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Authors

Manera, Karine E
Ju, Angela
Baumgart, Amanda
et al.

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ORIGINAL ARTICLE

Patient-reported outcome measures for life participation in peritoneal dialysis: a systematic review

Karine E. Manera [1,2], Angela Ju[1,2], Amanda Baumgart[1,2], Elyssa Hannan[2], Wenjing Qiao[2], Martin Howell [1,2], Melissa Nataatmadja [3], Martin Wilkie[4], Fiona Loud[5], Daniel Schwartz[6], Helen Hurst[7], Sarbjit Vanita Jassal[8], Ana Figueiredo[9], Rajnish Mehrotra[10], Jenny Shen[11], Rachael L. Morton[12], Thyago Moraes[13], Rachael Walker[14], Catherine Cheung[15], Janine F. Farragher[16], Jonathan Craig[17], David W. Johnson[18,19,20] and Allison Tong[1,2]

[1]Sydney School of Public Health, University of Sydney, Sydney, NSW, Australia, [2]Centre for Kidney Research, Children's Hospital at Westmead, Westmead, NSW, Australia, [3]Sunshine Coast Hospital and Health Service, Sunshine Coast University Hospital, Kawana Waters, QLD, Australia, [4]Department of Nephrology, Sheffield Teaching Hospital NHS Foundation Trust, Sheffield, UK, [5]Kidney Care UK, Alton, UK, [6]Division of Nephrology, Department of Medicine, University of British Columbia, Vancouver, BC, Canada, [7]Manchester Academic Health Science Centre, Manchester University NHS Foundation Trust, University of Manchester, Manchester, UK, [8]Division of Nephrology, Department of Medicine, University Health Network, University of Toronto, Toronto, ON, Canada, [9]School of Science and Life, Nursing School Pontifical Catholic University of Rio Grande do Sul, Porto Alegre, Brazil, [10]Kidney Research Institute and Harborview Medical Center, Division of Nephrology/ Department of Medicine, University of Washington, Seattle, WA, USA, [11]Division of Nephrology and Hypertension, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, CA, USA, [12]NHMRC Clinical Trials Centre, University of Sydney, Sydney, NSW, Australia, [13]School of Medicine, Pontifícia Universidade Católica do Paraná, Curitiba, Paraná, Brazil, [14]School of Nursing, Eastern Institute of Technology, Hawke's Bay, New Zealand, [15]Fraser Health Authority, British Columbia, Canada, [16]Department of Community Health Sciences, University of Calgary, Calgary, AB, Canada, [17]College of Medicine and Public Health, Flinders University, Adelaide, SA, Australia, [18]Department of Nephrology, Princess Alexandra Hospital, Brisbane, QLD, Australia, [19]Australasian Kidney Trials Network, Centre for Health Services Research, University of Queensland, Brisbane, QLD, Australia and [20]The Centre for Kidney Disease Research, University of Queensland, Brisbane, QLD, Australia

Corresponding author. Karine E. Manera; E-mail: karine.manera@sydney.edu.au

ABSTRACT

Background. Patients receiving peritoneal dialysis (PD) endure an ongoing regimen of daily fluid exchanges and are at risk of potentially life-threatening complications and debilitating symptoms that can limit their ability to participate in life activities. The aim of the study was to identify the characteristics, content and psychometric properties of measures for life participation used in research in PD.

Methods. We searched MEDLINE, Embase, PsychInfo, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Central Register of Controlled Trials from inception to May 2020 for all studies that reported life participation in patients on PD. The characteristics, dimensions of life participation and psychometric properties of these measures were extracted and analyzed.

Results. Of the 301 studies included, 17 (6%) were randomized studies and 284 (94%) were nonrandomized studies. Forty-two different measures were used to assess life participation. Of these, 23 (55%) were used in only one study. Fifteen (36%) measures were specifically designed to assess life participation, while 27 (64%) measures assessed broader constructs, such as quality of life, but included questions on life participation. The 36-Item Short Form Health Survey and Kidney Disease Quality of Life Short Form were the most frequently used measures [122 (41%) and 86 (29%) studies, respectively]. Eight (19%) measures had validation data to support their use in patients on PD.

Conclusions. The many measures currently used to assess life participation in patients receiving PD vary in their characteristics, content and validation. Further work to pilot and validate potential measures is required to establish a core patient-reported outcome measure to assess life participation in patients receiving PD.

Keywords: life participation, outcome measures, peritoneal dialysis

INTRODUCTION

Peritoneal dialysis (PD) is presented as allowing for greater independence and lifestyle flexibility compared with in-center hemodialysis. However, PD exchanges are required either multiple times a day or overnight (or both) and common and severe

KEY LEARNING POINTS

What is already known about this subject?

- Life participation is a critically important outcome for patients receiving peritoneal dialysis (PD). However, there is uncertainty about what measure to use and how to assess life participation.

What this study adds?

- We have identified the characteristics, content and psychometric properties of the outcome measures used to assess life participation in the PD population. We found that there is a high degree of uncertainty in the suitability of these measures for patients receiving PD, and further validation in this population is needed.

What impact this may have on practice or policy?

- This will inform the establishment of a relevant, valid and robust outcome measure for use as a core outcome to be reported in all trials in PD.

symptoms, such as cramping, abdominal fullness, pain and fatigue, can disrupt patients' daily activities, such as work, study, hobbies, sport and social and family events [1]. This can cause patients to feel frustrated and physically and emotionally depleted by PD and may contribute to patient and caregiver burnout [2, 3].

Patients on PD have emphasized that their choice of home-based dialysis therapy is influenced and encouraged by key advantages, including being able to work, travel, remain with family and participate in their usual life activities [4]. Life participation has also been identified as a critically important core outcome in PD by patients, caregivers and health professionals [5]. Life participation is defined as the ability to participate in activities, including but not limited to paid or voluntary work, housework, study, travel, hobbies, family duties, social events, recreation and leisure activities [6–8]. Various terms have been used to express this concept in studies of patients with chronic kidney disease (CKD), such as social functioning [3, 9], social participation [10] and activities of daily living [11]. The concept of life participation may also be embedded in broader constructs, such as health-related quality of life and health status [7].

