software Development GmbH, Berlin,

Germany) [86] was used to facilitate the coding and analysis of verbatim interview transcripts using methods derived from thematic analysis [87, 88]. Each transcript was assessed and patient comments that pertained to the main research questions were highlighted. After analysing each transcript, the coded statements were then moved into their relevant domains. A list of patient statements was generated for each domain and analysed accordingly.

3 Results

3.1 Review of the ZBI and Initial Modification to Form the SCQ

3.1.1 Review of the Literature Relating to Development and Validation of the ZBI

Consideration of existing literature summarising the development, validation and use of the ZBI as well as a review of the face validity of the ZBI by the authors highlighted a number of issues that might compromise the validity and sensitivity of the ZBI for use as a self-report questionnaire in clinical research in schizophrenia. As a result, the following operational changes were implemented to the questionnaire:

- Although the term ‘burden’ was appropriate for the ZBI (developed to be administered by interview), use of ‘burden’ in the title of a self-report questionnaire to be completed by caregivers may increase the likelihood of socially desirable answers that underestimate the magnitude of impact experienced. This could potentially manifest as floor effects on such questions (i.e. patients indicating ‘no impact’). The modified version of the ZBI for use in schizophrenia caregivers is therefore referred to as the SCQ.
- Questions 4, 5, 6, 13 and 17 were reworded to focus on the impact of the person’s schizophrenia or their behaviour and not the person with schizophrenia themselves, minimising the potential impact of social desirability bias.
- The original ZBI does not include a recall period, which makes it difficult to determine how long respondents are thinking back to when selecting their answers. This is of particular concern for questionnaires implemented in a clinical trial and where differences are to be assessed over time, and, consequently, may reduce sensitivity of the questionnaire. As such, a recall period of the “past four weeks” was implemented throughout the SCQ. Four weeks was specifically

chosen to minimise recall bias by keeping the recall period short, while limiting responder burden by minimising the potential frequency of assessment.

- ZBI questions make reference to caring for a relative, as it was intended that the interviewer would replace this word with the appropriate term (e.g. mother, son). In appreciation that the SCQ could be completed by non-family members who may provide care and support for people with schizophrenia, the questions were amended to no longer make reference to the relationship between care provider and care recipient.
- All questions in the ZBI ask respondents to “reflect how they sometimes feel when taking care of another person” and instruct “After each statement, indicate how often you feel that way”. Frequency measures are most appropriate for observable behaviours where an event is experienced or not. Emotional evaluations and attitudes, however, may be better understood in terms of magnitude or strength of feeling. SCQ items pertaining to the experience of emotions are therefore measured in terms of magnitude or strength of feeling where appropriate, while items measuring behaviour are measured in terms of frequency.
- Item 9 was deleted due to the presence of ambiguous wording (“strained”). Items measuring stress, tiredness and worry have been added to the SCQ and are intended to capture this concept.
- Finally, concerns emerged that a 5-point Likert-type response scale in the ZBI may be less sensitive to changes in the impact of caring for a person with schizophrenia given the extent of difference between adjacent response categories. Response options for all questions were therefore amended to an 11-point numerical rating scale (NRS) in the SCQ to provide greater opportunity for change (albeit only subtle changes) over time.

3.1.2 Review of the Qualitative Literature

Nineteen qualitative research articles were also reviewed to identify issues of importance to caregivers of people with schizophrenia [21–27, 29–44, 89]. Findings supported the relevance of many concepts assessed by the ZBI for caregivers of people with schizophrenia (Table 3). Review of this research also highlighted some concepts considered important to caregivers of people with schizophrenia that were not assessed by the original ZBI. As such, nine additional questions assessing these concepts were added to the SCQ for cognitive testing among schizophrenia caregivers (SCQ questions 6, 23–30) (Table 3).

