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Standardised Outcomes in Nephrology – Peritoneal Dialysis (SONG-PD): study protocol for establishing a core outcome set in peritoneal dialysis

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Abstract

Background—Worldwide, approximately 11% of patients on dialysis receive peritoneal dialysis (PD). Whilst PD may offer more autonomy to patients compared with haemodialysis, patient and caregiver burnout, technique failure, and peritonitis remain major challenges to the success of PD. Improvements in care and outcomes are likely to be mediated by randomised trials of innovative therapies, but will be limited if the outcomes measured and reported are not important for patients and clinicians. The aim of the Standardised Outcomes in Nephrology-Peritoneal Dialysis (SONG-PD) study is to establish a set of core outcomes for trials in patients on PD based on the shared priorities of all stakeholders, so that outcomes of most relevance for decision making can be evaluated, and that interventions can be compared reliably.

Methods—The five phases in the SONG-PD project are: a systematic review to identify outcomes and outcome measures that have been reported in randomised trials involving patients on PD; focus groups using nominal group technique with patients and caregivers to identify, rank, and describe reasons for their choice of outcomes; semi-structured key informant interviews with health professionals; a three-round international Delphi survey involving a multi-stakeholder panel; and a consensus workshop to review and endorse the proposed set of core outcome domains for peritoneal dialysis trials.

Discussion—The establishment of 3–5 high-priority core outcomes, to be measured and reported consistently in all trials in PD, will enable patients and clinicians to make informed decisions about the relative effectiveness of interventions, based upon outcomes of common importance.

Keywords

Core outcome set; Outcomes research; Patient-reported outcomes; Patient-centred outcomes; Clinical trials; Dialysis; Peritoneal dialysis; Chronic kidney disease

Background

End stage kidney disease (ESKD) is a global public health problem, with the number of patients requiring a kidney transplant or dialysis exceeding 2.6 million and continuing to rise.(1,2) Patients on dialysis, either haemodialysis (HD) or peritoneal dialysis (PD), have a five-year survival rate of only 30% to 50% in high-income countries, and severely impaired quality of life.(3–8) Approximately 11% of patients on dialysis worldwide use PD, although this proportion varies across countries from less than 0.1% in Egypt, 10% in the United States, 17% in the United Kingdom, 25% in Latin America, 23% in Australia, to 76% in Hong Kong.(6,9) Whilst PD is associated with lower health care costs and offers patients more independence, freedom, and flexibility compared with haemodialysis,(10–13) technique failure remains a major challenge to the success of PD.(14,15) Moreover, since PD is usually performed in the home by the patient or caregiver, the daily and ongoing responsibilities of PD can be demanding, stressful and overwhelming for some, which can

then lead to patient and caregiver burnout.(16) These issues emphasise the need for care which is informed by research relevant to patients, caregivers and clinicians.(17)

Despite the increase in the number of randomised trials in nephrology, and more specifically in PD, there is an apparent lack of patient-centred outcomes reported in trials.(18) Outcomes of value to PD patients, such as the ability to work or to travel,(16) are generally not reported. Concerns about the “idolatry of the surrogate”(18) have led to the growing recognition of the need to report patient-centred outcomes including mortality, functioning, symptoms, and other dimensions of quality of life. Incorporating patient values in research priority setting and study design not only improves patient-centred outcomes, but can optimise patient satisfaction and promote adherence to treatment.(19)

Instead of reporting patient-centred outcomes, trials frequently report surrogate outcomes, such as biochemical markers. Surrogate outcomes are typically chosen based on feasibility, i.e. those that require less time, resources, and trial participants to evaluate treatment efficacy.(20) This is problematic given that serum biomarkers are generally not well validated and may not translate into health and quality of life outcomes that are directly meaningful to patients.(21,22) For example, in a Cochrane review of biocompatible dialysis fluids for PD involving 36 studies (n=2719 participants), biochemical markers only were reported in most trials and only 17 (47%) studies reported death, 3 (8%) reported technique survival, 1 (3%) reported inflow pain, and 1 (3%) reported quality of life.(23)

