

Protocol

Development and Psychometric Evaluation of "Caregiver Burden Questionnaire for Family Caregivers of Patients Undergoing Hemodialysis": A Protocol for A Sequential Exploratory Mixed-Method Study

Sima Sadat Hejazi¹, Meimanat Hosseini^{2*}, Abbas Ebadi³, Hamid Alavi Majd⁴

Abstract

Objective: Caregiver burden is defined as the physical, financial, mental, and social problems stemmed from providing care for one of the family members who is involved with a medical problem. The precise measurement of caregiver burden is crucial, and it is essential to have an appropriate and specific tool for measuring caregiver burden. This study will be carried out using sequential exploratory mixed-method design with the aim of development and psychometric evaluation of a questionnaire for caregiver burden in family caregivers of hemodialysis patients.

Method: The study will be done in 2 phases: 1. qualitative study and literature review, and 2. designing and psychometric evaluation of the questionnaire. In the qualitative phase, family caregivers of hemodialysis patients, patients, nurses, physicians, and social workers will be selected using the maximum variation purposive sampling method. Data will be gathered through semi-structured interviews using a combination of the questions derived from the model and open-ended questions and will be analyzed using directed content analysis. The literature review will be carried out based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses to improve the reporting of the systematic review. After developing the primary item pool, in the quantitative phase, the psychometric properties of the questionnaire will be evaluated. In this regard, face, content, and construct validity (exploratory factor analysis), internal consistency (Alpha's Cronbach), reliability (test-retest), responsiveness, interpretability, and feasibility of the questionnaire will be assessed.

Results: The primary questionnaire will be developed based on the qualitative and systematic literature review; then, its psychometric properties will be assessed in the second phase. The result section will consist of the findings of these two phases.

Conclusion: It seems that a specific questionnaire could be a facilitator of identifying and measuring the actual caregiver burden.

Key words: *Caregiver Burden; End-Stage Renal Disease; Hemodialysis; Psychometrics; Questionnaire*

1. Student Research Committee, Department of Community Health Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
2. Department of Community Health Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
3. Behavioral Sciences Research Center, Life Style Institute, Faculty of Nursing, Baqiyatallah University of Medical Sciences, Tehran, Iran.
4. Department of Biostatistics, Faculty of Paramedicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

*Corresponding Author:

Address: Department of Community Health Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Vali Asr Avenue, Niayesh Cross Road, Niayesh Complex, Tehran, Iran, Postal Code: 1985717443.

Tel: 98-21 88655366, Fax: 98-2188655363, Email: m_hosseini@sbmu.ac.ir or meimanathosseini@yahoo.com

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Dialysis is considered as family involvement. One family member of dialysis patients is their partner and the caregiver in this process. On this occasion, in addition to the patient, the primary caregiver is the one who is greatly influenced by the process of the disease and its treatment (1). In contrast to the formal care that is provided by health care professionals and its cost is paid by the care receiver or other resources (such as health care insurance or social systems), the cost of informal care that is provided by nonprofessionals is not paid. To emphasize this unpaid care, the expression 'informal caregiving' is often considered as synonymous with 'family caregiving' (2). Studies have shown that better support provided by the family members or relatives is associated with survival improvement, more efficient adherence to and compliance of the treatment, and better quality of life of the patients suffering from end-stage kidney disease (3).

Current studies and resources have identified 2 sources of pressure on the family and close friends of kidney disease sufferers. Both hemodialysis and peritoneal dialysis have destructive effects on the family's social life, as 1. The family's daily and weekly plans are affected by the patient's dialysis schedule; 2. Most patients become feeble and vulnerable and lose their functional independence; consequently, their family is supposed to provide greater physical support to the patient (4). As the patient's care needs increase, family caregivers are isolated from social activities and it might predispose them to various physical and mental problems (5). Study results show that caregivers' general, physical, and mental health, social function, and energy level are remarkably low (6). Caregivers encounter several problems doing their personal affairs and maintaining their physical and mental health and feeling well (7). Additionally, caregivers of hemodialysis patients have low quality of life compared to the groups identical in terms of age and sex (1, 8, 9). The caregiver burden is defined as the physical, financial, mental, and social problems stemmed from providing care for one of the family members who is involved with a medical problem (5). In some sources, caregiver burden has been defined as a multifaceted response to physical, mental, emotional, financial, and social stressors associated with the caregiving experience. Caregiver burden is caused by potential stressful activities related to the objective and subjective aspects of providing care. The objective burden, considering the hours spent on giving care or the care type, is associated with physically provided care that is visible or cares provided by using tools and equipment. On the contrary, the subjective burden of care is associated with affective, mental, and social outcomes, such as depression or tension resulted from giving care (2). The mental health of the family caregiver has serious adverse effects on the health status of the patient suffering from chronic disease (6). Physical and mental

burden to the caregivers has a direct effect on the care they provide for the patient and it might lead to insufficient care or even patient abandonment (9). Consequently, identifying caregiver burden and its effects on caregivers' life is of great importance (6).