Despite the critical importance of this outcome to patients receiving PD, life participation is infrequently assessed as a research outcome, which may be due to the lack of validated and standardized methods of assessment. There is uncertainty about what measure to use and how to assess life participation, therefore it is important to have a psychometrically robust measure that assesses content that is relevant and meaningful to patients. This study aimed to identify the characteristics, content and psychometric properties of the outcome measures used to assess life participation in the PD population with the goal of informing the establishment of a relevant, valid and robust outcome measure for use in research in PD.

MATERIALS AND METHODS

Selection criteria

We searched for randomized and nonrandomized studies that included a patient-reported measure of life participation in adult patients receiving PD (e.g. ability to perform daily tasks or roles in the domains of self-care, social functioning, family, home, financial, work/education or in a general domain) [12]. Studies were eligible if they included adult patients, ≥18 years of age, with CKD and receiving PD. All studies that assessed life participation using a patient-reported outcome measure were included. Studies that included a measure of constructs other than life participation (e.g. quality of life, physical activity and general health status) were eligible if they included at least one question that was related to life participation. Life participation is recognized as a subjective outcome that should be assessed by patients, as they have direct experience of it [13], therefore we excluded all clinician-reported measures. Abstract-only citations were included if they provided sufficient information about the measure used to assess life participation.

Study sources and measures

The search strategy is provided in the Supplementary data, Table S1. We searched MEDLINE, Embase, PsycInfo, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Central Register of Controlled Trials from database inception to May 2020. We also reviewed the reference lists of relevant studies, such as systematic reviews of quality of life in dialysis and CKD. Two authors (K.E.M. and W.Q.) screened the results initially based on titles and abstracts, and then by full texts, and excluded those that did not meet the inclusion criteria. Any disagreements were resolved through discussion until a decision was reached.

Data extraction and analysis

From each study we extracted the author, publication year, sample size (total and number on PD, if specified), country, type of intervention (if applicable) and measure used. To summarize the characteristics of the identified measures, two authors (K.E.M. and W.Q.) referred to the source study and searched for the full measure to extract the following information: response format, number of items, recall period, cost of license to use the measure, completion time and language. Two authors (A.B. and E.H.) searched for validation work for each measure to extract psychometric data in patients on PD.

Content dimensions of life participation

Life participation can be considered as having two dimensions, obligatory (e.g. household tasks, employment and study) and nonobligatory activities (e.g. socializing, sport and recreation) [14]. We examined the content of each measure using this framework and categorized them according to their assessment of obligatory and/or nonobligatory activities.

Assessment of psychometric properties

In accordance with the COnsensus-based Standards for the selection of health Measurement INstruments—Core Outcome

Measures in Effectiveness Trials guideline [15], we examined the evidence, where available, for validity and reliability of the included measures in the PD population. This involved examining psychometric properties, such as content validity, criterion validity, cross-cultural validity, known groups validity, structural validity, responsiveness and reliability, including internal consistency and test–retest.

RESULTS

Characteristics of studies

We identified and included 301 studies involving 51 163 patients on PD across 53 countries. Of the included studies, 284 (94%) were nonrandomized studies [210 (70%) cross-sectional, 69 (23%) cohort, 3 (1%) nonrandomized trials, 1 (0.3%) case–control and 1 (0.3%) case series] and 17 (6%) were randomized trials. Figure 1 shows the search results. The study characteristics are provided in the Supplementary data, Tables S2 and S3.

Characteristics of measures

A total of 42 different measures were used to assess life participation. Of these, 23 were used only once in a single study. The most frequently used instrument that included a measure of life participation was the 36-Item Short Form Health Survey (SF-36; 122 studies), followed by the Kidney Disease Quality of Life Short Form (KDQOL-SF; 86 studies) and the European Quality of Life 5-Dimension scale (EQ-5D; 27 studies). Fifteen (36%) measures were specifically designed to assess life participation or the ability to participate in activities (e.g. physical activity or disability assessments, illness or treatment interference, activities of daily living and work productivity), while 27 (64%) measures aimed to assess broader constructs such as quality of life, health status and general or psychological well-being. Twenty-nine (69%) of the total measures were developed for the general population or diseases other than kidney failure. Six (14%) were developed for use in patients with CKD and six (14%) were developed for use in patients on kidney replacement therapy including dialysis. None were specifically developed for use in patients on PD.

The estimated amount of time taken to complete the measures ranged from <1 min to 75 min. The number of items in each measure ranged from 1 to 110. The recall period ranged from the day of assessment to the past year. Nine of the measures were free of charge, some of which required study registration. Only two of the measures [9-item Thai Health Status Assessment Instrument (9-THAI) and Swedish Health-Related Quality of Life Survey] were developed in a language other than English. Translated versions of eight measures [SF-36, 12-item Medical Outcomes Study Short Form (SF-12), KDQOL-SF, KDQOL-36, EQ-5D, Nottingham Health Profile, World Health Organization Quality of Life Instrument Short Form (WHOQOL-BREF) and CHOICE Health Experience

