The effects of psychosocial and economic factors on the quality of life of patients with end-stage renal disease and their caregivers in Klang Valley, Malaysia: protocol for a mixed-methods study

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ABSTRACT

Introduction The number of patients in Malaysia requiring dialysis is expected to rise substantially in the future due to the ageing population and increasing prevalence of diabetes mellitus and hypertension. Hence, more individuals will be expected to adopt the role of caregivers in the future. The upward trend of end-stage renal disease (ESRD) and caregiving for dialysis patients has detrimental consequences for both patients and caregivers in terms of their psychological wellbeing and quality of life. Despite the current circumstances, there are very few studies in Malaysia that have explored the psychosocial factors, specifically on the economic impact of the management of ESRD.

Methods and analysis This two-phase sequential explanatory mixed-methods design, incorporating a quantitative design (phase I) and a qualitative study (phase II), is to be conducted in 4 government hospitals and 10 other non-governmental organisations or private dialysis centres within Klang Valley, Malaysia. A cross-sectional survey (phase I) will include 236 patient-caregiver dyads, while focus group discussions (phase II) will include 30 participants. The participants for both phases will be recruited purposively. Descriptive statistics, independent sample t-tests and multiple regression analysis will be used for analyses in phase I, and thematic analysis will be used in phase II.

Ethics and dissemination Approval for the study has been obtained from the National Medical Research and Ethics Committee (MREC) (NMRR-21-1012-59714) and the Research Ethics Committee of Hospital Canselor Tuanku Muhriz UKM (UKM PPI/111/8/JEP-2021–079). Informed consent of the participants will be obtained beforehand, and no personal identifiers will be obtained from the participants to protect their anonymity. The findings will be published in peer-reviewed scientific journals and presented at national or international conferences with minimal anonymised data.

INTRODUCTION

According to the Global Burden of Disease, chronic kidney disease (CKD) is ranked among the top 20 causes of death, and is currently a significant public health concern. CKD is regarded as a high-stress illness due to the chronicity of the disease and the long-term treatment required, where end-stage renal disease (ESRD) is considered as the last stage of CKD. In Malaysia, the incidence and prevalence of patients with ESRD have been showing an upward trend for the past 20 years. The number of patients in Malaysia requiring dialysis is expected to rise substantially in the future due to the ageing population and increasing prevalence of diabetes mellitus and hypertension. Hence, more individuals will be expected to adopt the role of caregivers in the future. The upward trend of end-stage renal disease (ESRD) and caregiving for dialysis patients has detrimental consequences for both patients and caregivers in terms of their psychological wellbeing and quality of life. Despite the current circumstances, there are very few studies in Malaysia that have explored the psychosocial factors, specifically on the economic impact of the management of ESRD.
years, due to the ageing population and the increasing prevalence of diabetes mellitus and hypertension. In 2018, the 24th Report of the Malaysian Dialysis and Transplant Registry revealed that over the preceding 10 years, the acceptance rate for both haemodialysis (HD) and peritoneal dialysis (PD) has nearly doubled, while the prevalence rate has increased by more than twofold. A total of 39,711 patients received dialysis treatment in 2016, with 35,781 and 39,30 patients being on HD and PD, respectively. If the present trend remains unchecked, it is anticipated that by 2040, there will be more than 106,000 Malaysian patients with ESRD requiring dialysis. With this projected prevalence, the cost to the healthcare system is estimated to be 3.21 billion MYR. It is to be expected that more individuals will be adopting the caregiver role in the future due to the rising number of patients with renal failure.

Caregivers refers to those who are actively involved in helping patients to cope with and manage their chronic illness during their treatment. The chronicity of kidney failure and various treatment complications bring about significant changes in the lifestyles of patients, leading to caregivers having to shoulder a high burden of care. This burden of care is common among caregivers, and it typically refers to the kind of distress, comprised of physical, psychological, social and financial aspects, faced by them as a result of caregiving. The care burden among caregivers is often inter-related with the sociodemographics (age, gender, ethnicity, marital status, education, employment, income and religion/spirituality) of the caregivers and patients, disease-related factors (treatment modality, frequency of weekly dialysis sessions, duration and frequency of dialysis, duration of illness, comorbidity, level of patient’s dependency), situational and relational factors (relationship to the patient, the duration of caregiving), environmental factors, including social support, and psychological factors including depression and anxiety. Past literature has shown evidence that caregivers who seek social support from family and friends experience a lesser burden of care than caregivers without solid support networks. This is because social support can diminish the impact of the emotional burden and stress of care by providing solutions to problems, distractions from issues or facilitating the required healthy behaviours.