Identifying and understanding the caregiver's condition could be beneficial for them in providing support during the process of treatment and taking into account the mental aspects of care provided for the hemodialysis patient (3, 6). However, despite the identified complexities of giving care to the patient as well as the potential side effects in caregivers, health care systems have taken inadequate steps to help such people. Few health care systems have programs for screening and identifying caregiver burden and distress; also, limited numbers of institutes provide supportive services for such caregivers. As a matter of fact, early diagnosis of burdened and distressed caregivers is one of the critical factors of developing clinical programs to meet the caregivers' therapeutic-supportive needs and enhance their knowledge and awareness. Furthermore, the precise measurement of caregiver burden is crucial for conducting clinical research in this field (10).

This article is a research protocol. Objectives of the study are as follows:

1. Validation and extension of the meaning and aspects of caregiver burden in family caregivers of hemodialysis patients
2. Development and psychometric evaluation of the questionnaire of caregiver burden in family caregivers of hemodialysis patients

Materials and Methods

The present study will be carried out using sequential exploratory mixed-method (qualitative- quantitative) design. This method is an appropriate procedure for scale development (11). It will be done in 2 separate phases: qualitative study and literature review and designing, and psychometric evaluation of the questionnaire (quantitative phase). In the qualitative phase, data will be gathered through semi-structured interviews and will be analyzed using directed content analysis. The literature review will be carried out based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). After developing the primary item pool for the questionnaire based on the finding of the qualitative phase and literature review, in the quantitative phase, the psychometric properties of the questionnaire will be evaluated. The study phases are shown in Figure 1.

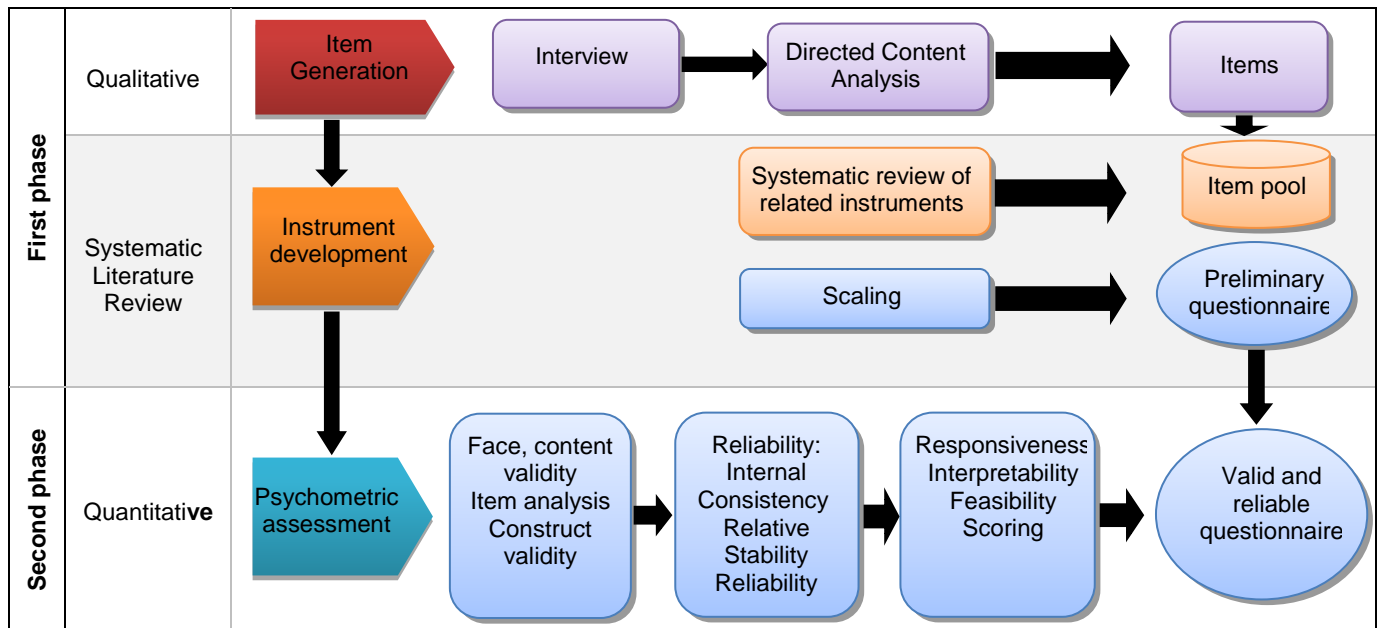


Figure1. Different Phases and Steps of the Study

The first phase of the research

This phase will be used for developing a framework for item generation .

