BURNOUT AMONG CARETAKERS OF PAEDIATRIC PATIENT WITH CHRONIC KIDNEY DISEASE IN HOSPITAL UNIVERSITI SAINS MALAYSIA, KELANTAN

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE (PAEDIATRICS)

UNIVERSITI SAINS MALAYSIA
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INTRODUCTION

Overview of Burnout among Caretakers of Chronic Patients

Taking care of a chronically ill patient is a stressful ordeal, especially in paediatric patient. Many studies have identified factors that may affect high stressor, but little study describes the prevalence of burnout among caretakers in chronically ill patients.

It is well established that caretakers of children on chronic peritoneal dialysis have a significantly lower quality of life, and the prevalence of probable depression is also considerably more common. [1]

Caretaker or caregiver here denotes care given by family members or friends, rather than professional who is imbursed for their services. A caretaker has all the features of chronic stress experience due to multiple reasons that frequently require a high level of vigilance. It creates physical and psychological strain over extended periods accompanied by high levels of unpredictability and uncontrollability. These can create secondary stress in multiple life domains such as work and family relationships. [2]

Burnout is a term first used in the 1970s by the American psychologist Herbert Freudenberger. There is a wide range of symptoms that is due to work-related or stress. One example of a source of stress outside of work is caring for a family member. There are three main areas that are considered to be symptoms of burnout. The symptoms are exhaustion, alienation from (work-related) activities, and reduced performance. The risk of depression is also increased in those with burnout. [3]

Overview of Paediatric Chronic Kidney Disease

Chronic Kidney Disease (CKD) in children differs from the adult population, especially in terms of causes, prevalence, and mortality. [4] Children with CKD face lifelong morbidity and mortality that may affect their quality of life and the whole family dynamics. The causes

for CKD in children are mostly due to congenital anomalies of the kidney and urinary tract (CAKUT), followed by hereditary nephropathies and glomerulonephritis. [4]

Multiple complications are seen in paediatric CKD patients. Due to numerous reasons, their growth and nutrition are affected, namely lack of appetite due to uremia, metabolic acidosis, and salt-losing nephropathies. These may cause stunted growth if not carefully managed and subsequently cause delayed puberty in later age. They may also develop renal osteodystrophy, which may cause bone deformities and pathological fracture if not treated. Anaemia is also one of the complications that must be treated as it was linked to a low quality of life and neurocognitive development. [4]

A retrospective cohort study found that patients with glomerular disease progress rapidly to CKD compared to patients with CAKUT anomalies. [5] A study by Wong et al. and Warady et al. found that in non-glomerular disease patient, the factors that led to a faster decline of renal function were urinary protein-creatinine ratio of >2 mg/mg, hypoalbuminemia, elevated BP, dyslipidaemia, male gender, and anaemia. Paediatric CKD differs from adult CKD in term of management for bladder dysfunction. [6–7] Paediatric patient especially teenagers also have issues like adherence to medication and transition to adult services. [4]

Research Objectives

This study aimed to determine the prevalence of burnout among paediatric patient caretakers with CKD in Kelantan and its associated factors. We also want to know the correlation between strain and burnout among caretakers of paediatric patients with CKD in Kelantan.

RESEARCH PROPOSAL

Research Title :

Study of burnout among caretakers of paediatric patients with chronic kidney disease in Hospital Universiti Sains Malaysia, Kelantan.

Principal Investigator: Assoc. Prof Dr Norsarwany Bt Mohamad (MPM33092)

Co- researchers:

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3)Dr Muhamad Ikram Ilias (MPM 40439)

4)Assoc. Prof Dr Azriani Berahim @ Ab Rahman (MPM 34417)

Introduction

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Caretaker or caregiver here denotes care given by family members or friends, rather than professional who is imbursed for their services. A caretaker has all the features of chronic stress experience due to multiple reasons that frequently require a high level of vigilance. It creates physical and psychological strain over extended periods accompanied by high levels of unpredictability and uncontrollability. These can create secondary stress in multiple life domains such as work and family relationships. (1)

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Not all people who have burnout develop depression, but it is shown to increase the risk of depression. (2)

Problem Statement and Study Rationale

Many studies have been done in other countries to determine the burden and quality of life in caretakers of chronic kidney disease (CKD) patients. (Mona et al., Fatemeh et al., Alan R. Watson, T-C Tsai, et al.) but lack of study in Malaysia or the ASEAN region.