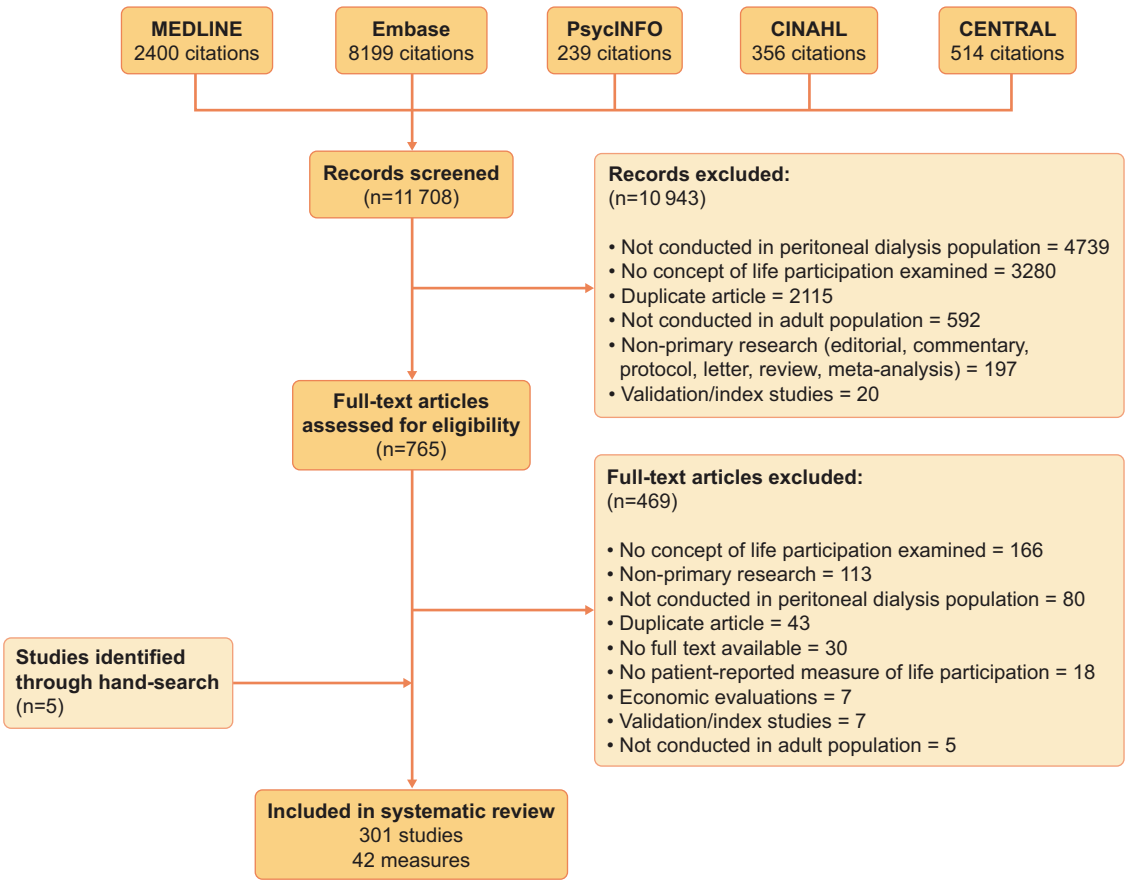

FIGURE 1: Search results.

Questionnaire (CHEQ)] were used across 35 different studies, with Chinese being the most frequent translation (Supplementary data, Tables S2 and S3). Detailed characteristics of the measures are provided in Table 1.

Content of measures

Thirty-two (76%) measures assessed both obligatory and nonobligatory dimensions of life participation, six (14%) measures assessed only obligatory activities and four (10%) measures assessed only nonobligatory activities. The activities stated within each dimension varied across studies, as did the specificity of the questions asking about the activities. For example, some measures assessed obligatory activities by specifically asking about a person's ability to wash or dress themselves, study or work, while other measures were more general in assessing one's ability to do the 'things you have to do'. Nonobligatory activities ranged from playing sports and socializing to doing the 'things you want to do'. Details of the activities assessed in each measure are presented in Table 2.

Psychometric properties

The assessment of validity and reliability for each measure in patients receiving PD is presented in the Supplementary data, Table S4. Of the 42 measures, only 8 (19%) were validated in the PD population. A summary of the psychometric data for each of these measures is provided in Table 3. The validation data or psychometric properties assessed for the measures were highly variable and no measure provided information across all psychometric domains.

Several of the identified measures were created specifically for the CKD population. The KDQOL-36 demonstrated good construct validity and was adapted from the KDQOL. which was developed with substantial content validity through the involvement of both patients and health professionals [57]. Scores on several subscales varied as expected by dialysis modality, diabetes status and employment status, indicating good discriminant validity. Convergent validity was demonstrated through moderate positive correlations between the KDQOL-36 and SF-12 subscales. Internal consistency for each KDQOL-36 domain was good. The KDQOL-SF was also derived from the KDQOL. Convergent validity was excellent when compared with the KDQOL and internal consistency was generally high, though inadequate for two subscales. The SF-12 has good predictive validity, with higher scores associated with a lower incidence of later death or hospitalization. Convergent validity was excellent when compared with the SF-36. The SF-36 demonstrated positive correlations between clinical markers such as albumin and scores indicating social and emotional support. As expected, patients on PD had lower scores than both healthy controls and transplant patients and higher scores were associated with a lower incidence of later death or hospitalization. Internal consistency was adequate in most subscales. The 6-dimension Short Form (SF-6D) demonstrated good convergent validity when compared with the ICEpop CAPability measure for Older people (ICECAP-O).

In addition to CKD-specific measures, several general quality of life measures have been validated in a PD population. The 9-THAI demonstrated a positive correlation between its mental domain score and patient hematocrit levels and a negative association between its physical domain score and patient hospitalization within the previous year [46]. Good convergent validity was demonstrated when compared with the SF-36 and test–retest reliability proved to be adequate [46]. The CHEQ was developed with substantial construct validity and content validity with input from both patients and health professionals [24]. The measure displayed adequate discriminant validity, the scores on the physical functioning scale were negatively correlated with the patient's number of comorbidities and subscale scores varied as expected between dialysis modalities and age groups [24]. Test–retest validity varied by subscale, with three subscales (finance, diet and work) demonstrating adequate test–retest reliability [55]. Internal consistency was assessed during pretesting and ranged by subscale from moderate to high, although it was not reassessed for the final form of the measure [55]. The ICECAP-O demonstrated convergent validity when compared with the SF-6D [56]. Overall scores on each measure were highly positively correlated and positive correlations between subscales on each measure varied from weak to moderate [56].

DISCUSSION

Life participation is a critically important outcome for patients on PD, but it is inconsistently reported, with 42 different measures being used across 301 studies. These measures varied in terms of response format, number of items, completion time, recall period, cost, content and availability of psychometric data. None of the measures were specifically designed for the PD population. The six most frequently used measures (SF-36, KDQOL-SF, EQ-5D, KDQOL-36, SF-12 and WHOQOL-BREF) were instruments that provided broader measures of quality of life with embedded questions on life participation. Most of the measures assessed life participation in terms of both obligatory and nonobligatory activities. Studies that evaluated the psychometric properties of the life participation measures specifically in patients receiving PD were sparse and incomplete, with only 8 (19%) of the 42 measures containing some validation data for the PD population. Less than half of the participant population in each of the identified validation studies were patients receiving PD and the psychometric properties assessed were limited and inconsistent. Most of the identified measures were originally developed in English and only two were developed specifically for languages other than English. However, many of the commonly used measures, including SF-36 and KDQOL-SF, have been translated and are available in a range of other languages. Based on the identified measures, there is a high degree of uncertainty in the suitability of these measures for patients receiving PD and further validation in this population is needed.