Table 3 Relevance of concepts included in the revised Schizophrenia Caregiver Questionnaire

Original ZBI question	Evidence from the literature	Relevance to caregivers	Revised SCQ question
1. Do you feel that your relative asks for more help than he/she needs?	✗	12/18	1. Over the past 4 weeks, how often did you feel that he/she asked for more help than needed?
2. Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	✓ [42, 50, 53-55, 71]	14/19	2. Over the past 4 weeks, how often did you feel that because of the time you spent with him/her you didn't have enough time for yourself?
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	✓ [50]	14/17	3. Over the past 4 weeks, how difficult was it for you to care for him/her and meet your other responsibilities?
4. Do you feel embarrassed over your relative's behavior?	✓ [35, 54] [44, 59, 62]	8/19	4. Over the past 4 weeks, how embarrassed did you feel about his/her behavior?
5. Do you feel angry when you are around your relative?	✓ [41, 53, 59, 62]	n/a	5. Over the past 4 weeks, how frustrated did you feel about his/her behavior?
6. Do you feel that your relative currently affects your relationship with other family members or friends in a negative way?	✓ [41, 53, 59, 62]	8/19	6. Over the past 4 weeks, how angry did you feel about his/her behavior?
7. Are you afraid what the future holds for your relative?	✓ [41, 50]	14/17	7. Over the past 4 weeks, how often did you feel that his/her schizophrenia affected your relationship with other family members or friends in a negative way?
8. Do you feel your relative is dependent upon you?	✓ [50, 53, 71]	13/16	8. Over the past 4 weeks, how afraid were you of what the future holds for him/her?
9. Do you feel strained when you are around your relative?	✓	7/15	9. Over the past 4 weeks, how often did you feel he/she was dependent upon you for financial support? Item deleted
10. Do you feel your health has suffered because of your involvement with your relative?	✓ [35, 41]	10/17	10. Over the past 4 weeks, how much did you feel that your physical health suffered as a result of caring for him/her?
11. Do you feel that you don't have as much privacy as you would like, because of your relative?	✗	7/18	11. Over the past 4 weeks, how often did you feel that you didn't have as much privacy as you would have liked, because of him/her?
12. Do you feel that your social life has suffered because you are caring for your relative?	✓ [44, 50, 51]	11/16	12. Over the past 4 weeks, how much did you feel that your social life suffered because you were caring for him/her?
13. Do you feel uncomfortable about having friends over, because of your relative?	✗	9/19	13. Over the past 4 weeks, how uncomfortable would you have felt about having friends over because of his/her behavior?
14. Do you feel that your relative seems to expect you to take care of him/her, as if you were the only one he/she could depend on?	✓ [41]	11/15	14. Over the past 4 weeks, how often did you feel that he/she was overly dependent on you to help with daily activities?
15. Do you feel that you don't have enough money to care for your relative, in addition to the rest of your expenses?	✓ [41, 56, 59]	8/18	15. Over the past 4 weeks, how often did you feel that you didn't have enough money to care for him/her, in addition to the rest of your expenses?
16. Do you feel that you will be unable to take care of your relative much longer?	✓ [46, 60, 61]	6/16	16. Over the past 4 weeks, how often did you feel that you would be unable to take care of him/her for much longer?

Table 3 continued

Original ZBI question	Evidence from the literature	Relevance to caregivers	Revised SCQ question
17. Do you feel you have lost control of your life since your relative's illness?	✓ [57]	8/19	17. Over the past 4 weeks, how often did you feel you weren't in control of your life because of his/her schizophrenia?
18. Do you wish you could just leave the care of your relative to someone else?	✗	10/19	18. Over the past 4 weeks, how often did you wish you could just leave the care of him/her to someone else?
19. Do you feel uncertain about what to do about your relative?	✗	10/19	19. Over the past 4 weeks, how often did you feel uncertain about how to care for him/her?
20. Do you feel you should be doing more for your relative?	✓ [44]	10/18	20. Over the past 4 weeks, how often did you feel you should be doing more for him/her?
21. Do you feel you could do a better job in caring for your relative?	✗	11/14	21. Over the past 4 weeks, how often did you feel that you were not able to care for him/her as well as you would have liked?
22. Overall, how burdened do you feel in caring for your relative?	✗	13/15	22. Over the past 4 weeks, how difficult was it to care for him/her?
	✓ [46, 61]	10/18	23. Over the past 4 weeks, how often did you feel alone in caring for him/her?
	✓ [52, 63]	13/16	24. Over the past 4 weeks, how tired did you feel due to caring for him/her?
	✓ [50, 55, 62]	14/16	25. Over the past 4 weeks, how stressed did you feel due to caring for him/her?
	✓ [71]	11/19	26. Over the past 4 weeks, how difficult was it to get him/her to take his/her medication?
	✓ [35, 60]	12/19	27. Over the past 4 weeks, how often did you worry that he/she might have an episode?
	✓ [54]	13/18	28. Over the past 4 weeks, how often did you worry that his/her schizophrenia might get worse?
	✓ [35, 62, 63]	8/17	29. Over the past 4 weeks, how often did you feel your sleep was disturbed because of caring for him/her?
	✓ [35, 42]	14/19	30. Over the past 4 weeks, how often did caring for him/her make you feel sad?
	✓ [62]	n/a	31. Over the past 4 weeks, how often did you experience emotional highs and lows ("an emotional rollercoaster") because of his/her schizophrenia?
	✓ [50, 55, 71]	n/a	32. Over the past 4 weeks, how often did you feel that caring for him/her affected your work (paid or unpaid) in a negative way?