These studies describe stressors, caregiver burden, and prevalence of depression, and quality of life.

We would like to know the level of stress among caretakers of chronically ill patients in Kelantan, specifically CKD patients, and the prevalence of burnout.

Later, these findings may aid in developing stress management intervention to improve their psychosocial well-being and improve treatment for patients as a whole.

Research Question

- What is the prevalence of burnout among caretakers of paediatric patients with CKD in Kelantan?
- What are the factors associated with burnout among caretakers of paediatric patients with CKD in Kelantan?
- What is the level of strains among caretakers of paediatric patients with CKD in Kelantan?

Objective:

- **General:**
    1. To determine the prevalence of burnout and its associated factors among caretakers of paediatric patient with CKD in Kelantan
- **Specific:**
    1. To determine the prevalence of burnout among caretakers of paediatric patient with CKD in Kelantan
    2. To determine the factors associated with burnout among caretakers of paediatric patient with CKD in Kelantan
    3. To determine the correlation between strain and burnout among caretakers of paediatric patient with CKD in Kelantan

Literature Review

A population-based study done by Lindstrom et al. reported an increase prevalence of burnout symptoms in parents of chronically ill children published in Acta Pediatrica 2010[3]. There were 252 parents of children with type 1 Diabetes Mellitus and 38 parents of children with inflammatory bowel disease with control of 124 randomly selected parents of healthy children. This study showed that significantly more parents of children with chronic illness (36%) scored for clinical burnout compared to parents of healthy children (20%).

In 1997, Alan R. Watson did a cross-sectional study about stress and the burden of care in families with children commencing renal replacement therapy [4]. About 38 patients were enrolled in 2 years (age range of 0.2-18.5 years). This study showed that mean stress, anxiety, and depression scores were higher in mothers than fathers and also in parents of patients of more than ten years of age.

An important study was done by Mona et al. and published in 1997. The study covered the topic of subjective burden and quality of life in family caregivers of patients with end-stage

renal disease [5]. This study enrolled 96 caregivers of 96 transplant candidates diagnosed with end-stage renal disease. This study showed that caregiver quality of life was significantly related to caregiver burden and caregiver self-rated health. Caregiver burden did not differ by dialysis type or employment status.

In 2006, another relevant study published in Journal Kidney International 2006 about psychosocial effects on caregivers for children on chronic peritoneal dialysis by Tsai et al. [6]. This study enrolled caretakers of 32 children with renal failure treated with CPD with a control group of 64 healthy children. The result showed that 25% of caregivers had full-time jobs in the study group; 66% had annual income <USD 15000. 16% were single-parent. Prevalence of probable depression was significantly more common in the study group than in control and referent groups (28% vs 5% and 9.44%; P= 0.001).

Fatemeh et al. published an article in 2015 about assessing caregiver burden in haemodialysis patients' caregivers [7]. Caregivers of 69 patients on haemodialysis were enrolled. The outcome showed that 72.5% of caregivers reported moderate to severe levels of caregiver burden.

Toledano-Toledano and Dominguez-Gedea have published an article recently in Biopsychosocial Medicine journal about psychosocial factors related to caregiver burden among families of children with chronic conditions [13]. Four hundred and sixteen families were involved in the studies. The sociodemographic profile from this study showed that most of the caretakers were women (81.7%), the mean age was 31.7 years (standard deviation, eight 8), most of them were married (79.3%) and those with primary education were about 62.7%.