Similarly, Nagarathnam, Sivakumar and Latheef stated that seeking social support is the dominant coping mechanism in caregivers of patients undergoing renal replacement therapy. Also, it has been established that caregivers of chronic patients are four times more likely to be diagnosed with depression and three times more likely to seek help for anxiety issues than individuals who are not caregivers.

There is a high correlation between the psychological well-being of caregivers and patients. Gerogianni et al. stated that caregivers have higher levels of anxiety and depression when dialysis patients under their care have high levels of anxiety and depression. In line with this study, past studies also reported that caregivers of HD patients have deteriorated psychological well-being compared with caregivers of PD or kidney transplant patients, so patients under HD treatment were perceived to be more difficult to care for compared with patients under treatment for other modalities. In contrast, Al Wakeel and Bayoumi and Cantekin, Kavurmacı and Tan suggested evidence that a higher burden of care was observed among caregivers of PD patients than caregivers of patients undergoing HD treatment. The educational level, age, health and capability of the patient with regard to self-care serve as the determinants of the burden of care among caregivers. Notably, caregivers of dialysis patients reportedly have a lower quality of life than caregivers of non-dialysis patients. The quality of life of caregivers of patients undergoing HD was reported to be lower in all aspects compared with the general healthy population due to the high burden of care; however, the quality of life of these caregivers was better than the patients under their care. Conversely, Monárrez-Espinò, Delgado-Valles and Ramirez-García concluded that there is no significant difference in terms of quality of life between caregivers of HD and PD patients.

Generally, ESRD is highly burdensome in the daily lives of patients and is also time-consuming, especially among elderly HD patients, resulting in patients experiencing frustration and causing them to perceive that they are a burden to their family members. This self-perceived burden arises when the recipients of care possess feelings of dependence, frustration and anxiety, leading to guilt about the hardship being imposed on the caregiver. The incidence and prevalence of ESRD have adverse effects on the psychological well-being of both patients and their caregivers, and their quality of life. Compared with their caregivers, patients with ESRD are more prone to depression and a lower quality of physical and psychological well-being. The prevalence of depression among patients with ESRD is estimated to be around 20%–30%, whereas their level of anxiety ranges between 12% and 52%. Depression and anxiety symptoms occur more frequently among patients undergoing dialysis than patients who have undergone kidney transplantation. Also, patients under PD have been reported to have significantly higher levels of depression symptoms than those on HD. Conversely, a qualitative study showed evidence that both HD and PD patients frequently experience depression along with other psychological problems, such as decreased social support, burn-out, despair and anxiety. Apart from these, patients and their caregivers have to face high treatment costs, out-of-pocket costs and other comorbidities that arise, which can be overwhelming and cause those in low-income or middle-income families to bear a financial burden. Based on past literature in other countries, the high treatment costs have led to numerous caregivers having to suffer a financial burden and to willingly mortgage their valuable items to cover those costs.
fully funded for their treatment may not face a financial burden, but those belonging to low-income families experience a tremendous financial burden. Mixed findings have been reported when comparing the quality of life of HD and PD patients. Al Wakeel et al.34 and Hsu et al.35 found that PD patients have a better quality of life than those on HD. Alternatively, Goncalves et al.36 concluded that HD has a more significant influence on the quality of life of patients compared with PD as the physical functioning (PF) and emotional functioning aspects have been reported to be higher among HD patients. Meanwhile, several past literatures have suggested evidence that there is no significant difference between the levels of quality of life between the two different dialysis modalities.29 37 38

The factors contributing to a lower quality of life among dialysis patients have been identified as the increasing prevalence of depression, anxiety and suicidal ideation.35 Conversely, perceived social support serves as a protective factor against a low quality of life among patients.40 41 A high perception of social support can reduce the risk of hospitalisation among HD patients by 15%, along with improving their quality of life.42 Also, a conducive environment helps HD patients to take a more positive attitude towards their disease, including improving their coping strategies.43