The substantial heterogeneity among outcomes measured and reported is a common problem across all trials, even when the outcome appears the same.(24) For example, in the same Cochrane review, peritonitis rates were variably reported as either incidence or episodes, and at a variety of different time points.(23) When outcome heterogeneity arises, it hampers the ability to compare the effectiveness of interventions across trials, and to combine trial results (such as in a meta-analysis), such that relative effectiveness of interventions is not able to estimated reliably.(24,25) This generates substantial inefficiencies in research and contributes to research waste, ultimately creating obstacles to greater evidence-based practice.(26)

Another issue which often diminishes the reliability and validity of clinical trials is that of outcome reporting bias.(27) This type of selective reporting occurs as a result of reporting only the outcomes that favour the intervention, thereby potentially overestimating the effect.(28) This may also occur when researchers omit or change outcomes in trial publications which had previously been recorded as primary outcomes in their protocols or registries. When adverse events are not reported, patients are potentially at risk of being exposed to the ineffective or harmful effects of interventions.(27,29,30)

To address these multifaceted problems of outcomes that are reported in clinical trials, there are many discipline-specific and global initiatives to develop core outcome sets – an agreed minimum set of standardised outcomes that should be measured and reported in all trials of a specific condition.(24,31–33) The conceptual schema of core outcome domains is shown in Figure 1. Major advantages of core outcome sets include enabling the direct comparison of the effects of different interventions, enhancing the relevance and importance of outcomes to

patients and health care providers, and minimizing reporting bias.(24,32,34,35) The Outcome Measures in Rheumatology (OMERACT) initiative was formed in 1992 and set the foundation for development of core outcomes, specifically in rheumatology trials.(36) With the engagement of patients, health care providers, and policy makers, OMERACT has improved the relevance of outcome reporting in rheumatology trials.(36–38) Studies from other conditions have also successfully applied the OMERACT methodology to develop core outcomes sets.(39,40) To facilitate the development and collation of core outcome sets across all diseases internationally, the Core Outcome Measures in Effectiveness Trials (COMET) initiative was established and they provide a database of initiatives and resources for developing core outcome sets.(41)

The Standardised Outcomes in Nephrology (SONG) initiative aims to establish core outcome domains and outcome measures across the full spectrum of chronic kidney disease, with the streams SONG-HD (haemodialysis),(42) SONG-Tx (kidney transplantation),(43) and SONG-Kids (children and adolescents)(44) currently underway. The specific aims of SONG-PD are to: 1) describe the scope, quality, and consistency of outcomes used in PD trials; 2) identify outcomes that are important to patients and caregivers; 3) ascertain health professional attitudes, values, and beliefs regarding outcomes for PD trials; 4) generate a consensus-based prioritised list of core outcome domains; and 5) establish a set of core outcome domains for trials conducted in people on PD.

Methods/design

The SONG-PD process will follow the standard methods used in previous streams of the SONG Initiative, which were informed by the OMERACT framework that has been recognised by the World Health Organisation (WHO) as a valid approach for developing core outcomes.(36,45) As the core outcomes are to be reported in all PD trials, identifying 3 to 5 core outcomes has been recommended based on feasibility.(36,46) We will use the Core Outcome Set – Standard for Reporting (COS-STAR)(47) to report all phases of the SONG-PD project. SONG-PD involves five phases: a systematic review, focus groups using nominal group technique, semi-structured key informant interviews, an international online Delphi survey, and a consensus workshop (Figure 2).

Phase 1: Systematic review of outcome domains reported in randomised controlled trials of interventions for peritoneal dialysis

The systematic review will identify and assess the scope and consistency of outcome domains and outcome measures reported in randomised controlled trials (RCTs) of interventions for adults on PD.

Search strategy—We will conduct a comprehensive search of MEDLINE, Embase, Clinicaltrials.gov and the Cochrane Kidney and Transplant Specialised Register of trials to identify all RCTs that enrolled patients aged 18 years or older receiving PD for trials published (or trial protocols registered) within the last five years (2011 – 2016). No language restrictions will be applied.

Types of studies—We will include all RCTs published in peer-reviewed journals and trial protocols. Protocols are included because they define the intended outcome(s) of a trial. Abstracts and conference reports will not be included as they do not provide a complete and reliable source of all the outcomes reported and measured in trials.

Inclusion criteria—Any intervention used to treat and manage adult patients on PD will be included. These may include pharmacological, surgical, technical (e.g. PD catheters, dialysis solutions), lifestyle, psychosocial, and health service interventions. Studies including adult patients aged 18 years or older on PD will be included. Studies with patients on other forms of treatment (kidney transplantation, haemodialysis, not on renal replacement therapy) will be included if they enrolled more than 50% of patients on PD.