So far, no similar study has been done in Malaysia that describes burnout among paediatric patient caretakers with chronic kidney disease. A study was done by Raynuha et al. in 2013 about stress in breast cancer patients in oncologic treatment at a Malaysian General Hospital [12], which involved 130 participants, showed a high proportion of the family

caregivers experienced stress. Several studies from Malaysia also reported burnout among healthcare professionals like nurses or doctors, but there were no studies about burnout among caretakers of paediatric patients.

This study will describe the prevalence of burnout among caretakers of paediatric patients with chronic kidney disease. This will help us to identify factors that predispose to burnout among caretakers and predict measures or intervention that we can take later to help them as to reduce their burden and at the same time improve patient's management as a whole.

Research Design

This is a cross-sectional study using validated questionnaires – Copenhagen Burnout Inventory- Malay version (CBI-M), also the Caregiver Strain Index (CSI-M).

Study Area and Study Population

This study will be conducted among caretakers of paediatric chronic kidney patients (less than 18 years old, with chronic kidney disease stage 3 and above) in Hospital Universiti Sains Malaysia during data collection.

Subject Criteria

Inclusion criteria

Patient:
Aged 3 months to 18 years old.
CKD patient stage 3 and above

Caretaker:
Primary guardian or parent who takes care of the patient most of the time, age 18 years above.
Not paid for the care.

Exclusion Criteria:
Primary caretaker not around or not consented
The caretaker did not understand Malay/ English.

Sample Size Estimation

1. **The sample size for the first objective**

$$n = \frac{Z^2 p(1-p)}{d^2}$$

n= min. required sample
Z = value of standard normal distribution = 1.96
d= precision = 10%
p= 36% (prevalence of burnout symptoms among parents of chronically ill children (Lindstrom et al, 2009))
n= **88**
Considering 10% non-response, minimum required sample is 88 + 8= **96**

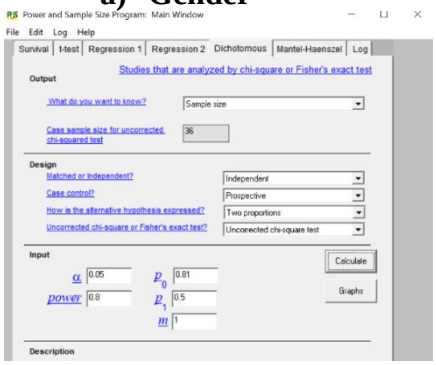
- **We will be using the immense sample size from all three objectives, which is 96.**

2. **The sample size for the second objective**

Sample size calculation for the second objective will be calculated for categorical variables only as sample size calculation for numerical variables will be smaller than categorical variables.