n/a item was not included in the questionnaire that was completed by patients in the cognitive debriefing interview, SCQ Schizophrenia Caregiver Questionnaire, ZBI Zarit Burden Interview, ✗ indicates no evidence in the qualitative literature, ✓ indicates evidence in the qualitative literature

Table 4 Demographic characteristics for persons with schizophrenia ($n = 19$)

Demographic characteristic	Persons with schizophrenia
Age (years) [mean (range)]	51.84 (21–82)
Sex (n)	
Male	7
Female	12
Ethnicity (n)	
Black/African American	12
Hispanic/Spanish American/Latin (of any race)	1
White/Caucasian	6
Years since diagnosis [mean (range)]	16 (3–42)
Schizophrenia subtype (n)	
Paranoid	10
Disorganized	4
Undifferentiated	2
Catatonic	2
Paranoid, disorganized	1
Schizophrenia severity (n)	
CGI-S score 4	9
CGI-S score 5	5
CGI-S score 6	5
Medication (n)	
Typical antipsychotics	6
Haloperidol	5
Chlorpromazine	3
Atypical antipsychotics	11
Abilify [®]	4
Risperdal [®]	5
Zyprexa [®]	3
Seroquel [®]	0
Symbyax [®]	1
Geodon [™]	2
Other	6
People with schizophrenia taking both typical and atypical treatments	5

CGI-S Clinical Global Impression–Severity scale

3.2 Cognitive Debriefing of the SCQ

3.2.1 Demographic Characteristics

A diverse sample of 19 caregivers of people with schizophrenia was recruited who cared for a diverse sample of people with schizophrenia (Tables 4, 5). The average age of caregivers was 51.6 years and the caregiver sample was predominantly female (79 %), which is consistent with previous research in samples of caregivers of people with schizophrenia [34, 90]. Caregivers were related to the person with schizophrenia in a number of ways, including

parent, sibling, spouse or child, and the majority ($n = 15$) lived with the person with schizophrenia. Most of the caregivers worked and caregivers had a range of educational statuses. On average, caregivers had been caring for the person with schizophrenia for 10 years (range 1–32 years) and more than half ($n = 11$) spent over 40 h a week caring for the person.

People with schizophrenia had an average age of 52 (range 21–82) years and were also predominantly female (12/19). On average, they had been diagnosed with schizophrenia for 16 (range 3–42) years and they represented five DSM-IV-TR subtypes [91] and had a range of severities of schizophrenia as rated by the CGI.

3.2.2 Cognitive Debriefing Findings

Feedback from participants indicated that completing the SCQ was “easy” and “straightforward” with few difficulties encountered during completion. Feedback also supported the initial modifications made to the questionnaire following the literature review. The newly specified 4-week recall period for all SCQ questions, for example, was universally understood by participants, and when asked to explain their answers to SCQ questions participants consistently referred to their experiences in the past 4 weeks.