Data extraction—All records retrieved from the electronic searches, including full texts of all potentially relevant RCTS, will be independently assessed by two reviewers. Any disagreement on the eligibility of studies will be resolved through discussion with a third reviewer. Characteristics from all included trials will be extracted by one reviewer and will include the following: first author, publication date, country in which trial was conducted, participant characteristics (age, gender), trial duration, type of peritoneal dialysis (continuous ambulatory peritoneal dialysis or automated peritoneal dialysis), name and type of intervention (e.g. surgical, pharmacological, psychosocial, lifestyle), and all outcomes as reported in the trial (including definitions, measurement instruments, thresholds, measurement time points or time frames, changes in level or percentage, scores).(48) At least two reviewers will cross check the data extraction.

Data analysis and presentation—One reviewer will group similar outcomes into outcome domains, which will be classified as surrogate, clinical, or patient-reported. A surrogate endpoint or outcome is a biochemical, imaging, or other marker used as a substitute for a clinical outcome.(49) A clinical outcome will be defined as a medical event or comorbidity (e.g. mortality, peritonitis, hospitalisation) diagnosed by the clinician.(50) Patient-reported outcomes are reported directly from patients regarding how they function or feel in relation to a health condition and its therapy, without interpretation by a healthcare professional or anyone else.(51) The domains will be reviewed and discussed by the SONG-PD Steering Group to assess the appropriateness of domain name and grouping of outcomes. We will ascertain the frequency of reporting across trials for each outcome domain. We will assess the number of different outcomes (including outcome measures and measurement time points) and the number of trials that assessed each specific outcome. We will perform statistical analyses of the frequency of outcomes using the software package R version 3.2.3 (*R Foundation for Statistical Computing, Vienna, Austria)*.

Phase 2: Focus groups with nominal group technique

We will conduct focus groups to identify outcomes important to patients on PD and their caregivers. Patients and caregivers will be asked to identify outcomes that they consider relevant in trials, and to explain the reasons for their choices. The focus group/nominal group technique provides a structured and transparent process of gaining consensus based on group discussion, and has been successfully used to define research and outcome priorities

in other areas including haemodialysis and kidney transplantation.(52–54) This technique is useful for generating and prioritizing ideas, and facilitates a balanced and equitable contribution of ideas by all participants.

Participants and recruitment—Patients and caregivers aged 18 years or over who have current or previous experience with PD will be invited to participate. Approximately 15 nominal groups will be convened. The final number of groups will depend on when data saturation occurs i.e. when further sampling of participants does not contribute to new outcomes or ideas are being raised.

Participants will be initially recruited from three participating centres in Australia (Westmead Hospital, Monash Medical Centre, and Princess Alexandra Hospital), one centre in the United States (Harbor-UCLA Medical Center), and four centres in Hong Kong (Queen Mary Hospital, Princess Margaret Hospital, Pok Oi Hospital, and Tuen Mun Hospital). Depending on feasibility and saturation, focus groups may be organised at additional sites. We will purposively sample patients to include a wide range of demographic (age, gender, socioeconomic status, ethnicity) and clinical (diagnosis, PD modality [continuous ambulatory peritoneal dialysis, automated peritoneal dialysis], duration on dialysis, transplant wait-listing status) characteristics. Informed consent will be obtained from all participants. Ethics will be obtained from the Human Research Ethics Committee (HREC)/ Institutional Review Board (IRB) for all participating sites.

Data collection—Focus groups will be approximately 2 hours in duration and held in a convenient location external to the hospital to minimise censoring of discussion that may have otherwise occurred in a healthcare setting. A trained and experienced facilitator will moderate the discussion. A note-taker will record contextual details of the discussion including participants' dispositions and interactions. All discussions will be audiotaped and transcribed verbatim. The question guide will be adapted from previous guides designed and used to elicit outcomes in adult haemodialysis patients or kidney transplant recipients, (53,54) and includes the following:

- **i.** Welcome and introduction – including explanation about outcomes research (15 min)
- **ii.** Focus group discussion (20 min) – participants will be asked to discuss their experiences of PD and perceived benefits, harms, and complications of PD and PD-related interventions.
- **iii.** Nominal group technique (50 min) – participants will be asked to individually write one or two outcomes that they believe are important for research. The facilitator will ask participants to read their outcomes to the group and these will be listed on a board. Each outcome will be defined and discussed, and other outcomes identified from Phase 1 (systematic review) will be added to the list. A copy of the consolidated list will be printed for each participant and they will be asked to rank the outcomes in the order of perceived importance, from 1 (most important) to X (least important). The similarities and differences in ranking between participants will be discussed amongst the group.