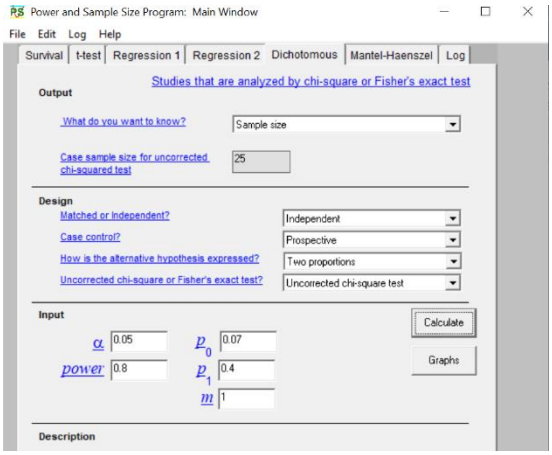
Variables

a) Gender



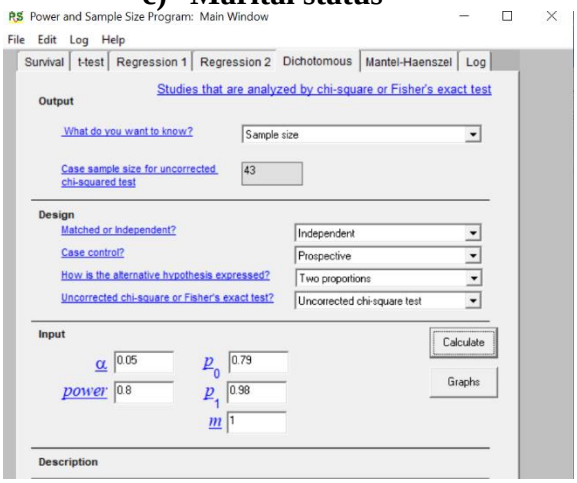
Sample size was calculated using PS software for variable gender.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of female caregiver among families of children with chronic illness (13-Toledano-Toledano and Dominguez-Gedea, 2019)
= 81%
p_1 = expected proportion of female burnout caregivers = 50%
m = ratio between burnout and non-burnout caregivers =1
n = 36 x 2 (+ 10% dropout) = 79

b) Occupation



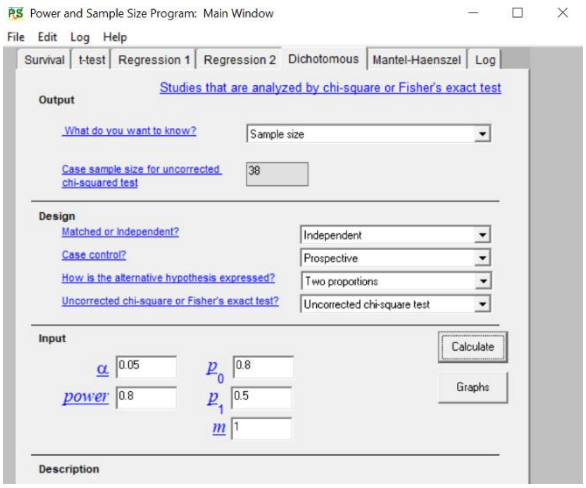
The sample size was calculated using PS software for variable occupation.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of unemployed caregiver among families of children with chronic illness (13-Toledano-Toledano and Dominguez-Gadea, 2019)
= 6.7%
p_1 = expected proportion of unemployed burnout caregivers = 30%
m = ratio between burnout and non-burnout caregivers =1
n = 25 x 2 (+ 10% dropout) = 55

c) Marital status



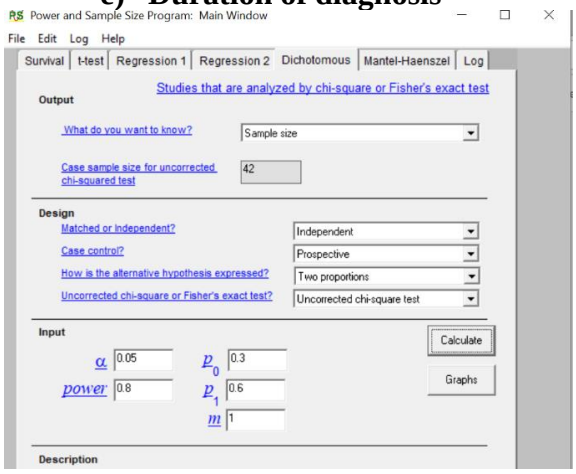
Sample size was calculated using PS software for variable gender.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of married caregiver among families of children with chronic illness (13-Toledano-Toledano and Dominguez-Gedea, 2019)
= 79%
p_1 = expected proportion of female burnout caregivers = 98%
m = ratio between burnout and non-burnout caregivers =1
n = 43 x 2 (+ 10% dropout) = 94

d) Caretaker education level



Sample size was calculated using PS software for variable occupation.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of caregiver with basic education level among families of children with chronic illness (13-Toledano-Toledano and Dominguez-Gedea, 2019) = 80%
p_1 = expected proportion of unemployed burnout caregivers = 50%
m = ratio between burnout and non-burnout caregivers =1
n = 38 x 2 (+ 10% dropout) = 84