Despite the mixed findings, there is still a dearth of research, particularly with regard to the psychosocial factors and the economic impact of ESRD among patients and caregivers in Malaysia. Studies focusing on the well-being of Malaysian patients with ESRD are sorely lacking and almost non-existent in the case of caregivers. Therefore, there is a need for further investigations to be carried out in this area, particularly with regard to the quality of life, burden of care, depression, anxiety, coping mechanisms and social support of patients and their caregivers. Another neglected area is the economic burden faced by patients with ESRD and their caregivers with regard to the management of this disease. As far as is known, thus far, no studies have been conducted in the south-east Asian region on the economic costs incurred by patients with ESRD and their caregivers. Given this situation, this study will compare the psychosocial factors, economic factors and quality of life of patients with ESRD undergoing HD and PD treatment modalities and their caregivers. Apart from that, the associations between demographic factors, psychosocial factors, economic factors and quality of life among caregivers and patients with ESRD will be examined. Lastly, the perception of psychosocial well-being and economic burden in the management of the illness and its impact on the quality of life of patients with ESRD and their caregivers will be explored in-depth.

**Study objectives**

Phase I of this study focuses on the following objectives:

1. To compare the psychosocial factors, economic factors and quality of life between caregivers of patients undergoing HD and caregivers of patients undergoing PD.

2. To compare the psychosocial factors, economic factors and quality of life between patients undergoing HD and patients undergoing PD.

3. To determine the variables (demographic, psychosocial and economic factors) associated with quality of life among patients with ESRD.

4. To determine the variables (demographic, psychosocial and economic factors) associated with quality of life among patients with ESRD.

**Phase II of this study focuses on the following objective:**

1. To explore the perceptions of patients with ESRD and their caregivers regarding their psychosocial well-being and economic burden in the management of ESRD and its impact on their quality of life.

**METHODS AND ANALYSIS**

**Design and methods**

This study involves the use of a sequential explanatory mixed-methods design incorporating methodological and investigator triangulation. Phase I of the study involves the collection of quantitative data, while phase II has to do with a qualitative study.44 Generally, an explanatory design is used when researchers need qualitative data to expand on or explain their initial quantitative findings45 or when quantitative results are required to direct the selection of participants for a qualitative study.46 Thus, the collection of qualitative data emerges from and is linked to the quantitative results.47 Therefore, due to the rigidity of the questionnaire in phase I, a sequential explanatory mixed-methods study design is imperative in this study to elicit more in-depth information, specifically on the psychosocial well-being and economic factors faced by the participants. Thus, phase II will be conducted to elicit more in-depth information from the participants and to gain a better overall understanding of the phenomena being studied. Doyle, Brady and Byrne48 stated that a sequential explanatory mixed-methods design is used to substantiate the findings from a quantitative study by providing supporting evidence from the findings of a qualitative study. However, triangulation involving a mixed-methods design increases the credibility and validity of the research findings.49 In phase I, a cross-sectional survey will be conducted among patients with ESRD and their caregivers. A cross-sectional approach is preferred as it saves time in terms of the distribution of questionnaires and the collection of information from a sizeable number of participants.50 Meanwhile, in phase II, a qualitative study will be conducted involving focus group discussions among patients with ESRD and their caregivers. A focus group discussion approach can give a fruitful and in-depth understanding of an individual’s experiences and perceptions of a specific phenomenon.51 Furthermore, compared with individual interviews with participants, focus groups tend to provide more ideas and information.52 The focus group discussions will enable the participants to consider and share their perspectives regarding the psychosocial well-being and
economic burden they have to undertake when it comes to the management of ESRD and the impact of these on their quality of life. The data findings from phase I and phase II of the study will be integrated through the triangulation process to provide a more holistic and comprehensive insight into the psychosocial factors, economic factors and quality of life experienced by caregivers and their patients with ESRD undergoing different treatment modalities. This mixed-methods integration technique will be the answer the objectives of this study. Also, the role of triangulation in the mixed-methods study will be beneficial in confirming the findings, providing more comprehensive data, increasing the validity and enhancing the understanding of the phenomena being studied.

Study setting
The investigation will be conducted in the nephrology units of Hospital Canselor Tuanku Muhriz Universiti Kebangsaan Malaysia (HCTM), Hospital Selayang (HSEL), Hospital Kuala Lumpur (HKL) and the University of Malaya Medical Centre (UMMC), along with 10 other non-governmental organisations (NGOs) or private dialysis centres in Klang Valley, Malaysia. The hospitals were chosen purposively based on their location in Klang Valley, and are specialist hospitals, NGOs and private centres offering dialysis treatment for patients with ESRD.