Data analysis

Quantitative rating/ranking—The top ten ranked outcomes for each participant will be assigned a value of 10 (most important) through to 1 (least important). Outcomes excluded from the top ten will be assigned a value of zero. We will obtain a mean priority score for each outcome by summing the ranked scores and dividing this by the maximum possible ranking score for that outcome. To calculate the maximum possible ranking score, we will multiply the maximum rank (10) by the number of participants who considered the outcome. For example, a priority score of 100% indicates that all participants who ranked a given outcome scored it as the most important. A priority score of 0% for a given outcome indicates that none of the participants scored it in the top 10. We will calculate the number of participants who rank a specific outcome in the top ten. We will also conduct a subgroup analysis of mean priority scores according to key demographic and clinical characteristics. Analysis of variance will be used to assess differences in mean priority scores. The statistical package SPSS version 22 (SPSS Inc., Chicago, IL, USA) will be used to conduct the analysis.

Qualitative analysis—Transcripts will be imported into HyperRESEARCH (ResearchWare Inc. www.researchware.com, version 3.7.3) software. Using thematic analysis and drawing from the principles of grounded theory, as detailed by Corbin and Strauss,(55) the transcripts will be reviewed line by line and inductively coded to identify concepts, based on reasons underpinning the participants' ranking choices. Similar concepts will be grouped into themes and corresponding subthemes. Discussion amongst the research team will ensure that the preliminary themes capture the full range and depth of the data.

Phase 3: Semi-structured key informant interviews

Semi-structured key informant interviews will be conducted to elicit a broad array of individual beliefs, values, attitudes, and perspectives towards establishing core outcomes for PD. Reporting of interviews will be based on the Consolidated Criteria for Reporting Qualitative Health Research (COREQ).(56)

Participants and recruitment—Interviews will be conducted with health professionals involved in the care of patients on PD, such as nephrologists, surgeons, nurses, psychologists, occupational therapists, physiotherapists, social workers, and dietitians. A minimum of 60 health professionals will be recruited across all regions internationally, and identified from established networks of the Investigators and Steering Group. We will purposively sample participants to ensure representation of demographic, professional, cultural, and regional characteristics and experiences. Recruitment will occur until theoretical data saturation has been achieved. Informed consent will be obtained from all participants.

Data collection—The interview guide will incorporate the results from phases 1 (systematic review) and 2 (focus groups). One investigator (KEM) will conduct face-to-face interviews, and Skype or telephone interviews will be possible if in-person interviews cannot be arranged. Participants will be asked to reflect and discuss: i) their experiences of providing care for patients on PD; ii) advantages and risks of peritoneal dialysis; iii)

outcomes they perceive as important to include in PD trials and their justifications; and (iv) their perspectives on the results obtained from patient/caregiver focus groups. Interviews will take approximately 30–45 minutes and will be audio-recorded and transcribed.

Data analysis

All outcomes identified by participants will be extracted from the transcripts. As detailed in phase 2, we will use grounded theory and thematic analysis to identify themes which reflect the perspectives, beliefs, priorities, and values about core outcomes for PD. To ensure that the complete range and depth of the data are included, at least two investigators will be involved in coding the data to develop descriptive and analytic themes (investigator triangulation in qualitative research). The preliminary results will also be checked by the interview participants and the SONG-PD Steering Group.