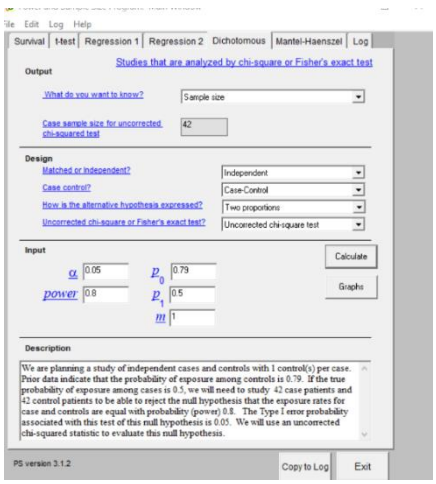
e) Duration of diagnosis



Sample size was calculated using PS software for variable occupation.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of children who diagnosed more than 1 year among children with chronic illness (13-Toledano-Toledano and Dominguez-Gedea, 2019) = 30%
p_1 = expected proportion of burnout caregivers = 60%
m = ratio between burnout and non-burnout caregivers =1

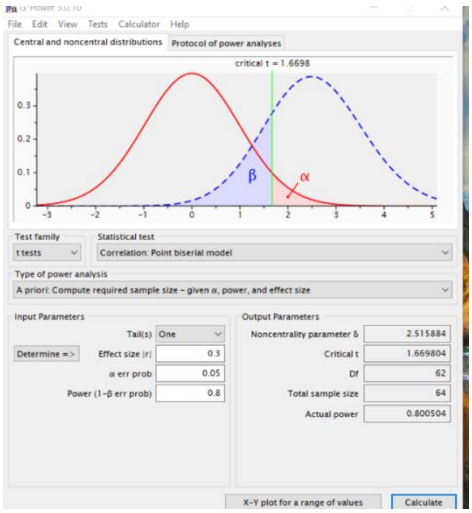
n = 42 x 2 (+ 10% dropout) = 92

f) Type of treatment



The sample size was calculated using PS software for variable children on hemodialysis.
α = level of significance = 0.05
power of study = 0.8
p_o = proportion of CKD children who underwent hemodialysis in the general Malaysian population. (24th report of Malaysian Dialysis and Transplant Registry 2016)
= 79%
p_1 = expected proportion of CKD children who underwent hemodialysis among burnout caregivers = 50%
m = ratio between burnout and non-burnout caregivers =1
n = 42 x 2 (+ 10% dropout) = 92

3. The sample size for the third objective



The sample size for the 3rd objective was calculated using G Power 3.0 software.

Effect size (r) = 0.3

α = 0.05

Power = 0.8

n =**64**

Sampling Method and Subject Requirement

Convenience sampling is the sampling method of choice in this study due to the study population's limitation. Hence, after considering the inclusion and exclusion criteria, convenience sampling suits this study in achieving the objectives.

Research Tool

1. **Sociodemographic Pro-forma**
2. **Caregiver Strain Index- Malay Version (CSI-M)**

- There are 13 questions about the level of strain on caregivers while taking care of patients at home. Some of the items given include emotional status, financial, time, physical, and family relationship. The question has a simple yes/no answer. Scores of more than 7 indicate a high level of stress.
- The CSI-M is a brief and easily administered measurement scale (Robinson 1983). Its internal consistency reliability is high, with Cronbach's alpha 0.86. It has good construct validity as supported by correlations with the caregiver's physical and emotional health and subjective views of the caregiving situation. It has been tested on cancer caregivers (Ugur 2010) and stroke patients (Van Exel 2004 and Post 2007).

A Malay version of this CSI questionnaire (CSI-M) has been validated in Kelantan's local setting (Zahiruddin 2014). The Cronbach alpha was 0.79. based on the scope covered by the questions and the ease of its administration, this validated Malay questionnaire was chosen to be the tool used in this research.