Milestones and timelines
The literature review for this study has been completed, and currently, this research is in the pilot testing stage. The pilot study to test the validity and reliability of the instruments for the quantitative data collection in the main study is expected to be completed in 2 months. The qualitative data collection will take approximately 3 months to be completed, and the qualitative data collection, which will last for 2 months, will commence once the quantitative data collection is finalised. The expected timeline for the completion of this study is approximately 7 months, with the final manuscript expected to be completed in October 2022.

Patient and public involvement
One patient, caregiver, health psychologist, and two formal care providers (namely, a nephrologist and a dialysis nurse) will be recruited to form the Advisory Committee. This committee will be tasked with reviewing the protocol and structuring the interview schedule and questionnaire to provide the design for the study. The Advisory Committee will also be referred to for advice and feedback, whenever necessary, throughout this study.

Participants and recruitment
Patients with ESRD and their caregivers will be recruited in dyads in both phases of the study. Specifically, potential patients in phase I will be recruited purposively through referrals from nephrologists or nurses in the nephrology units. In contrast, the caregivers in phase I will be recruited purposively through referrals from the patients themselves. This sampling method will ensure that the data accumulated from the participants will be effective, efficient and cost-effective. However, the participants in phase II will be a subset of the participants in phase I. The participants in phase II will be selected purposively to share their views on their psychosocial well-being, economic burden and quality of life in focus group discussions to ensure that different perspectives are represented. The demographic variables to be considered are age group (young adults, middle-aged adults and older adults) and gender (male and female). A set of inclusion and exclusion criteria will be used within the overall eligible population to ensure that the samples fulfill the aims of this study. The inclusion and exclusion criteria for both phases are similar. Patients have to fulfil these criteria: ESRD diagnosis, above 18 years old, Malaysian nationality, and currently receiving treatment at a hospital, an NGO establishment, or a private dialysis centre in Klang Valley. It is also essential that the potential participants are able to communicate in and read Bahasa Malaysia, the national language of Malaysia. All patients diagnosed with ESRD and their caregivers are welcome to participate in this study. There is no restriction on the duration of the patients’ initiation to dialysis in order to recruit a wide range of study participants. However, patients exhibiting severe mental illness or those who have undergone a kidney transplant will be excluded from the study. As for the recruitment of caregivers, they must be above 18 years of age and be verified as the family caregiver of a patient with ESRD currently undergoing dialysis treatment at a hospital, an NGO establishment or a private dialysis centre in Klang Valley. The caregiver is also required to have undergone the experience of accompanying the patient for dialysis treatment at least once, and must be able to read and communicate in Bahasa Malaysia. Formal caregivers, caregivers of patients who have undergone a kidney transplant or caregivers exhibiting symptoms of severe mental illness will be excluded from the study.

Sample size
Phase I: Quantitative study
The proposed quantitative study sample size calculation is based on the multiple linear regression formula by Tabachnick and Fidell, which is expressed as n=50+8m, where m is the number of predictors. This study will include six predictors (depression, anxiety, coping strategies, social support, burden of care and economic burden), and the sample size, based on the calculation by Tabachnick and Fidell, is estimated to be 98 participants. However, as the participants are to be recruited in dyads, it is assumed that there will be 98 pairs of patients and caregivers. Besides that, the estimated sample size is also calculated via a power analysis using the G*Power program for the F test (multiple linear regression: fixed model, R² deviation from 0) with an effect size of 0.15 (medium), α at 0.05, power at 0.80 and six predictors. Similarly, the power analysis estimated a minimum sample size of 98, which corresponds with the estimated
sample size by Tabachnick and Fidell.\textsuperscript{55} For this study, taking into consideration the dropout rate, non-response rate and incomplete submission of data by participants, the sample size has been increased by 20%.\textsuperscript{56, 57} Hence, 118 pairs of HD patients-caregivers and 118 pairs of PD patients-caregivers (n=236 pairs), which is equivalent to a sample size of 472 participants, will be recruited for the quantitative study.