Qualitative section

Study Method

The qualitative section of this study will be performed with the aim of validation and extension of the meaning and the aspects of caregiver burden using directed content analysis. The data will be collected using semi-structured interviews based on ‘Chou’s Model of Caregiver burden (12, 13) from which codes, subcategories, and categories will be extracted. The codes will be investigated by the research team and the repeated and overlapped cases or the ones unable to explain the caregiver burden will be removed. Afterward, conceptually identical codes will be fallen into the same subcategory. Similarly, identical subcategories will be classified in one category. In this research, the directed qualitative content analysis will be conducted based on the approach proposed by Elo and Kyngas (2008) (14), which was modified by Assaroudi et al (2018) (15) using MAXQDA software .

Research Setting

The research setting for the qualitative section, according to the participants’ choice, will be a convenient and peaceful room in hemodialysis wards of Tehran’s teaching hospitals .

Participants

The study population of the qualitative section will consist of hemodialysis patients, family caregivers, dialysis nurses (formal caregiver), physicians, and social workers of teaching hospitals of Tehran and the Iranian Kidney Foundation, Tehran, Iran. Family caregivers of hemodialysis patients will enter the study if they are

willing to participate in the study, do not suffer from any known mental disorder, do not have a history of hospitalization in psychiatric wards, are able to make verbal communication, perceive, speak and answer the interview questions in Persian language, and are in charge of a direct care to the patient at home. Also, the patients who are receiving dialysis and are above 18 years will enter the study. Regarding professional caregivers, the nurses employed in the dialysis units of Tehran teaching hospitals who have at least 1 year of work experience in the dialysis unit and are willing to participate in the study will enter the research. The specialists will be nephrologists or kidney and blood pressure specialists who have patients in the hemodialysis unit and are willing to participate in the study, in addition to social workers in mentioned hospitals that are eager to participate in the study, will enter the research.

Sampling Method

Qualitative researchers, regardless of how the first participants were selected, try to select individuals in a purposive manner based on initial findings. Purposive sampling uses many strategies, one of which is sampling with maximum variation. This type of sampling is a method of conscious selection of samples with a wide variety (16). To this end, attempts will be made to select individuals who are considered as ‘good informants’, are aware of the caregiver burden, involved in daily life, and able to describe their experiences in detail (17). Therefore, in this study, the maximum variation purposive sampling will be done (16). To this end, efforts will be made to the variety of sex, age, educational attainments, treatment duration, and a social-economical class of participants to be met .

Sample Size

Interviews with new participants will continue until data saturation is achieved. This means continuing the interviews until there is no new finding (18).

Data Collection

Data will be collected using in-depth and semi-structured interviews using a combination of the questions derived from the model and open-ended questions. Interview time will be selected according to the participants' ideas and agreement in a convenient and peaceful place. Interviews will be administered face to face without the presence of other people and will be recorded after getting permission from participants. A list of open-ended questions will be provided before the interviews. The purpose, framework, and approximate duration of the interviews will be explained to the participants in advance. Efforts will be made to clarify the discussion subject. The purpose of voice recording will be explained to the participants and they will be assured that their interviews will be kept confidential. An extra explanation will be provided about the following issues: in case participants do not understand any question, they are free to ask about it; they are not obliged to answer undesired questions; they are free to withdraw from the interview at any point; and there is an opportunity for them to eliminate any part after the interviews end based on Whiting idea (2008) (17). Also, informed consent will be obtained from the participants.

Providing Study Accuracy and Rigor

In the present study, data rigor will be sought. Guba (1981) and Guba and Lincoln (1994) identified the credibility, dependability, transferability, and confirmability that described practical strategies to attain rigor in a study (19).

Data Credibility

One of the best ways to create credibility is by prolonged engagement with the subject matter. Another way is to check whether or not participants recognize the findings to be true about their experiences. Returning the findings to the participants to recognize and confirm is referred to as 'member checking'. Peer debriefing is another way to improve the credibility of the study findings (19). The researcher asks a peer or research consultant to review the coding process and discuss. Another way to increase study credibility is to utilize participants' utterances (20). In this study, a combination of mentioned ways will be used to guarantee study credibility.

Dependability

Adequate information about the implementation of the interviews will be provided for the participants. Moreover, precise documentation of interviews and data collection processes will be collected to be investigated by the external audit (21). Also, all participants will be asked identical questions. Eventually, participants' utterances will be referred to frequently while writing the study report.

Transferability

Efforts will be made to increase transferability by providing an accurate report on the methods as well as study findings and quotations. Transferability is the probability that the findings might have a similar meaning in other similar situations (19).

Confirmability

To improve study confirmability, some methods, including field notes, request from participants to clarify their quotations, and meticulous record of study phases for the external audit to evaluate them will be used.

Literature Review Section

This section will be carried out based on the PRISMA (22) to identify current scales and questionnaires of measuring caregiver burden in family informal caregivers. Using PRISMA can improve the reporting of systematic reviews and meta-analysis (22).