3. Copenhagen Burnout Inventory – (CBI -M)

- Comprises three main domains, which include personal burnout, work-related burnout, and client-related burnout with 19 questions.

- Type of Likert's scale is used

- 12 questions were rated by the Likert's scale ranged from:

(0) = always

(1) = Often

(2) = Sometimes

(3) = Seldom

(4) = Never/Almost never

- 7 questions were rated by the Likert's scale ranged from:

(0) = Toa very high degree

(1) = To a high degree

(2) = Somewhat

(3) = To a low degree

(4) = To a very low degree

- Mean score was used for interpretation purposes whereby a mean score of 50 or more signified significant burnout.

- The Malay version was validated by a study conducted by Chin et al. on **Investigating validity evidence of the Malay translation of the Copenhagen Burnout Inventory** published in 2018. The face validity index was more than 0.8. The Cronbach's alpha value of the three factors ranged from 0.83 to 0.87.

Operational Definition

Term	Definition
Burnout	It is defined as an exhaustion of physical or emotional strength or motivation resulting from prolonged stress or frustration. (Merriam-Webster Dictionary) In this study, burnout will be assessed using the CBI-M Questionnaire consist of 19 questions with three domains. Those with a mean score >50 is regarded as having a burnout.
Stressor	It is defined as a stimulus that causes stress. (Merriam-Webster Dictionary) In this study, the stressor is assess using CSI-M consisting of 13 questions A score of 7 and more indicates a high level of stress.
Paediatric Patient with Chronic Kidney Disease	Patient from age three months to 18 years old with abnormalities of structure or function of the kidney, more than three months duration (eGFR < 60ml/min/1.73 m2 – stage 3 and above) (Kidney International Supplements (2013) 3, 19–62; doi:10.1038/kisup.2012.64)
Caretaker	One that gives physical or emotional care and support, primary guardian or parent. (Merriam- Webster Dictionary)

Data Collection Method

All participants that fulfil the inclusion criteria will be identified, and questionnaires will be distributed. Each consented participant will receive an explanation regarding the study and related questionnaires used.

Each participant will spend about 15-20 minutes to answer all the questions by themselves. There is no specific time allocated, but the time frame is set not to disrupt the ward/clinic work in progress. The researcher is available if any question arises.

Participants will be involved in this study during the outpatient clinic day. As this study is part of a bigger study, patients may be called to participate in the intervention study later if the patient consents.

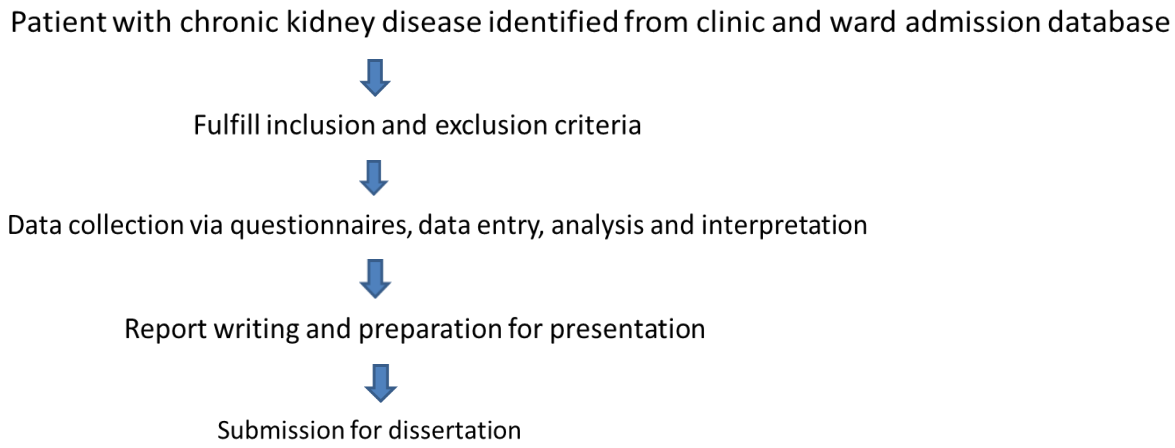
Data collection will only use initials to ensure confidentiality. Each participant will be assured that the data collected, and its result will not be disclosed to others.