Across the measures used in the PD population, life participation was seldom assessed as a separate construct. Instead, it was often incorporated as a dimension of quality of life and often included few items that assessed life participation directly. It is important to note that the measures that contained some validation data for the PD population were primarily measures of

Table 1. Characteristics of measures used to assess life participation in patients on PD ($n = 42$)

Measure	Response format	Number of items	Recall	Cost	Completion time[a]	Specific to PD, KRT or CKD	Frequency of use (number of studies)
SF-36 [16]	Yes/no, 3-/5-/6-point Likert scale	36	Current, past 4 weeks	License fee upon request	5–10 min	No	122
KDQOL-SF [17][b]	Yes/no, 3-/5-/6-/10-point Likert scale, open-ended response	80	Current, past 4 weeks	No charge	~16 min	CKD	86
EQ-5D [18][c]	'Indicate which statements best describe. . .', VAS	16	Current	License fee upon request	<5 min	No	27
KDQOL-36 [19]	Yes/no, 3-/5-/6-point Likert scale	36	Current, past 4 weeks	No charge	~10 min	CKD	26
SF-12 [20]	Yes/no, 3-/5-/6-point Likert scale	12	Current, past 4 weeks	License fee upon request	~2 min	No	23
WHOQOL-BREF [21]	5-point Likert scale	26	Current, past 2 weeks	Contact World Health Organization	~5 min	No	21
IIRS [22]	7-point Likert scale	13	Current	Contact author	<15 min	No	6
NHP [23]	Yes/no	45	Current	Contact Galen Research	~9 min	No	5
CHEQ [24]	Yes/no, 3-/5-/6-/7-point Likert scale, open-ended responses	83	Current, past 4 weeks	Contact author	~16 min	KRT	4
15D [25]	5-point ordinal scale	15	Current	No charge	~3 min	No	3
IEQ [26][d]	7-point Likert scale	20	Current	Contact author	~4 min	No	3
SF-6D [27]	4-/5-/6-point ordinal scale	6	Current	No charge for academic/non-commercial use with study registration. License fee for commercial use upon request.	<2 min	No	3
HAP [28]	3-point ordinal scale: 'still doing, have stopped doing, never did'	102	Current	Contact author	5–10 min	No	3
GHQ-28 [29]	4-point Likert scale	28	Past few weeks	5.50 AUD	~5 min	No	2
PAQOL [30][d]	Open-ended responses, 10-point Likert scale	19	Current	Contact author	~4 min	No	2
SIP [31]	'Check those that apply'	136	Current	Contact the Medical Outcomes Trust	20–30 min	No	2
SWED-Qual [32]	4-/5-/6-point Likert scale	61	Current, past week	Contact author	~12 min	No	2
FACIT-Fatigue [33]	5-point Likert scale	13	Past 7 days	No charge with study registration	5–10 min	No	2
QLQ-C30 [34]	4-/7-point Likert scale	30	Current, past week	No charge for academic/non-commercial use with study registration.License fee for commercial use upon request.	~6 min	No	2
RQLP[d]	5-point Likert scale	43	Current	Contact author	5–7 min	CKD	1
PASE [35]	4-point Likert scale, open-ended responses, number of hours, yes/no, 'which of the following categories best describes. . .'	10	Past 7 days	Contact New England Research Institutes	5–15 min	No	1
WPAI-GH [36]	Yes/no, number of hours, 11-point Likert scale	6	Current, past 7 days	Contact author	<2 min	No	1
KDQ [37][d]	7-point Likert scale	26	Past 2 weeks	Contact author	10–15 min	CKD	1
GHQ-12 [29]	4-point Likert scale	12	Past 4 weeks	2.25 AUD	~2 min	No	1
DUKE [38]	3-point Likert scale, number of days	17	Current, past week	Contact author	~3 min	No	1
HMQ [39]	Yes/no, 3-/4-/6-point ordinal scale, VAS, open-ended responses	37	Current, past 2 weeks	Contact author	<10 min	No	1
WHODAS II [40]	5-point Likert scale, number of days	15	Past 30 days	License fee upon request	~5 min	No	1
IPAQ [41]	Yes/no, time spent on activities	27	Past 7 days	No charge	~5 min	No	1

Continued

Table 1. Continued

Measure	Response format	Number of items	Recall	Cost	Completion time[a]	Specific to PD, KRT or CKD	Frequency of use (number of studies)
ICECAP-O [42]	4-point Likert scale	5	Current	No charge with study registration	~1 min	No	1
MHIQ [43][d]	Yes/no, 3-/5-point Likert scale	59	Current	Contact author	~20 min	No	1
PGWB [44]	6-point Likert scale	22	Past month	Contact author	<5 min	No	1
DRM [45]	4-/5-/7-point Likert scale, percentage of time, open-ended responses, yes/no, ;check all that apply;	≥110	Current, yesterday	Contact author	45–75 min	No	1
9-THAI [46]	5-point Likert scale	9	Past month, last year	Contact author	~2 min	No	1
RAND-36 [47]	Yes/no, 3-/5-/6-point Likert scale	36	Current, past 4 weeks	No charge	5–10 min	No	1
Author-developed measures (for own study, not validated)							
Dąbrowska-Bender *et al.* [48][d]	10-point Likert scale	NA	NA	Contact author	NA	KRT	1
Devins *et al.* [49][d]	Yes/no, number of hours per week	5	Past 7 days	Contact author	<2 min	CKD	1
Fernandes da Silva[d]	NA	NA	NA	Contact author	NA	KRT	1
Juergensen *et al.* [50]	10-point Likert scale, open-ended responses	20	Current	Contact author	10–15 min	KRT	1
Panagopoulou[d] [51]	NA	NA	NA	Contact author	NA	KRT	1
Szabo[d] [52]	NA	NA	NA	Contact author	NA	NA	1
Tapson[d] [53]	NA	NA	NA	Contact author	NA	KRT	1
Tell[d] [54]	Yes/no	1	NA	Contact author	<1 min	CKD	1