The databases that will be searched are MEDLINE (via PubMed), Web of Knowledge, Scopus, CINAHL (via EBSCO), PsycINFO (via EBSCO), and ProQuest. The reference lists of relevant primary studies, theses or dissertations, and conference proceedings will be searched for additional studies.

All the quantitative studies in which the authors specifically develop a new instrument or the main goal of the authors is the psychometric properties evaluation of an existing instrument via classic test theory will be included. The instruments should be for informal or family caregivers. If the psychometric properties evaluation was based on expert opinion or qualitative methods or the main goal of the study was not the evaluation of psychometric properties or instrument development, it will be excluded. Instruments for measurement of caregiver burden in informal caregivers of pediatric, adult or elderly patients, acute or chronic and mental or physical illnesses or disabilities in hospitalized or ambulatory patients and any type of instrument (questionnaire, inventory, scale, ...), measures (general or specific), and assessment method (self-reported or performance-based) will be included.

For data extraction: First, the title and abstract of the found articles would be evaluated by one reviewer to exclude the unrelated ones. Then, according to the inclusion and exclusion criteria of this study, the eligibility of the full texts of the remaining articles will be assessed by 2 reviewers independently using a data extraction form which was made according to inclusion and exclusion criteria. The data extraction form will be piloted previously.

The data extracted from included studies are study characteristics: (authors, publication year, country, goal of the study, setting, population, and sample size), instrument characteristics: (name, goal, target population, type, number of items and domains, scaling, scoring), and psychometric properties: (validity, reliability, responsiveness, interpretability, and feasibility). Any disagreement will be resolved by consensus between the 2 authors when this is not

possible, a third reviewer will act as an arbitrator and will decide on the data entered. Two independent reviewers will assess the quality of included studies by the assessment Consensus-based Standards for the selection of the health status Measurement Instruments (COSMIN) (23) checklist.

Second Phase: Designing and Psychometric Evaluation of the Questionnaire

Designing

In this study, the designing of the questionnaire will be based on Waltz's method (24) whose steps are the selection of conceptual model, explication of objectives for the questionnaire, development of a blueprint, and construction of the questionnaire. After selecting a conceptual model (which was explained in the qualitative phase) and defining objectives, a blueprint and an item pool will be developed based on the results of the qualitative and literature review phase. The blueprint will be evaluated by the research team. Several steps of editing will be done and duplicated or overlapped items will be removed. Items will also be reviewed and corrected for accuracy, appropriateness, relevance to the concept, grammar, appearance, bias, readability. Also, the scaling of the questionnaire will be determined in this phase.

Validity

Having obtained satisfaction with the precise implementation of the previous sections, questionnaire validity will be investigated. In the present study, questionnaire validity will be evaluated through the following steps:

Face Validity

To identify qualitative face validity, face-to-face interviews will be implemented with 10 hemodialysis patients after providing them with an explanation about study purposes and the questionnaire and they will be requested to evaluate the items in terms of difficulty, relevance, and ambiguity (25). Then, needed modifications and reviews will be applied to the items.

To identify the quantitative face validity, after applying modifications according to the participants' opinion, during the next step, the quantitative method of 'item impact' will be used to reduce the number of inappropriate items or remove them and identify the importance of each item. The questionnaire will be handed out to 10 family caregivers and the impact score of each item will be calculated. A decision will be made by the research team on the items with an impact score below 1.5 (26).

Content Validity

1. Qualitative Content Validity

In this study, the questionnaire will be handed out to 10 family caregivers of hemodialysis patients, nursing research experts, and psychometrics specialists and they will be requested to express their opinion about the grammar, wording, item allocation, and scaling (27).

2. Quantitative Content Validity

The quantitative method will be used as a complementary way of identifying content validity after receiving qualitative feedback from the audit and modifying the items.

a. Content Validity Ratio (CVR):

In this study, the questionnaire will be handed out to 10 experts and for each item, CVR will be calculated. Based on Lawsche Table, considering the number of experts (10) in this study, the items whose content validity ratio is at least 0.62 will be maintained (28).

b. Content Validity Index (CVI):