Phase II: Qualitative study
A qualitative study typically emphasises data saturation, where the saturation point is achieved when no new information, ideas or themes are forthcoming from the participants.\textsuperscript{58} Data saturation can be identified within 5\textsuperscript{59} or 3–6 focus group discussions\textsuperscript{60} with a minimum of 4 and a maximum of 12 participants in a group.\textsuperscript{61} This process is typical for qualitative studies, whereby the emphasis is on arriving at the saturation point. Therefore, based on past literature, six focus group discussions will be conducted in this research, with each group being comprised of at least five participants for this qualitative study. Hence, a minimum of 30 participants (15 patients and 15 caregivers) will be involved in the focus group discussions.

Instruments
Phase I: Quantitative study
The web-based or paper-based questionnaire to be distributed to the participants consists of three sections: demographic sheet, economic assessment and psychosocial assessment (table 1).

Demographic information
The demographic information of the patients and their caregivers, which will be collected through the questionnaire, covers age, gender, race, religion, marital status, education level, occupation, monthly household income, relationship with patient/caregiver, method of dialysis, duration of dialysis, frequency of dialysis and duration of care extended by caregivers.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Summary of instruments for patient and caregiver participants</th>
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<tbody>
<tr>
<td>Patient</td>
<td>Caregiver</td>
</tr>
<tr>
<td>Demographic information</td>
<td>Age, gender, race, religion, marital status, education level, occupation, monthly household income, relationship with patient/caregiver, method of dialysis, duration of dialysis, frequency of dialysis, and duration of care extended by caregivers.</td>
</tr>
<tr>
<td>Economic assessment</td>
<td>Source of funding, monthly cost, weekly cost (time), and perceived economic burden.</td>
</tr>
<tr>
<td>Psychosocial assessment</td>
<td>Brief Coping Orientation to Problems Experienced Inventory (Brief-COPE)</td>
</tr>
<tr>
<td>Coping behaviour</td>
<td>Zarit Burden Interview (ZBI)</td>
</tr>
<tr>
<td>Perceived burden</td>
<td>Medical Outcome Study Social Support Survey (MOS-SSS)</td>
</tr>
<tr>
<td>Social support</td>
<td>Patient Health Questionnaire-9 (PHQ-9)</td>
</tr>
</tbody>
</table>

Economic assessment
The second section of the questionnaire, the economic assessment, covers the source of funding, monthly cost, weekly cost (time) and perceived economic burden of the participants.

Psychosocial assessment
The final section of the questionnaire consists of six scales for the psychosocial assessment. However, the coping strategy and burden of care scales differ between patients and caregivers. The coping behaviour among the patients will be evaluated by the Malay version of the Brief Coping Orientation to Problems Experienced Inventory (Brief-COPE), which is comprised of 28 items with 14 dimensions: self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion and self-blame.\textsuperscript{62} The Malay version of Brief-COPE, which has been validated by Malaysian women patients with breast cancer, has good internal consistency (α=0.51–0.99).\textsuperscript{63} Meanwhile, the Caregiver Cope Questionnaire, developed by Ibrahim et al,\textsuperscript{64} will be used to assess the coping strategies employed by the caregivers. This questionnaire consists of 19 items, with 6 domains of coping strategies, namely, distraction, caring for the patient, venting, religion, recreation and social support. The participants will be rated based on a 5-point Likert Scale (1=I have never done this; 5=I do this very frequently). The validation study conducted among caregivers of patients with schizophrenia in Malaysia yielded Cronbach’s α values ranging between 0.54 and 0.82.\textsuperscript{64}

To assess the self-perceived burden among patients with ESRD, the Self-Perceived Burden Scale (SPBS) will be distributed to the patients.\textsuperscript{24} The SPBS, which consists of 10 items, is rated by a 5-point Likert Scale (1=Not at all; 5=all the time). The Malay version of the 10-item SPBS used in the study by Ting et al\textsuperscript{65} revealed that this is a valid and reliable scale for patients with urolological cancer (α=0.99). Meanwhile, the care burden on caregivers will be examined by 22 items in the Zarit Burden...
Interview (ZBI). The participants will rate their burden on a 5-point Likert Scale (0=rarely, 4=nearly always). In Malaysia, the Malay version of the ZBI has been validated by family caregivers of patients with cancer, with a scale delivering a high internal consistency (α=0.89). The 19-item Medical Outcome Study Social Support Survey (MOS-SSS) developed by Sherbourne and Stewart will be used to examine the participants’ perception of social support. This brief, multidimensional, self-administered scale, rated using a 5-point Likert Scale (1=None at all; 5=Available at all times), measures four categories of social support: informational, instrumental, positive social interactions and affectionate support. In Malaysia, the Malay version of MOS-SSS has been validated through a sample of patients with HIV. This Malay version of the survey portrayed good psychometric properties, with high Cronbach’s α values for all the subscales (α=0.87) and the overall scale (α=0.96).