Phase 4: Delphi consensus survey

A Delphi survey will be conducted to gain consensus on the 3 to 5 core outcome domains which are most important to stakeholders internationally. The survey will be conducted online and will involve three rounds of surveys completed by a panel of anonymous participants who have experience or expertise in PD.(31,52) Individual participants will be able to provide feedback and contribute their perspectives on the results from each round to the group. This in turn will provide the opportunity for participants to revise their choices in response to the views of others.(57) The Delphi is a validated technique which has been used across a variety of health disciplines to generate consensus on core outcomes for clinical trials.(58–62)

Participants and recruitment—There is no universal agreement on the appropriate sample size for a Delphi panel.(63) The majority of Delphi surveys used to develop core outcome sets have included less than 200 respondents, although Delphi surveys used to develop core outcomes for trials involving adults on haemodialysis (SONG-HD) and kidney transplantation (SONG-Tx) have included more than 1000 respondents.(64,65) The minimum target sample size for SONG-PD will be 1000 respondents with at least 500 of these being patients on PD/caregivers. The study will aim to recruit nephrologists and surgeons (minimum n = 300); nursing, dietitians, and allied health professionals (n = 100); and policy makers, researchers, and representatives from industry (n = 100); who have experience or expertise in PD outcomes.

We will use an opt-in recruitment strategy with snowball sampling, i.e. where key informants are identified for recruitment by existing study subjects, to ensure that a broad range of participant characteristics and experiences are captured. Patients/caregivers will be recruited through the participating hospital/university institutions of the SONG-PD Steering Group and investigators, patient/consumer organisations, and the SONG Initiative database. Health professionals from a range of countries will be recruited via existing SONG investigator networks and professional PD societies.

Data collection

Generating the list of outcomes: The Delphi survey will include outcome domains from the systematic review of outcomes reported in RCTs (phase 1), outcomes identified in the nominal group technique (phase 2), outcomes identified in the key informant interviews (phase 3), and from other relevant studies including qualitative studies on patient perspectives of PD.(16,19) For feasibility, the outcomes will be listed individually but grouped under the relevant domain; surrogate, clinical, or patient-reported. All outcomes will include a plain language definition. The survey will be reviewed by the SONG Executive Committee and SONG-PD Steering Group, and piloted with at least 10 patients/caregivers.

Survey administration: All participants will register their name and email address via www.songinitiative.org. Informed consent will be obtained from all participants at the beginning of the survey. The surveys will be completed through the online survey platform LimeSurvey, which will be optimised for both desktop and mobile viewing. The survey will be piloted online by members of the SONG-PD Steering Group and with at least 10 patients/caregivers prior to launch. Each participant will be given a unique identifier so that their responses from each round of the survey can be linked anonymously. A minimum of three reminders will be sent to the participants during the Delphi rounds in an attempt to retain a response rate of at least a 70% across all three rounds. Participants who complete all 3 rounds will receive a copy of the preliminary results to provide feedback and comment.

Round 1: Participants will be asked to rate each of the outcome domains (approximately 30) using the GRADE 9-point Likert scale.(66) The visual scale used for each outcome will indicate ratings 1 to 3 as “limited importance”; 4 to 6 as “important, but not critical”; and 7 to 9 as “critical importance.” An option of “unsure” will also be provided. Responses to the rating questions will be mandatory. For each outcome, an optional free-text box will be provided where participants can provide comments. To minimise ordering bias, the sequence of outcomes shown will be randomised. At the end of the round, participants can suggest new outcomes. All new outcomes that are suggested by more than 10% of participants that do not overlap or duplicate existing outcomes will be recoded and grouped by at least two investigators and reviewed by the SONG-PD Steering Group, then carried through to round 2.

We will review the distribution of scores across all outcomes, and any outcome with a median and mean of more than 7 (with greater than 70% of both patient/caregiver and health professionals rating the outcome 7–9; based on the OMERACT criteria for “consensus in”) will be retained in round 2. Any outcomes that are not retained in subsequent rounds will be listed in the middle and outer tier (Figure 1).

Round 2: Participants will be presented with a column graph of the distribution of scores for each outcome for the following groups: (1) patients/caregivers, (2) health professionals, and (3) all participants (with scores weighted evenly between groups). An explanation of how to read the graph will be provided to ensure that participants can understand and interpret the graph clearly. They will also see comments from round 1 by patients/caregivers and health

professionals. Their own response from round 1 will be highlighted in the rating scale. Participants will re-rate each outcome and any additional outcomes identified in round 1 using the same Likert scale. An optional free-text box will be provided for participants to explain reasons for their rating or to provide responses to the comments.

An outcome with a median and mean of more than 7 (with greater than 70% of both patient/caregiver and health professionals rating the outcome 7–9) will be included in round 3.