Two types of content validity indices are calculated for the questionnaire: Individual Item-CVI and Scale-CVI. To identify Item-CVI, the questionnaire will be handed out to 10 experts (16) and they will be requested to score each item as follows: (1) irrelevant, (2) moderately relevant, (3) relevant, and (4) absolutely relevant. Afterward, by dividing the number of experts scoring the items 3 or 4 by the total number of experts, Individual Item-CVI will be calculated. After calculating Individual Item-CVI for each expression of the questionnaire, Modified Kappa Statistics will be identified. To compute Modified Kappa, first, the probability of chance agreement needs to be calculated using the following formula in which N is the number of panelists and A is the number of panelists who agree that the item is relevant:

$$P_c = [N! / A! (N-A)!] * 0.5N$$

Second, modified Kappa will be calculated using the following formula:

$$K = (I-CVI - PC) / (1 - PC)$$

Through using the criterion proposed by Fleiss (1981), based on which Kappa values higher than 0.75 are considered as 'excellent'. Polit et al (2007) indicated that each I-CVI value higher than 0.78 is equal to one modified Kappa higher than 0.75; therefore, it could be used as a proof of adequate relevance of the question (29). To compute the overall validity index, the questionnaire will be handed out to 10 experts and Scale-CVI-Average will be calculated. The scale for ensuring the overall content validity index of the questionnaire will be 0.9 (29).

Item Analysis

In the present study, interitem correlation and corrected item-total correlation (29, 30) will be calculated. The major purpose of the item analysis is to conclude which items should be removed from the questionnaire and which items should be added (29).

Construct Validity

In this study, exploratory factor analysis (EFA) will be utilized for investigating construct validity. Important decisions should be taken during the implementation of EFA (31), some of which that are related to this research are introduced below:

1. Decision on sample size: In the present study, 300 samples will be used to conduct EFA (29). Samples will be family caregivers of hemodialysis patients

referred to teaching hospitals and the Iranian Kidney Foundation of Tehran City, Iran .

2. Decisions on the data extraction approach and the number of maintained factors: based on the distribution of the variable, one of the methods of Principle axis or Maximum Likelihood (32) will be used .
In this study, to make decisions about the factors that are supposed to be maintained, Eigenvalues (the only factors with eigenvalue of 1 or higher) will be investigated for significance and the factors below 1 will be overlooked (32) and Scree Plot will be used (33). To this end, the Statistical Package for the Social Sciences (SPSS) software will be used.
3. Normal distribution of the data: Normality of the data will be controlled based on the skewness of ± 3 and kurtosis of ± 7 .
4. Linearity: Data will be investigated in terms of being linear.
5. Outliers: Variables will be inspected for outliers through plotting dispersion diagram.
6. Correlation: The correlation of 0.3 to 0.7(32) will be sought.
7. Number of variables in each factor: The minimum proposed number of variables in each factor is 3 (for instance, 3 items of a questionnaire) that will be taken into account in designing the questionnaire in this study.
8. Sampling adequacy: In the output of SPSS software, 2 tests of Bartlett and Kaise-Meyer-Olkin (KMO) will be investigated as a result of examining sampling adequacy (29, 32).
9. Rotation of the extracted factors: Based on the correlation system or factors independence, an appropriate rotation method will be chosen .

Reliability

Internal Consistency

Internal consistency is assessed through the computing Alpha coefficient (also called Cronbach's Alpha) (16). In this phase of the study, the questionnaire will be handed out to 30 family caregivers of hemodialysis patients. Alpha coefficient values higher than 0.7 will be considered as acceptable (26).

Relative Stability Reliability

In this study, stability reliability will be investigated through test-retest. To this end, the questionnaire will be completed by 15 family caregivers of hemodialysis patients once and 2 weeks later for the second time. After the questionnaire is completed twice, the internal consistency coefficient (ICC) will be measured (34). The ICC of 0.7 is assumed as a minimum standard for reliability (35). In this study, the ICC higher than 0.8 will indicate the appropriate reliability of the questionnaire .

Responsiveness

To measure the responsiveness of the questionnaire, 2 methods of absolute stability through calculating standard error of measurement (SEM) and minimal

detectable change (MDC) will be used. The MDC will be computed through calculating SEM at z-score for confidence level (95% CI) and the square root of 2 (36).

Interpretability

To evaluate interpretability, ceiling and floor effects as well as minimal important change (MIC) (37) will be assessed.

Feasibility

Two criteria including 'measuring the duration of completing the questionnaire' and 'calculating the percentage of missed items' will be used to assess the ease of questionnaire administration (26).

Scoring

As the characteristics of the expressions of the questionnaire have not been clarified yet, after terminating the qualitative and quantitative sections, decisions on the choices will be made by the research team .

To better understand the scoring and comparability, scores of all factors will be transformed: zero to 100 (26).

$$\text{Factor Score} = \frac{\text{Obtained score from each factor} - \text{The minimum score}}{\text{Maximum score} - \text{Minimum score}} \times 100$$

Validation of a Mixed-method Study

Choosing unfitting individuals and disproportionate sample size at the time of collecting data, designing a questionnaire that lacks good validation features, selecting weak qualitative data for using in the quantitative section, and comparing and integrating qualitative and quantitative data rather than associating them are among the threats to validity of a study .