[a]Where data on completion time were unavailable, authors estimated based on ~12 s/item.
[b]Studies used versions 1.1, 1.2 or 1.3.
[c]Some studies used EQ-5D-5L and others used EQ-5D-3L.
[d]Could not retrieve measure in full.
KRT: kidney replacement therapy; IIRS: Illness Intrusiveness Ratings Scale; NHP: Nottingham Health Profile; 15 D: 15 dimensions; IEQ: Illness Effects Questionnaire; GHQ-28: General Health Questionnaire 28-item; HAP: Human Activity Profile; PAQOL: patient-assessed quality of life; SIP: Sickness Impact Profile; RQLP: Renal Quality of Life Profile; PASE: Physical Activity Scale for the Elderly; WPAI-GH: Work Productivity and Activity Impairment General Health; KDQ: Kidney Disease Questionnaire; GHQ-12: 12-item General Health Questionnaire; DUKE: Duke Health Profile; HMQ: Health Measurement Questionnaire; WHODAS II: World Health Organization Disability Assessment Schedule 2.0; IPAQ: International Physical Activity Questionnaire; QLQ-C30: Quality of Life Questionnaire; MHIQ: McMaster Health Index Questionnaire; PGWB: Psychological General Well-Being Index; DRM: Day Reconstruction Method; FACIT: Fatigue, Functional Assessment of Chronic Illness Therapy—fatigue scale; SWED-Qual: Swedish Health-Related Quality of Life Survey.

quality of life and were not focused on measuring life participation as the primary construct. This means that these measures are not necessarily validated to assess life participation and a measure that is validated specifically to assess life participation is required.

Life participation is a multifaceted construct and detailed classifications for the specific constructs of activities and participation have been developed as part of the World Health Organization's International Classification of Functioning, Disability and Health, which includes learning and applying knowledge, general tasks and demands, communication, mobility, self-care, domestic life, interpersonal interactions and relationships, major life areas and community, social and civic life [60]. Outside the field of nephrology, studies have shown that large variations remain in the content and comprehensiveness of existing patient-reported measures of participation across generic and disease-specific measures, suggesting that many measures do not capture all the key concepts related to life participation [61]. It will therefore be important to ensure that a measure of life participation for patients receiving PD captures all of the relevant domains of participation that are considered important to patients.

Life participation has also been identified as a critically important outcome for kidney transplant recipients [62]. A systematic review of outcome measures used to assess life participation in kidney transplantation similarly found that quality of life measures, including the SF-36, KDQOL and EQ-5D, were most commonly used to assess life participation [63]. Some of the measures were specifically developed for use in kidney transplant recipients, whereas none of the measures used for patients receiving PD were specifically developed for the PD population. Compared with many kidney transplant recipients who benefit from being able to return to activities following transplant, patients receiving PD are required to follow a treatment regimen of multiple, daily exchanges that can limit their ability to participate in life [3, 64]. Thus life participation may be conceptualized differently or different aspects of life participation may be more important and this needs to be expounded upon in further research in patients receiving PD.

Table 2. Dimensions of life participation assessed by each measure

Measure	Obligatory	Nonobligatory	Types of activities
SF-36	•	•	Lifting heavy objects, participating in strenuous sports, moving a table, pushing a vacuum cleaner, playing golf, carrying groceries, climbing stairs, bathing or dressing
SF-12	•	•	Moving a table, pushing a vacuum cleaner, bowling, playing golf, climbing stairs
KDQOL-SF	•	•	Running, lifting heavy objects, participating in strenuous sports, moving a table, bowling, carrying groceries, bathing or dressing, work outside the home, housework, social activities
EQ-5D	•	•	Washing, dressing, leisure activities, housework, work, study
KDQOL-36	•	•	Moving a table, pushing a vacuum cleaner, playing golf, climbing stairs, work outside the home, housework, travel
HAP	•	•	Cooking meals, putting on shoes, climbing steps, sweeping, walking, mowing the lawn, dining at a restaurant, dancing
RQLP	•	•	Eating, drinking, physical activities, psychosocial activities, leisure time
IEQ		•	Family life, social life
IIRS	•	•	Work, sports, reading, listening to music, community/civic involvement
NHP	•	•	Work, cleaning, cooking, home repairs, going out, seeing friends, going to the movies, sports, vacations
PASE	•	•	Reading, watching TV, doing handcrafts, walking, bowling, shuffleboard, fishing, sport, housework, home repairs, paid work
WPAI-GH	•	•	Work, housework, shopping, childcare, exercising, studying
KDQ	•		Housework
WHOQOL-BREF	•	•	Leisure activities, getting around, daily living activities, work
GHQ-28	•		Normal day-to-day activities
GHQ-12	•		Normal day-to-day activities
DUKE	•	•	Social activities, religious activities, recreation activities, visiting friends or relatives
HMQ	•	•	Washing or dressing oneself, eating or drinking, seeing friends or relatives
15D	•	•	Employment, studying, housework, free time activities, walking
SIP	•	•	Eating, work, housework, recreation, walking, travel, caring for children
SF-6D	•	•	Bathing, dressing, vigorous activities, work outside the home, housework, social activities
WHODAS II	•	•	Household responsibilities, community activities, walking, washing, dressing, work, maintaining friendships
CHEQ	•	•	Climbing stairs, walking, bathing or dressing, recreation, work outside the home, housework, travel
IPAQ	•	•	Heavy lifting, walking, traveling, scrubbing floors, aerobics, swimming, running, cycling
ICECAP-O	•	•	Things that make you feel valued, enjoyment and pleasure, love and friendship, independence
QLQ-C30	•	•	Carrying a heavy shopping bag, carrying a suitcase, dressing, washing, hobbies, leisure time activities, social activities
MHIQ	•	•	Self-care, physical activities, work, participation with family and friends
PGWB	•	•	Things you like to do, things you have to do
DRM	•	•	Commuting, shopping, housework, work, preparing food, caring for children, socializing, exercise
PAQOL	•	•	Work, social life, family life, exercise
9-THAI	•	•	Self-care, work outside the home, housework, social/community activities
FACIT-Fatigue	•	•	Usual activities, social activities, things you want to do
RAND-36	•	•	Lifting heavy objects, participating in strenuous sports, moving a table, pushing a vacuum cleaner, playing golf, carrying groceries, climbing stairs, bathing or dressing
SWED-Qual	•	•	Walking, climbing stairs, dressing, carrying groceries, work outside the home, housework, parenting, strenuous sports, hiking
Author-developed measures (for own study, not validated)			
Dąbrowska-Bender *et al.*[67]	•		Work, study, eating or drinking
Devins *et al.*[68]	•		Walking, climbing stairs, housework, work outside the home
Fernandes da Silva	•		Walking, eating, bathing, climbing stairs, shopping, driving, house cleaning
Juergensen *et al.* [69]	•	•	Family life, social life, recreation/hobbies, exercise
Panagopoulou [51]	•	•	Work, family life, social life, recreation
Szabo [52]		•	Outdoor activities, community activities, hobbies
Tapson [53]		•	Social life
Tell [54]		•	Leisure time activities