The General Anxiety Disorder-7 (GAD-7), a screening tool and severity indicator developed by Spitzer et al., will be used to assess the generalised anxiety disorder among the participants. The scale contains seven items and is rated using a 4-point Likert Scale (0=Not at all; 3=Nearly every day). The Malay version of GAD-7, which has been validated through female patients in a government-funded primary care clinic, delivers a good internal consistency reliability (α=0.74).

The participants’ severity of depression will be assessed through the Patient Health Questionnaire-9 (PHQ-9). PHQ-9 consists of 9 items and is rated using a 4-point Likert Scale (0=Not at all; 3=Nearly every day). In Malaysia, the questionnaire has been validated through female patients in a primary care clinic, and the Malay version of PHQ-9 shows a good internal reliability (α=0.70).

The 36-item Short Form Survey (SF-36) will be used to assess the health-related quality of life of the participants. SF-36 consists of eight subscales for measuring different domains of health-related quality of life, namely, PF, role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). Also, two main component scores are derived from the eight subscales. These are the physical component summary, which consists of PF, RP, BP and GH, and the mental component summary, which consists of VT, SF, RE and MH. The Malay version of SF-36, which has been validated by postcoronary artery bypass grafting surgery patients, delivers good internal consistency reliability, with Cronbach’s α values ranging from 0.73 to 0.90 for the subscales.

Phase II: Qualitative study

A focus group discussion schedule will be developed, based on a literature review and expert input by nephrologists in the research team. The questions for the focus group discussions will be tailored to elicit responses from patients with ESRD and their caregivers regarding their psychosocial well-being and the economic burden being faced by them, and its impact on their quality of life. The focus group discussion schedule will be piloted among the caregivers and patients to examine the clarity and feasibility of the questions. The focus group discussions will be divided into five sections: demographic details, source of ESRD treatment funding, costs of ESRD management, the impact of their psychosocial well-being on their quality of life, and lastly, the impact of the economic burden experienced by them on their quality of life.

Data collection

Phase I: Quantitative study

Conventional paper-and-pencil/web-based questionnaires will be used. The response rate of the participants who respond positively out of those potentially eligible participants who are invited to be involved in the study will be recorded. Potential participants (patients), identified through referrals from nephrologists or nurses in the nephrology units, will be recruited during their dialysis treatments in the respective hospitals/dialysis centres. In contrast, potential participants (caregivers) will be approached while waiting for their patients’ treatment to be completed. For the caregivers who are not present during the patients’ treatment, the researchers will call them up or meet with them during the patients’ subsequent treatment at the respective hospitals/dialysis centres. The recruitment process will progress with the researcher briefing the caregivers and patients on the aims and procedures of the study. Potential participants who respond in the affirmative as to whether they have been previously diagnosed with severe mental illness will be excluded from the study. Potential participants will be given ample time to consider their involvement in the study. On receiving their consent, the participants will be provided with a questionnaire, which can be completed in approximately 30 min. The researchers will entertain any questions the participants may have regarding the questionnaire. The completed questionnaires will be kept securely for the data analysis process. The criteria for the withdrawal of a subject include a situation whereby the participant voluntarily withdraws his/her consent to participate in the study or when the principal investigator, for any reason, ends the participation. Participants are free to withdraw from the study at any time by stating their intention to do so during the course of the survey or by emailing the principal investigator, whose email address and telephone number are included in the informed consent form. As the calculation of the sample size takes into account the dropout rate of participants, those who withdraw from the study will not be replaced.