In this study, to prevent the threats while collecting the data, different participants will be recruited in the qualitative and quantitative sections and efforts will be made to prevent the entrance of any participant from the qualitative to quantitative section, as an interval of several months will be considered for collecting qualitative and quantitative data. In the qualitative section of the study, an adequate number of participants will be used until data saturation is reached. However, in the quantitative section, bigger sample size will be utilized. Sampling adequacy will be investigated and confirmed using the sampling adequacy index in the factor analysis model. In designing the questionnaire, categories, and themes that emerged from the qualitative section will be used. All questionnaire designing and validating processes will be scrutinized by one of the researchers and reviewed by other research team members. To reduce the potential threats of interpretation time, first, qualitative data and then quantitative data will be interpreted. This is because based on common approaches of exploratory design, a quantitative study is carried out based on the qualitative study. At last, the researchers will associate qualitative and quantitative results to each other.

This protocol has been extracted from a PhD dissertation and investigated in the Ethics Committee of Shahid

Beheshti University of Medical Sciences and approved with a code number of IR.SBMU.PHARMACY.REC.1398.199 and will be sponsored by this university. In all phases of the study, written informed consent will be obtained from the participants. The researchers intend to publish the findings of each phase as a separate article.

Results

After the qualitative phase, an item pool will be developed based on the extracted codes and subclasses and items of similar tools obtained by the systematic review of the literature. The number of codes and the description of subcategories, generic and main categories derived from the qualitative study, and the number of related tools were derived from the systematic literature review will be reported. The research team will examine the item pool, and similar items with overlap will be deleted or merged. So, the primary questionnaire will be developed. The number of items in the primary and final item pool will be reported. At this stage, the questionnaire will also be scaled. In the second phase, the psychometric properties of the primary tool will be assessed according to these steps:

After assessing qualitative and quantitative face validity, the content validity of the questionnaire will be evaluated. At first, the qualitative content validity will be assessed. After the modifications, the CVR, I-CVI, and scale- CVI will be calculated, and the deletion of items will be done according to them. The number of deleted or modified items and all indexes will be reported at each step .

Before the assessment of construct validity, the item analysis will be assessed. The number of items that were deleted at this step will be declared. In the construct validity assessment step, with EFA, the possible subdomains of the questionnaire and the total variance explained by the questionnaire as well as the number of questionnaire items before and after the EFA and the factor loading and communalities of each item will be reported. In assessing reliability, the consistency of values obtained from an attribute, question, or position in a study or clinical practice will be evaluated. In this regard, the questionnaire's internal consistency and relative stability will be assessed, and the Cronbach's Alpha and the ICC of each domain will be reported. After that, the responsiveness will be evaluated to ensure the questionnaire's ability to detect the changes in the caregiver burden concept over time. In this regard, SEM and MDC will be reported. Then the interpretability will be evaluated to ensure the ability of the questionnaire to refer qualitative meanings to quantitative scores, and ceiling and floor effect and MIC will be reported. At the next step, for reporting the feasibility of using the questionnaire, the duration of completing the questionnaire and the percentage of missed items will be declared. Finally, in the last step, the scoring of the questionnaire will be determined and reported.

Discussion

The present study will be performed in Tehran using the Sequential Exploratory Mixed Method Design with the aim of designing and validating a specific questionnaire of measuring caregiver burden in family caregivers of hemodialysis patients .

There are limited numbers of studies that have provided information about the life of family caregivers of hemodialysis patients and investigated their caregiver burden (3, 6). In these studies, the tools for measuring caregiver burden mainly included the Zarit Burden Interview Questionnaire (ZBI), Caregiver Burden Scale (CBS), Oberst Caregiver Scale (3, 8). ZBI is a 29-question self-report questionnaire that was firstly designed for measuring the burden in caregivers of dementia patients and investigates caregiver burden in caregivers through assessing their health, psychological health, financial status, social life, and the relationship between the patients and their caregivers (38). CBS is a 22-question scale that has been designed for measuring caregiver burden in caregivers of patients diagnosed with a stroke. This scale consists of general strain, seclusion, depression, affective involvement, and environment subscales (39). Oberst Caregiver Scale is a 15-question scale with 2 subscales of the Difficulty of Caregiving Tasks and the Time Needed for Giving Care that has been designed for the patients diagnosed with stroke (40). The mentioned and most other current tools investigate the problems and general aspects of the caregiver burden. However, they do not inspect the overall dimensions of caregiver burden in caregivers of hemodialysis patients. Reviews did not indicate any specific tools for measuring caregiver burden in caregivers of hemodialysis patients .