Filled circle indicates:If the measure assessed obligatory, non-obligatory, or both dimensions of life participation IIRS: Illness Intrusiveness Ratings Scale; NHP: Nottingham Health Profile; 15 D: 15 Dimensions; IEQ: Illness Effects Questionnaire; GHQ-28: General Health Questionnaire 28-item; HAP: Human Activity Profile; PAQOL: Patient-assessed quality of life; SIP: Sickness Impact Profile; RQLP: Renal Quality of Life Profile; PASE: Physical Activity Scale for the Elderly; WPAI-GH: Work Productivity and Activity Impairment General Health; KDQ: Kidney Disease Questionnaire; GHQ-12: 12-item General Health Questionnaire; DUKE: Duke Health Profile; HMQ: Health Measurement Questionnaire; WHODAS II: World Health Organization Disability Assessment Schedule 2.0; IPAQ: International Physical Activity Questionnaire; QLQ-C30: Quality of Life Questionnaire; MHIQ: McMaster Health Index Questionnaire; PGWB: Psychological General Well-Being Index; DRM: Day Reconstruction Method; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy—fatigue scale; SWED-Qual: Swedish Health-Related Quality of Life Survey.

Table 3. Psychometric properties of measures of life participation that have reported validation studies in patients receiving PD

Measure ($n = 8$)	Validity	Reliability
9-THAI (Population: 21% PD, 35% HD and 44% transplant) [46]	Construct: *Convergent:* Participants' hematocrit levels were positively associated ($P = 0.028$) with the 9-THAI's standardized T-summated mental domain scores (MEN) *Discriminant:* Hospitalization in the past year was negatively associated with lower 9-THAI standardized T-summated physical domain scores (PHY) ($P < 0.001$) Criterion: *Concurrent:* Spearman's rank correlations between 9-THAI and SF-36 domains revealed that the 9-THAI PHY was positively associated with the SF-36 PCS ($\rho = 0.40$), and that the 9-THAI MEN was positively associated with the SF-36 MCS ($\rho = 0.56$). Other significant associations included the positive correlation between the 9-THAI illness/discomfort domain and the SF-36 bodily pain domain ($\rho = 0.43$).	Test–retest: Intraclass correlation coefficients for initial PHY and MEN scores and those at follow-up 1 month later exceeded the recommended 0.7, at 0.79 and 0.78, respectively
CHEQ (Population in pretest: 25% PD, 75% HD) [24] (Same population as above study, of which 63% completed measure again at follow-up; 23% PD, 77% HD) [55]	Content: Measure development involved a literature review, focus groups and surveys with patients and health professionals, comprehension test with patients, clinical review, psychometric pretest with patients and an acceptability review with health professionals Construct: Multitrait analysis found that item-scale correlations were at least two SEs greater than the correlations of the item to other scales 99% of the time *Discriminant*: Patients' number of comorbidities was negatively correlated with the CHEQ physical functioning subscale. Patients' on HD and PD scored significantly differently on the physical functioning, bodily pain, role-emotional, travel restrictions, dietary restrictions, recreation, dialysis access problems, sexual functioning and quality of life subscales. Patients >65 years old and those younger scored significantly different on the physical function, bodily pain, general health, mental health, financial, diet restrictions, work, body image, symptoms, sleep, sexual functioning and dialysis access problems subscales Criterion:*Predictive*: At follow-up 1 year later, 19–30% of all patients scored lower on the CHEQ and worsened, 50–65% of patients' scores did not change and 16–24% of patients scored higher on the CHEQ and improved. From baseline to follow-up 1 year later, PD patients compared with HD patients experienced significantly lower improvement in physical functioning, general health, sleep and quality subscales. However, PD patients showed greater improvement in the finance subscale compared with HD patients	Test–retest: Correlations between the baseline and follow-up scores 1 year later for the single-item kidney-specific domains (travel, finance, diet, recreation, work and body image) ranged from 0.55 to 0.79 with three domains equal to or exceeding the recommended 0.7 Internal consistency: Cronbach's αs for the SF-36 domain and additional kidney-specific subscales ranged from 0.57 to 0.93, with all but 2 (time and quality of life) above the recommended $\alpha = 0.70$. After psychometric pretesting, 11 items of the additional kidney-specific subscales were removed and 3 items were changed—there was no subsequent testing for internal consistency
ICECAP-O (Population: 10% PD, 54% HD, 36% conservative care) [56]	Criterion: *Concurrent*: Overall ICECAP-O score was positively correlated with overall SF-6D score ($r = 0.65$, $P < 0.001$), and all SF-5D domain scores ($r = 0.30$ to 0.56, $P < 0.05$). ICECAP-O attachment domain score was positively correlated with SF-6D mental health domain score ($r = 0.19$, $P < 0.001$), and ICECAP-O enjoyment domain score was positively correlated with all domain scores of the SF-6D with the exception of the role limitations domain ($r = 0.27$ to 0.43, $P < 0.05$). ICECAP-0 security domain score ($r = 0.21$ to 0.35, $P < 0.05$), role domain score ($r = 0.28$ to 0.51, $P < 0.05$) and control domain score ($r = 0.27$ to 0.53, $P < 0.05$) were positively correlated with all SF-6D domain scores	Test–retest: NA Internal consistency: NA
KDQOL-36 (Population: 12% PD, 86% HD, 2% other [not specified]) [57]	Content: The KDQOL-36 was derived from the KDQOL and KDQOL-SF Construct: Confirmatory factor analysis supported the three-factor structure of the kidney-specific items of the KDQOL-36. Multitrait analysis found all kidney-specific items were most correlated with the scales they were hypothesized as part of. These three subscales were also significantly positively correlated ($r = 0.48$ to 0.62, $P < 0.05$) *Discriminant*: PD patients had higher scores than HD patients on PCS-12, MCS-12 and all three kidney-specific subscales ($P < 0.05$). Patients with diabetes had lower scores on all domains than those without diabetes ($P < 0.001$) and patients employed full-time had higher scores on all domains than those not employed full-time ($P < 0.05$) Criterion: *Concurrent:* Each of the three KDQOL-36 subscales were positively correlated with PCS-12 and MCS-12 scores ($r = 0.40$ to 0.52, $P < 0.001$), with	Internal consistency: Cronbach's α revealed adequate internal consistency for Burden of Kidney Disease ($r = 0.85$), Symptoms ($r = 0.83$) and Effects of Kidney Disease ($r = 0.85$) domains. Cronbach's α was not reported for the PCS-12 and MCS-12