Phase II: Qualitative study

The response rate of participants who respond positively out of those potentially eligible participants who are invited to be involved in the study will be recorded. Potential participants from phase I will be recruited purposively out of those potentially eligible participants who are invited to be involved in the study will be recorded. Potential participants (patients), identified through referrals from nephrologists or nurses in the nephrology units, will be recruited during their dialysis treatments in the respective hospitals/dialysis centres. In contrast, potential participants (caregivers) will be approached while waiting for their patients’ treatment to be completed. For the caregivers who are not present during the patients’ treatment, the researchers will call them up or meet with them during the patients’ subsequent treatment at the respective hospitals/dialysis centres. The recruitment process will progress with the researcher briefing the caregivers and patients on the aims and procedures of the study. Potential participants who respond in the affirmative as to whether they have been previously diagnosed with severe mental illness will be excluded from the study. Potential participants will be given ample time to consider their involvement in the study. On receiving their consent, the participants will be provided with a questionnaire, which can be completed in approximately 30 min. The researchers will entertain any questions the participants may have regarding the questionnaire. The completed questionnaires will be kept securely for the data analysis process. The criteria for the withdrawal of a subject include a situation whereby the participant voluntarily withdraws his/her consent to participate in the study or when the principal investigator, for any reason, ends the participation. Participants are free to withdraw from the study at any time by stating their intention to do so during the course of the survey or by emailing the principal investigator, whose email address and telephone number are included in the informed consent form. As the calculation of the sample size takes into account the dropout rate of participants, those who withdraw from the study will not be replaced.
Participants will be given sufficient time to consider their participation in the focus group discussions. The discussion will be held at a designated date, time and venue to be decided by the researchers, and is anticipated to last for an hour. The discussions will be recorded, and the data will be transcribed verbatim, after which, the recording will be deleted, in keeping with established ethical standards. The subject withdrawal criteria include a situation where the participant voluntarily withdraws his/her consent to participate in this study or when the principal investigator, for any reason, ends the participation. Participants are free to withdraw from the study at any time by stating their intention to do so during the course of the discussion or by emailing the principal investigator, whose email address and telephone number are included in the informed consent form. The arrival at the data saturation point will not be affected by the withdrawal of a participant(s), who will not be replaced.

Data analysis
Phase I: Quantitative study
The IBM SPSS software for Windows (V.27) \(^76\) will be used for data processing, while descriptive statistics, independent sample \(t\) tests and multiple regression analyses will be used for data analysis. Statistical significance will be set at 0.05, and descriptive statistics will be used to compute the frequencies, percentages, means and SD, and to summarise the data from the respondents. To answer Objectives 1 and 2, which are to examine the differences in the treatment modalities on the participants’ psychosocial factors, economic factors and quality of life, independent sample \(t\) tests will be conducted between caregivers of HD and PD patients (Objective 1) and between HD and PD patients (Objective 2).

To answer Objectives 3 and 4, two multiple linear regression models will be fitted to examine the association between the psychosocial factors (depression, anxiety, coping strategies, social support, burden of care and self-perceived burden), economic factors and the quality of life of caregivers (Objective 3) and patients with ESRD (Objective 4), while adjusting for potential demographic and clinical confounding factors (age, gender, race, religion, marital status, education level, occupation, monthly household income, relationship with patient/caregiver, method of dialysis, duration of dialysis, frequency of dialysis and duration of care extended by caregivers).

ESRD, end-stage renal disease.

The data will be analysed by a team of researchers using NVivo software for Windows (V.11) (update 4). \(^79\) The coding process begins with open coding by coding lines, statements and/or paragraphs. Data analysis will be considered to have reached saturation point when no new categories emerge. Each transcript will be coded and recoded several times. \(^76\) Next, a cross-validation to check the coding and transcripts will be undertaken by an independent rater, who will be provided with six interview transcripts. The independent rater’s task will be to conduct a thematic analysis and check the appropriateness of that analysis. The independent rater’s feedback will be compared with the identified themes. Any disagreements that may emerge in terms of subthemes and themes will be discussed with the independent rater, and will be resolved through discussions with the independent rater and feedback from the research team.

Phase II: Qualitative study
This qualitative study will facilitate an in-depth examination of the participants’ perception of their psychosocial well-being and economic burden in the management of ESRD and its impact on their quality of life. A thematic analysis approach will be employed to analyse the data from the focus groups. \(^77\) \(^78\) The data from the focus groups will be audio recorded and then transcribed accordingly. A copy of the transcripts will be given to the participants involved in the focus groups for feedback and approval before the analysis is carried out. For storage purposes, the data will be kept in a safety cabinet with a passcode, and only the research team will have access to the stored data. An initial reading of the focus group transcripts will be carried out. The transcripts will be re-read and coded individually to identify the key components of the psychosocial well-being, economic burden and quality of life of participants. The data will be analysed by a team of researchers using NVivo software for Windows (V.11) (update 4). \(^79\) The coding process begins with open coding by coding lines, statements and/or paragraphs. Data analysis will be considered to have reached saturation point when no new categories emerge. Each transcript will be coded and recoded several times. \(^76\) Next, a cross-validation to check the coding and transcripts will be undertaken by an independent rater, who will be provided with six interview transcripts. The independent rater’s task will be to conduct a thematic analysis and check the appropriateness of that analysis. The independent rater’s feedback will be compared with the identified themes. Any disagreements that may emerge in terms of subthemes and themes will be discussed with the independent rater, and will be resolved through discussions with the independent rater and feedback from the research team.