Distinct and specific features of end-stage chronic kidney disease, different and particular medical treatment of such patients (hemodialysis patients), various underlying diseases, specific care-needs such as complications concerning specific therapeutic regimen (limited reception of liquids, or Sodium and Potassium restricted diet), numerous medical regimen, a need for meticulous dialysis sessions, and spending 3 or 4 hours a week for dialysis and its side effects, dependency on a dialysis machine, care issues related to vascular access (9, 41-45), high prevalence of sleep disorders, and fatigue and depression (46) in these patients bring about a specific kind of caregiver burden that has not been dealt with in most current tools of caregiver burden. Therefore, in these tools, there is a gap in detecting the challenges of long-term care, caregivers' sexual and social issues that they encounter as a result of caring for the patient; also, occupational issues that the caregiver is involved with due to taking the patient to hemodialysis sessions (6) as well as designing the tools based on the current theories. Consequently, it seems that designing and validating a specific questionnaire for measuring caregiver burden in family caregivers of hemodialysis patients is crucial.

Limitation

One of the potential limitations of this study could be that the participants are only being recruited from Tehran, the capital of Iran, which might influence the discovery of other aspects of caregiver burden in rural, deserted, and underprivileged areas.

Conclusion

It seems that a specific questionnaire for measuring caregiver burden in family caregivers of hemodialysis patients could be a facilitator of identifying and measuring the actual caregiver burden and making supportive decisions to reduce the burden. Identifying the authentic aspects of caregiver burden provides the opportunities for more purposeful plans for service providers.

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Conflict of Interest

None.

References

1. Cantekin I, Kavurmacı M, Tan M. An analysis of caregiver burden of patients with hemodialysis and peritoneal dialysis. *Hemodial Int*. 2016;20(1):94-7.
2. Fekete C. Caregiver Burden. *International Encyclopedia of the Social & Behavioral Sciences*. 2nd ed. Oxford: Elsevier; 2015.
3. Hoang VL, Green T, Bonner A. Informal caregivers' experiences of caring for people receiving dialysis: A mixed-methods systematic review. *J Ren Care*. 2018;44(2):82-95.
4. Low J, Smith G, Burns A, Jones L. The impact of end-stage kidney disease (ESKD) on close persons: a literature review. *NDT Plus*. 2008;1(2):67-79.
5. Oyegbile YO, Brysiewicz P. Exploring caregiver burden experienced by family caregivers of patients with End-Stage Renal Disease in Nigeria. *Int J Afr Nurs Sci*. 2017;7:136-43.
6. Salehitali S, Ahmadi F, Hasanpour Dehkordi A, Noorian K, Fereidooni-Moghadam M, Zarea K. Progressive exhaustion: A qualitative study on the experiences of Iranian family caregivers regarding patients undergoing hemodialysis. *Int J Nurs Sci*. 2018;5(2):193-200.
7. Alnazly E. Coping strategies and socio-demographic characteristics among Jordanian caregivers of patients receiving hemodialysis. *Saudi J Kidney Dis Transpl*. 2016;27(1):101-6.
8. Gilbertson EL, Krishnasamy R, Foote C, Kennard AL, Jardine MJ, Gray NA. Burden of

- Care and Quality of Life Among Caregivers for Adults Receiving Maintenance Dialysis: A Systematic Review. *Am J Kidney Dis*. 2019;73(3):332-43.
9. Sajadi SAM, Ebadi AP, Moradian STP. Quality of Life among Family Caregivers of Patients on Hemodialysis and its Relevant Factors: A Systematic Review. *Int J Community Based Nurs Midwifery*. 2017;5(3):206-18.
10. Glajchen M, Kornblith A, Homel P, Fraidin L, Mauskop A, Portenoy RK. Development of a brief assessment scale for caregivers of the medically ill. *J Pain Symptom Manage*. 2005;29(3):245-54.
11. Creswell J, Creswell D. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. 5th ed: SAGE Publications; 2018.
12. Chou KR, LaMontagne LL, Hepworth JT. Burden experienced by caregivers of relatives with dementia in Taiwan. *Nurs Res*. 1999;48(4):206-14.
13. Chou KR. Caregiver burden: a concept analysis. *J Pediatr Nurs*. 2000;15(6):398-407.
14. Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs*. 2008;62(1):107-15.
15. Assarroudi A, Heshmati Nabavi F, Armat MR, Ebadi A, Vaismoradi M. Directed qualitative content analysis: the description and elaboration of its underpinning methods and data analysis process. *J Res Nurs*. 2018;23(1):42-55.
16. Polit DF, Beck CT. *Essentials of Nursing Research: Appraising Evidence for Nursing Practice*. 9th ed. Wolter Kluwer; 2017.
17. Whiting LS. Semi-structured interviews: guidance for novice researchers. *Nurs Stand*. 2008;22(23):35-40.
18. Sandelowski M. Sample size in qualitative research. *Res Nurs Health*. 1995;18(2):179-83.
19. Speziale HS, Streubert HJ, Carpenter DR. *Qualitative research in nursing: Advancing the humanistic imperative*: Lippincott Williams & Wilkins; 2011.
20. Thomas E, Magilvy JK. Qualitative rigor or research validity in qualitative research. *J Spec Pediatr Nurs*. 2011;16(2):151-5.
21. Lincoln YS, Guba EG. But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. *New directions for program evaluation*. 1986;1986(30):73-84.
22. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*. 2009;6(7):e1000097.
23. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol*. 2010;63(7):737-45.
24. Waltz C, Strickland OL, Lenz E. *Measurement in Nursing and Health Research*. Fifth ed. New York: Springer Publishing Company; 2016.

25. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. *J Caring Sci.* 2015;4(2):165-78.
26. Nikpour M, Tirgar A, Ebadi A, Ghaffari F, Firouzbakht M, Hajiahmadi M. Development and psychometric evaluation of a women shift workers' reproductive health questionnaire: study protocol for a sequential exploratory mixed-method study. *Reprod Health.* 2018;15(1):22.
27. Taghizadeh Z, Ebadi A, Montazeri A, Shahvari Z, Tavousi M, Bagherzadeh R. Psychometric properties of health related measures. Part 1: Translation, development, and content and face validity. *Payesh (Health Monitor).* 2017;16(3):343-57.
28. Lawshe CH. A quantitative approach to content validity. *Personnel psychology.* 1975;28(4):563-75.
29. Polit. D F, Yang. F. *Measurement and the Measurement of Change.* 1st ed: LWW; 2015.
30. Piedmont RL, Hyland ME. Inter-item correlation frequency distribution analysis: A method for evaluating scale dimensionality. *Educ Psychol Meas.* 1993;53(2):369-78.
31. Gaskin CJ, Happell B. On exploratory factor analysis: a review of recent evidence, an assessment of current practice, and recommendations for future use. *Int J Nurs Stud.* 2014;51(3):511-21.
32. Plichta Kellar S, Kelvin E. *Munro's Statistical Methods for Health Care Research* 6th ed: Lippincott Williams & Wilkins; 2012.
33. Hair Jr J, Black W, Babin B, Anderson R. *Multivariate Data Analysis.* Seventh ed: Pearson; 2014.
34. Polit DF. Assessing measurement in health: Beyond reliability and validity. *Int J Nurs Stud.* 2015;52(11):1746-53.
35. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol.* 2007;60(1):34-42.
36. Ebadi A, Taghizadeh Z, Montazeri A, Shahvari Z, Tavousi M, Bagherzadeh R. Translation, development and psychometric properties of health related measures-Part 2: construct validity, reliability and responsiveness. *Payesh (Health Monitor).* 2017;16(4):445-55.
37. Mokkink LB, Terwee CB, Gibbons E, Stratford PW, Alonso J, Patrick DL, et al. Inter-rater agreement and reliability of the COSMIN (Consensus-based Standards for the selection of health status Measurement Instruments) checklist. *BMC Med Res Methodol.* 2010;10:82.
38. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist.* 1980;20(6):649-55.
39. Elmståhl S, Malmberg B, Annerstedt L. Caregiver's burden of patients 3 years after stroke assessed by a novel caregiver burden scale. *Arch Phys Med Rehabil.* 1996;77(2):177-82.
40. Bakas T, Austin JK, Jessup SL, Williams LS, Oberst MT. Time and difficulty of tasks provided by family caregivers of stroke survivors. *J Neurosci Nurs.* 2004;36(2):95-106.
41. Ravaghi H, Behzadifar M, Behzadifar M, Taheri Mirghaed M, Aryankhesal A, Salemi M, et al. Prevalence of Depression in Hemodialysis Patients in Iran: a Systematic Review and Meta-analysis. *Iran J Kidney Dis.* 2017;11(2):90-8.
42. Mellon L, Regan D, Curtis R. Factors influencing adherence among Irish haemodialysis patients. *Patient Educ Couns.* 2013;92(1):88-93.
43. Katzir Z, Boaz M, Backshi I, Cernes R, Barnea Z, Biro A. Medication apprehension and compliance among dialysis patients--a comprehensive guidance attitude. *Nephron Clin Pract.* 2010;114(2):c151-7.
44. Alosaimi FD, Asiri M, Alsuwayt S, Alotaibi T, Bin Mugren M, Almufarrih A, et al. Psychosocial predictors of nonadherence to medical management among patients on maintenance dialysis. *Int J Nephrol Renovasc Dis.* 2016;9:263-72.
45. Aghakhani N, Sharif F, Molazem Z, Habibzadeh H. Content analysis and qualitative study of hemodialysis patients, family experience and perceived social support. *Iran Red Crescent Med J.* 2014;16(3): e13748.
46. Song YY, Hu RJ, Diao YS, Chen L, Jiang XL. Effects of Exercise Training on Restless Legs Syndrome, Depression, Sleep Quality, and Fatigue Among Hemodialysis Patients: A Systematic Review and Meta-analysis. *J Pain Symptom Manage.* 2018;55(4):1184-95.