Continued

Table 3. Continued

Measure ($n = 8$)	Validity	Reliability
	the largest correlations between the MCS-12 and burden ($r = 0.52$) and effects ($r = 0.50$) scales	
KDQOL-SF (Population: Patient focus groups 46% PD, 54% HD; proportion of PD participants not reported for correlation or internal consistency coefficients) [17]	Content: The KDQOL-SF was adapted from the KDQOL, for which the development process included three patient focus groups, one health professional focus group and a literature review. To create the KDQOL-SF, regression analyses using Goodnight's maximum R-squared improvement procedure were conducted to determine the subset of each KDQOL domains' items which accounted for ~90% of the domain's variance. Consultation with the Baxter Renal Outcomes Study also led to response scale and item changes Criterion: *Concurrent*: All KDQOL-SF domain scores had strong correlations with their corresponding KDQOL domain scores ($r = 0.91$ to 1.00, $P < 0.05$)	Internal consistency: Cronbach's α for all domains ranged from 0.61 to 0.90 with all the domains above the recommended 0.7 with the exception of the quality of social interaction and cognitive function domains (0.61–0.68 respectively)
SF-12 (Population: 6% PD and home HD combined, 94% in-center HD) [58]	Criterion: *Predictive*: Each incremental point of the SF-12 PCS-12 was associated with a 2.4% lower adjusted associated HR of death and 0.4% decline in HR for first hospitalization. Each incremental point of the SF-12 MCS-12 was associated with 1.2% improved HR of death and 0.6% decline in HR for first hospitalization *Concurrent*: The PCS-12 had a high correlation ($r = 0.94$, $P < 0.001$) with the PCS from the SF-36. Similarly, the MCS score from the SF-12 had a high correlation ($r = 0.94$, $P < 0.001$) with the MCS from the SF-36. For both comparisons, the Spearman's rank correlations were $\rho = 0.94$ and the intraclass correlation coefficient values were 0.94 (all $P < 0.001$)	Test–retest: NA Internal consistency: NA
SF-36 (Population: 21% PD, 44% transplant, 35% HD; subgroup comparisons made with age and sex-matched control group) [59]	Construct: *Convergent*: Kendall's tau-b coefficients revealed in the overall dialysis participant group, SF-36 domain scores were modestly correlated to individual item-scores on an eight-question measure with ESRD-specific symptoms (highest tau-b = 0.30). All SF-36 domains were positively correlated to hemoglobin, albumin, total protein and social and emotional support ($P < 0.05$). The physical functioning, role physical, general health, vitality and mental health domains were positively correlated with the duration of treatment ($P < 0.05$) *Discriminant*: All patient groups had lower scores on all SF-36 domains compared with healthy controls ($P < 0.001$). PD patients tended to have lower scores on all domains compared with transplant recipients. All SF-36 domains were negatively correlated to age, health-risk, time taken to travel to treatment and sex (male coded as 0) ($P < 0.05$). The bodily pain, social functioning and role emotional domains were negatively correlated with the duration of treatment ($P < 0.05$)	Internal consistency: Cronbach's α exceeded 0.8 for each subscale except social functioning, which had an α of 0.72. For dialysis patients only, the social functioning subscale had a Cronbach's α of 0.60
(Population: 6% PD and home HD combined, 94% in-center HD) [58]	Criterion: *Predictive*: Each incremental point of the PCS-36 was associated with a 2.4% lower adjusted associated HR of death and 0.4% decline in HR for first hospitalization. Each incremental point of the MCS-36 was associated with 1.3% improved HR of death and 0.6% decline in HR for first hospitalization *Concurrent*: The PCS had a high correlation ($r = 0.94$, $P < 0.001$) with the PCS-12 from the SF-12. Similarly, the MCS score had a high correlation ($r = 0.94$, $P < 0001$) with the MCS-12 from the SF-12. For both comparisons, the Spearman's rank correlations were $\rho = 0.94$ and the intraclass correlation coefficient values were 0.94 (all $P < 0.001$)	Test–retest: NA Internal consistency: NA
SF-6D (Population: 10% PD, 54% HD, 36% conservative care) [56]	Criterion: *Concurrent*: Overall SF-6D score was positively correlated with overall ICECAP-O score ($r = 0.65$, $P < 0.001$). SF-6D mental health domain score was positively associated with all ICECAP-O domain scores ($r = 0.19$ to 0.39, $P < 0.05$). SF-6D physical health ($r = 0.32$ to 0.40, $P < 0.05$), social functioning ($r = 0.25$ to 0.35, $P < 0.05$), pain ($r = 0.29$ to 0.53, $P < 0.05$) and vitality domain ($r = 0.21$ to 0.48, $P < 0.05$) scores were positively correlated with all ICECAP-O domain scores with the exception of the attachment domain. SF-6D role limitations domain score was positively associated with all ICECAP-O domain scores with the exception of the attachment and enjoyment domains ($r = 0.21$ to 0.31, $P < 0.05$)	Test–retest: NA Internal consistency: NA

PCS: physical component summary; MCS: mental component summary; HR: hazard ratio. Validation studies were excluded if they were not available in full, were for a translation of the original measure or were not written in English.