Figure 1 Analytical plan for Objective 3 and Objective 4 of the study

Figure 1. Analytic plan for Objective 3 and Objective 4 of the study Two multiple linear regression models will be fitted to examine the association between the psychosocial factors (depression, anxiety, coping strategies, social support, burden of care and self-perceived burden), economic factors and the quality of life of caregivers (Objective 3) and patients with ESRD (Objective 4), while adjusting for potential demographic and clinical confounding factors (age, gender, race, religion, marital status, education level, occupation, monthly household income, relationship with patient/caregiver, method of dialysis, duration of dialysis, frequency of dialysis and duration of care extended by caregivers).
that is, psychosocial well-being, economic burden and the impact of these on the quality of life of caregivers and patients. These phenomena will be examined from different methodological angles using quantitative and qualitative methods.\footnote{This approach will provide the means to verify and/or interrogate the data, thereby increasing the confidence in the results. Therefore, two types of triangulations will be involved. The first type is data triangulation using different approaches (quantitative and qualitative designs) in which information will be gathered from different sources, namely the participants (caregivers and patients), discussions and feedback from the research team, and with the participation of an independent rater or checker for the analysis. The second type is investigator triangulation, in which different investigators (ie, student researchers, supervisors) will be involved in the data collection and an independent rater will participate in the data analysis. The use of two or more investigators independently can lead to more valid and reliable data,\footnote{Properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial.} and checking for divergences between researchers will result in minimal divergence, that is, reliability.}

\section*{ETHICS AND DISSEMINATION}

\subsection*{Ethics approval}
The work has been approved by the Medical Research and Ethics Committee (MREC) (NMRR-21-1012-59714) and the research ethics committees of HCTM (UKM PPI/111/8/JEP-2021-078) and UMMC (MREC ID NO: 202178–10346). Also, the relevant permission and approvals have been obtained from the directors of HSEL and HKL.

\subsection*{Ethical considerations}
The researchers will adhere to the principles of the Declaration of Helsinki\footnote{Participants will be required to provide informed consent. The privacy of the participants will be protected during the data collection process by separating the informed consent forms from the paper-based questionnaire responses. All the documents will be deposited in a secure cabinet, and all the data will be stored in a password-protected computer to which only the researchers will have access. All the documents and data will be stored for 7 years, after which they will be shredded and deleted. No participant identifiers (name, identity card number, address, phone number) will be traceable, and a unique study ID will be assigned. No medical records will be accessible. Participants will have no access to any personal information, and to ensure the element of anonymity, they will not be informed of the study findings.} and the Malaysian Good Clinical Practice Guidelines.\footnote{Minimal anonymised data will be uploaded as supplementary material for review purposes in scientific journal publications or conferences, and these will adhere strictly to the ethical principles stipulated. Only group data will be published, and no personal identifier will be collected or made public. The relevant permission will be obtained from all the parties involved before any publication. The findings from this study can serve as a guide for Malaysian policymakers, healthcare providers, and society to improve the quality of life of patients with ESRD and their caregivers through the engagement of constructive and holistic interventions.}

\subsection*{Dissemination}
The findings from this study will be published in peer-review scientific journals and at national or international conferences. Minimal anonymised data will be uploaded as supplementary material for review purposes in scientific journal publications or conferences, and these will adhere strictly to the ethical principles stipulated. Only group data will be published, and no personal identifier will be collected or made public. The relevant permission will be obtained from all the parties involved before any publication. The findings from this study can serve as a guide for Malaysian policymakers, healthcare providers, and society to improve the quality of life of patients with ESRD and their caregivers through the engagement of constructive and holistic interventions.

\section*{REFERENCES}


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