“I was thinking over the last month”. (101-F-58-U)

Similarly, feedback from participants indicated that the 0–10 NRS used in the SCQ was well understood and was an intuitive means of reporting the impact of caring for a person with schizophrenia:

“None of the time, all the time, half of the time—I’m going to give it a seven. A little more than half of the time. That’s how I’m splitting it up” (211-F-59-D)

Furthermore, despite the small sample ($n = 19$), the caregivers interviewed as part of this study provided responses for the majority of SCQ items that were distributed across the entire response continuum, providing preliminary support for the validity of the 0–10 NRS response scale in this population (Fig. 2).

Feedback from the cognitive debriefing interviews indicated that all items were well-understood and consistently interpreted by caregivers as referring to impacts due to their role as a caregiver. No participants reported discomfort in answering any of the SCQ items or feeling that items were putting blame on patients in any way.

While SCQ questions were generally considered by participants to be well-worded and few difficulties in understanding of the questions were evident, some caregivers proposed valid suggestions of ways in which question wording could be modified to further improve understanding

Table 5 Caregiver demographic characteristics ($n = 19$)

Demographic characteristic	Caregivers
Age (years) [mean (range)]	51.63 (28–69)
Sex (n)	
Male	4
Female	15
Ethnicity (n)	
Black/African American	11
Hispanic/Spanish American/Latin (of any race)	2
White/Caucasian	6
Relationship to person with schizophrenia (n)	
Parent	6
Partner/spouse	2
Sibling	6
Son/daughter	3
Other	2
Sex match (n)	
Yes	
Female	10
Male	2
No	7
Education (n)	
High school diploma	7
College or university degree	5
Graduate or professional degree	5
Some years of college	2
Work status (n)	
Working full- or part-time	12
Full time homemaker	3
Not working	1
Retired	2
Other	1
Co-residence (n)	
Yes	15
No	4
Years spent caring for person with schizophrenia [mean (range)]	10.24 (1–32)
Hours per week spent caring for person with schizophrenia (n)	
<20	1
21–40	7
40+	11
Range	14–168
Mean	86.33

and relevance. One such change included rewording question 27 from “worry that he/she might have an episode of disturbing or violent behaviour?” to “worry that he/she might have an episode?” to make it more relevant to behaviours present in all subtypes of schizophrenia.

Caregiver feedback indicated that the SCQ provided a comprehensive assessment of the issues that may affect

caregivers of people with schizophrenia. On the basis of caregiver feedback, however, three additional questions were added to the SCQ. These questions aimed to assess caregivers’ frustration at the person with schizophrenia’s behaviour, caregivers’ experience of emotional highs and lows, and the impact of caring for a person with schizophrenia on caregivers’ ability to complete paid or unpaid work.

“There’s times I’ve yelled at my mother when I’ve gotten frustrated. So I’ve—of course I feel guilty of that and the guilt causes stress”. (103-F-38-P)

“Emotionally, it’s a rollercoaster”. (318-M-55-P)

“So I gave up my business basically so I could be home more—uh, to take care of him.” (109-F-69-P).

Feedback from caregivers interviewed as part of this study also supported the validity of the CaGI scales, with these newly developed scales being readily understood by caregivers who provided responses across the whole response continuum.

“That’s a good question... You have very mild, mild... Because there can be so many degrees of it”. (104-F-48-D).