Patient-reported outcome measures are increasingly being recognized as important tools in practice and policy to improve the quality and cost of care [65]. There is a need to systematically identify and collect patients' perspectives on outcomes that reflect how they feel and function and evaluate treatment benefits and harms through the use of patient-reported outcome measures [66, 67]. However, concerns regarding the use of invalid or unreliable measures must be addressed to ensure improvements in quality of care that are meaningful to patients can be made [65, 68]. This review provides necessary evidence to inform the selection of a suitable patient-reported outcome measure for life participation, which was identified as a critically important outcome for patients receiving PD based on a consensus among patients, caregivers and healthcare providers [69].

We conducted a comprehensive review of measures used to assess life participation in adult patients receiving PD, although we acknowledge that we may not have included every measure of life participation that has been used in other populations. This review was limited to patient-reported measures. Life participation is a construct that relies in part on an individual's subjective meaning assigned to life roles and activities, which is why we did not include clinician-reported or performance-based measures [13]. As such, we did not include measures assessed through clinical interview, such as the Psychosocial Adjustment to Illness Scale [70], or those designed for completion by proxy (i.e. a caregiver or clinician), such as the Karnofsky Performance Status Scale [71]. We also note that a risk of bias assessment was not undertaken, as our aim was to evaluate the patient-reported outcome measures used to measure life participation in adults receiving PD.

As part of the Standardized Outcomes in Nephrology–Peritoneal Dialysis initiative, further work will be conducted to establish a core outcome measure for life participation in patients on PD. This will include a consensus workshop with patients, caregivers and health professionals to discuss and decide on an appropriate measure for life participation, including the need to develop a new measure. Following the identification or adaptation of an existing measure, or development of a new measure, piloting and validation will be undertaken to ensure that the measure is valid and reliable for use by patients on PD. Translating and adapting the established measure for use in different cultural contexts will be an important part of establishing a core outcome measure for life participation in patients receiving PD.

A standardized and validated measure for life participation is necessary to ensure that life participation is consistently, reliably and meaningfully assessed in patients on PD. This will improve the evaluation of life participation and may ultimately contribute to the development of interventions that could enhance a patient's ability to participate in daily living.

SUPPLEMENTARY DATA

Supplementary data are available at ndt online.

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CONFLICT OF INTEREST STATEMENT

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article. The results presented in this article have not been published previously in whole or part, except in abstract form.

DATA AVAILABILITY STATEMENT

The data underlying this article are available in the article and in its online supplementary material.

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Impact of dialysis modality on major adverse cardiovascular events and all-cause mortality: a national population-based study

Ping-Jen Hu[1,2], Yu-Wei Chen[3,4,5], Tzu-Ting Chen[6,7], Li-Chin Sung[8,9,10], Mei-Yi Wu[3,5,7,10,11] and Mai-Szu Wu[3,5,11]

[1]Department of Internal Medicine, Division of Gastroenterology and Hepatology, Taitung Mackay Memorial Hospital, Taitung, Taiwan, [2]Department of Internal Medicine, Division of Gastroenterology, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan, [3]Department of Internal Medicine, Division of Nephrology, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan, [4]Graduate Institute of Clinical Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan, [5]TMU Research Center of Urology and Kidney, Taipei Medical University, Taipei, Taiwan, [6]Center for Neuropsychiatric Research, National Health Research Institutes, Miaoli County, Taiwan, [7]Institute of Epidemiology and Preventive Medicine, College of Public Health, National Taiwan University, Taipei, Taiwan, [8]Department of Internal Medicine, Division of Cardiology, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan, [9]Department of Internal Medicine, Division of Cardiology, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan, [10]Department of Primary Care Medicine, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan and [11]Department of Internal Medicine, Division of Nephrology, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan

Correspondence to: Mei-Yi Wu; E-mail: e220121@gmail.com

ABSTRACT

Background. Only few studies with inconsistent results comparing the relative risk of cardiac mortality between peritoneal dialysis (PD) and hemodialysis (HD). Switches between renal replacement therapy (RRT) modalities render objective assessment of survival benefits a greater challenge.

Methods. Data were retrieved from Taiwan's National Health Insurance Database from 1 January 2006 to 31 December 2015. We included 13 662 and 41 047 long-term dialysis patients in a propensity score matching study design and a time-varying study design, respectively, to compare major adverse cardiovascular events (MACEs) between patients receiving PD and HD. We also included 109 256 dialysis patients to compare the all-cause mortality among different RRT modalities.

Results. For MACE, the hazard ratio (HR) for PD patients compared to HD patients was 0.95 [95% confidence interval (CI) 0.89–1.02] in the propensity score study design and 1.06 (95% CI 1.01–1.12) in the time-varying study design. For all-cause mortality, the HR for PD patients compared to HD patients was 1.09 (95% CI 1.05–1.13) in the propensity score study design and 1.13 (95% CI 1.09–1.17) in the time-varying study design. The HR for death was higher at a level of statistical significance for females (1.21, 95% CI 1.15–1.28), patients ≥65 years old (1.30, 95% CI 1.24–1.36) and diabetes mellitus (DM; 1.28, 95% CI 1.22–1.34).

Conclusions. The HR for MACE is significantly higher among PD patients in time-varying design analysis. In addition, all-cause mortality was higher in PD patients compared to patients with HD, especially in those who were aged ≥65 years, female or DM.

Keywords: dialysis modality, hemodialysis, major adverse cardiovascular events, peritoneal dialysis