Round 3: Participants will view the distribution of scores for each outcome for all participants and by the stakeholder groups, and comments from round 2. Participants will see their own scores from round 2 highlighted in the rating scale and re-rate all outcomes. An optional free-text box will be provided for participants to make any additional comments. After the rating questions, participants will be asked to complete a best-worst scale survey.(67) They will be presented with up to six lists each of which will contain a subset of six of the outcomes remaining in round 3. Participants will be asked to choose the most important and least important outcomes from each list. To minimise survey fatigue, the best-worst scale survey will use a balanced incomplete block design(68) split into four blocks with participants randomly assigned to complete one of the four blocks. The design will be finalised after completion of round 2. The best-worst scaling survey will quantify the relative importance of each of the round 2 outcomes.

Data analysis

We will summarise the distribution of scores for the three rounds and calculate the mean, median, and proportion for ratings of each outcome. The scores will be calculated separately for patients/caregivers and health professionals. We will use a Wilcoxon sign rank test or t test to compare the mean difference in rating scores between both stakeholder groups, with a significance value of $P<0.05$. Data analysis for the best-worst scale survey will involve calculating the relative importance score for each of the round 2 outcomes. Multinomial logistic regression models will be used to calculate a relative importance score for each outcome normalised to the range 0 (least important) to 10 (most important). Importance scores will be calculated separately for patients, caregivers and health professionals. The influence of demographic factors, such as age and time on dialysis will also be investigated.

As the distribution of scores is unknown until after Round 3, it is not possible to provide an *a priori* definition of consensus based on ratings and best-worst scale scores. However, based on previous SONG initiatives,(65) “consensus” for outcome domains will be based on both patients/caregivers and health professionals having a median score of greater than or equal to 8; a mean score greater than or equal to 7.5; the proportion of participants rating the outcome 7 to 9 (critically important) being greater than or equal to 75%. To ensure feasibility, the study will aim to identify 3 to 5 critically important outcome domains. The definition of consensus will also be discussed at the consensus workshop (phase 5).

Phase 5: Consensus workshop

We will convene a consensus stakeholder workshop at the 17th Congress of the International Society for Peritoneal Dialysis(69) in Vancouver. The purpose of the workshop is to review

results from phases 1 to 4, and to discuss the potential core outcome domains. Strategies to develop outcome measures will also be discussed. The aim will be to have at least 60 participants, with a minimum of 20 patients and family members. Purposive sampling i.e. selecting participants based on their ability to contribute towards the topic, will be applied to ensure that a wide range of participant characteristics and expertise are captured. Invitations will be extended to health professionals (physicians [nephrologists, surgeons, and psychiatrists], nurses and allied health professionals [including psychologists, dietitians, social workers, occupational therapists, and physiotherapists], researchers, policy makers, industry) with experience in PD practice, research and policy. To facilitate implementation, we will also invite health professionals who have key roles in specialty professional organisations (e.g. International Society of Peritoneal Dialysis), guidelines (e.g. Kidney Disease Improving Global Outcomes), registries, journals (e.g. Peritoneal Dialysis International); as well as regulatory agencies and funding organisations. The workshop will be audio-recorded and transcribed.

Participants will be sent a copy of the results from phases 1 to 4 prior to the workshop and asked to consider the results to date, so that they are more prepared and engaged to relay their feedback. The workshop will include three parts:

Part 1: Introduction—We will present an introduction to SONG-PD by outlining the aims and the process, and the results from phases 1 to 4, including the preliminary set of core outcome domains and proposed consensus classification.

Part 2: Breakout groups—Participants will be assigned to five breakout groups with approximately 12 participants per group (each with a facilitator and co-facilitator). Groups will include a variety of stakeholders, including a minimum of two patients/family members to promote a wider dynamic discussion and exchange of different perspectives. A trained facilitator will moderate the group discussion that will be focussed on the potential core outcome domains, as well as strategies for implementation. A briefing session will be held for all facilitators prior to the breakout groups and a detailed run sheet with the question guide will be provided.

Part 3: Plenary discussion—Following the breakout groups, groups will reconvene to participate in a broader group discussion. Each breakout group will summarise their discussion and relay this to the wider group. Participants will be encouraged to comment on the issues raised by other groups. The workshop chair (DJ) will moderate the forum and summarise key points.