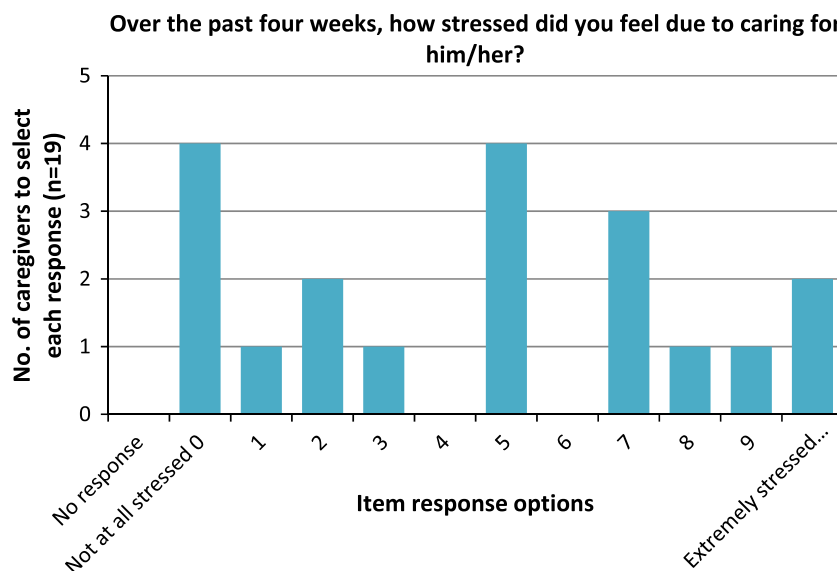
4 Discussion

A survey by Rethink Mental Illness in 2003 showed that 90 % of caregivers are adversely affected by the caring role in terms of leisure activities, career progress, financial circumstances and family relationships, and 41 % have significant or moderately reduced mental and physical health [9]. A review of existing qualitative research and insights from qualitative interviews outlined in this manuscript reinforce the impact that caring for a person with schizophrenia has on caregivers and confirms findings from prior qualitative research conducted by the authors [6].

Assessment of caregiver burden in both clinical trials and clinical practice could improve awareness, tracking and management of impact on caregivers, thus providing opportunity for increased support. In turn, this could reduce the substantial direct and indirect costs associated with caregiver healthcare needs, loss of productivity and reliance on formal caregivers. This is of increasing importance to healthcare decision makers such as the National Institute for Health and Care Excellence (NICE), who highlighted the need for caregiver support in their latest guidance on schizophrenia management [92].

The ZBI is a well-validated and widely used instrument for measuring caregiver burden in caregivers of patients

Fig. 2 Example response distributions for SCQ item



with Alzheimer's disease. The SCQ was adapted from the ZBI in accordance with best practice recommendations for the development and modification of self-report questionnaires [20, 60] to provide a disease-specific means of assessing the impact of caring for a person with schizophrenia. It addresses many of the limitations of the ZBI (e.g. lack of specified recall period, limited response continuum), making it more appropriate for use as an assessment in clinical trials and non-interventional observational studies. There is also potential for the SCQ to be used to support clinical practice, where it may help to identify cases where additional support from healthcare professionals and/or social care services is needed to minimise impact on caregivers' physical/psychological health and their ability to provide informal care to the person with schizophrenia.

Although our findings provided strong support for the face and content validity of the SCQ, it is recognised that further evidence from quantitative studies in informal caregivers of people with schizophrenia is needed to confirm the validity of the SCQ and the CaGI scales. Prior research has supported the psychometric validity of the ZBI (although there is only limited evidence specific to schizophrenia) [11–15, 19, 46, 51–53]. Further exploration of the content validity of the SCQ using item–response theories are therefore planned to help ensure adequate targeting of the SCQ to the caregivers of people with schizophrenia (e.g. absence of gaps in measurement and clusters of questions) and (combined with traditional psychometric analyses) will be used to inform questionnaire domain structure and questionnaire scoring. Sensitivity of the questionnaire to changes in caregiver burden and definition of minimal important differences will then be explored during interventional studies.

It is noted that initial research was only conducted in the USA with US English-speaking caregivers; a conceivable limitation of the questionnaire, therefore, being that it may not be culturally or linguistically relevant in other countries. To facilitate use of the SCQ in other languages and cultures, work is currently ongoing to translate and linguistically validate the SCQ for use in other countries using industry gold-standard techniques. Future research may also look to investigate the impact of caring for a person with predominantly negative symptoms (such as being emotionless or withdrawn) versus the impact of caring for a person with predominantly positive symptoms (such as hallucinations or delusions) as research suggests that issues for caregivers of such patients may be different.

5 Conclusions

The newly developed SCQ is a disease-specific questionnaire for assessing the impact of providing informal care to a person with schizophrenia. The questionnaire has demonstrated strong face and content validity but further research is needed to establish the psychometric validity of the scale. Nonetheless, the SCQ represents a promising tool for use in clinical research and clinical practice.

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Author contributions DR and CB conceived the study. DR, CB, AG, and LA designed the research and provided scientific oversight and review throughout the research process. CT and CM performed the literature review, conducted the interviews and the primary data analysis. All authors were all involved in the interpretation of research findings and developed the manuscript.

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