Following the workshop, the transcripts of the break out group and plenary discussion will be entered into HyperRESEARCH (ResearchWare Inc. www.researchware.com, version 3.7.3) software. One investigator (KEM) will code and analyse the data to identify participant perspectives on the potential core outcome set, and key challenges and recommendations for implementation. A workshop report summarising the key findings will be produced and reviewed by workshop participants for feedback prior to publishing.(70)

Finalisation of core outcome domains

Phases 1 to 5 of the SONG-PD process, including the proposed outcomes, will be published in a plain language report. This report will be circulated to participants involved in the Delphi (phase 4) and consensus workshop (phase 5), and to stakeholder groups. It will be made available on the SONG website for 3 weeks to obtain public comment. Feedback will be reviewed by the SONG Steering Group and used to finalise the SONG-PD core outcome set.

Discussion

SONG-PD uses a validated, robust, and systematic approach to develop a consensus-based prioritised set of core outcome domains to be reported in all trials in patients on PD. This may be considered for other contexts including registries and clinical quality indicators, particularly given the increasing attention to pragmatic and registry-based trials. Once the SONG-PD core outcome domains have been established, we will identify or develop core outcome measures for each of the core outcome domains. This will be done using the OMERACT filter to ensure that measures are truthful, discriminative, and feasible.(71) We will also use the guidelines developed jointly by the Core Outcome Measures in Effectiveness Trials (COMET) and Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) initiatives, on methods for selecting outcome measures for core outcome domains.(72)

To facilitate the translation of the core outcomes into trials and research, national and international stakeholders will be consulted and dissemination strategies will be developed. We will also evaluate the impact of SONG-PD on improving the consistency of reporting directly meaningful outcomes across trials. Ultimately, the implementation of a consensus-based set of high priority outcome domains will enable patients and their clinicians to make informed decisions about treatment.

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Abbreviations

CKD	Chronic Kidney Disease
COMET	Core Outcome Measures Effectiveness Trials
OMERACT	Outcome Measures Rheumatoid Arthritis Clinical Trials
RCT	Randomised Controlled Trial
SONG-PD	Standardised Outcomes in Nephrology-Peritoneal Dialysis

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Figure 1.
Conceptual schema of core outcome domains

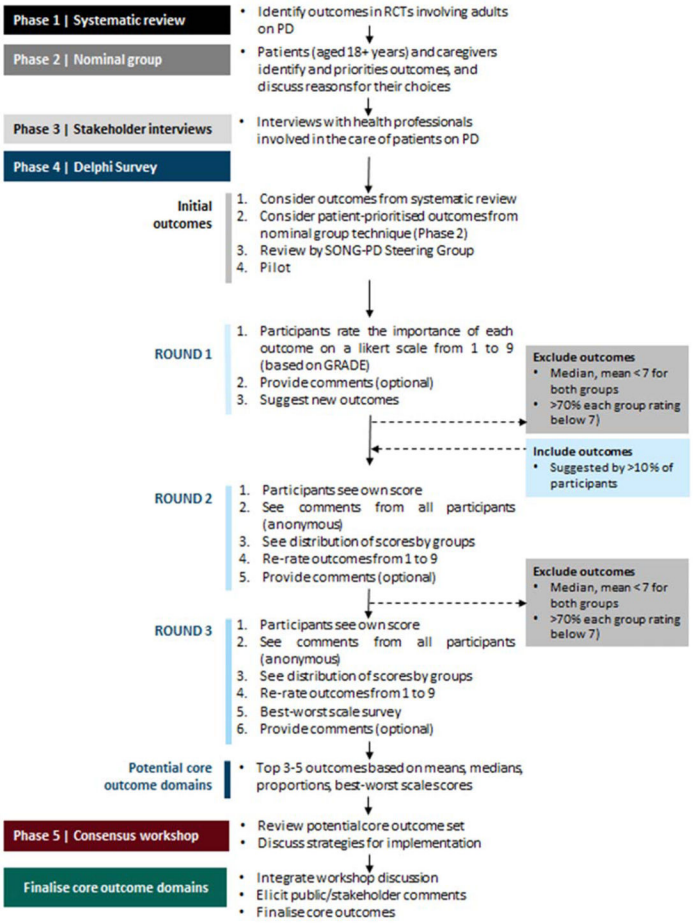

Figure 2.
SONG-PD process