Participants will be offered the opportunity to approach the principal investigator privately upon completing the questionnaire if they have any concerns regarding stress or burnout, and referral to their respective specialty will be done if indicated.

Subject recruitment

Sample size 96 is achievable for pediatric patients with CKD stage 3 and above. The total outpatient for paediatric nephrology clinic is about 40 patients per week, with an estimated average of 5 to 10 patients with CKD stages three and above. Data collection can be completed within six months of the study.

Study Flowchart



Data Analysis

Data will be manually entered and analysed using the IBM SPSS Version 24. Descriptive statistics will be used to summarise the sociodemographic characteristics of participants. Numerical data will be presented as mean (SD) if normally distributed and, if not, as medians and interquartile ranges. Categorical data will be presented as frequency and percentage.

Statistical analysis includes:

Prevalence will be calculated using Chi-Square tests with formula X/n, where 'X' is the number of participants reported burnout, with 'n' is the total number of participants in the study.

Single and multiple logistic regression is used to test and estimates relationships between factors and categorical outcomes.

Spearman's correlation analysis will be applied to study the correlation between stressor domain and burnout.

Expected Results

Table 1: Sociodemographic data of caretakers

Characteristics	n (Number)	%	Mean	SD
Gender Male Female				
Age				
Ethnicity				
Education level				
Religion Muslim Christian Hindu Others				
Occupation Unemployed Self-employed Government-employed				
Monthly income				
Marital status Single Married Divorced				
Family dependent				
Duration since diagnosis < 1 year >1 year				
Type of treatment Medication Peritoneal Dialysis (CAPD) Hemodialysis (HD)				
Frequency of ward admission < 6 months Nil 1-2 >2				
Ward admission average stays				

Table 2: Prevalence of Burnout

Burnout score (mean)	N	%
Overall burnout >yes <no		
Personal burnout >yes <no		
Work-related burnout >yes <no		
Client- related burnout >yes <no		

Table 3: Factors associated with burnout

Characteristics	Simple Logistic Regression (95% CI)	P-value	Multiple logistic regression (95% CI)	P-value
Age				
Gender				
Ethnicity				
Relationship to children				
Education level				
Religion				
Occupation				
Monthly income				
Marital status				
Family dependent				
Duration of diagnosis				
Type of treatment				
Frequency ward admission				
Average ward stays				

Table 4: Correlation between burnout and stressor

Variables		Correlation Coefficient	P-value
Significant Strain	Total burnout		

Gantt Chart and Milestone

Activity	2018	2019								2020					
	12	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Proposal	x														
Ethical approval		x	x	x											
Data collection					x	x	x	x	x	x					
Data analysis											x	x	x		
Report writing														x	
Submission															x

Budget Proposal

This study is part of a Research University (Individual) Grant (RUI); ID 1001/PPSP/8011292. The proposed budget is as below:

No	List	Estimation	Total
1.	Honorarium and Incentives Honorarium to participant	 RM 15 per person	 96 x RM15 = RM1440
2.	Photocopy Questionnaires Consent forms	 4 pages x RM 0.10 9 pages x RM 0.10	 100 x RM0.40 = RM40 100x RM0.90 = RM 90
3.	Printing and photocopy of dissertations	RM25 per copy	4x RM25 = RM 100
		Total	RM 1670

Ethical Consideration

1. Subject vulnerability

The participants are vulnerable in several ways; thus, multiple steps will be taken to reduce vulnerability.

Participants may feel obliged with this study as the co-researcher is the specialist in charge of the patient. Thus, we will ensure that we will reassure the participant that this study is done

voluntarily during consent taking. It will not affect patient treatment in any way if they decide not to participate in this study. The co-researcher will not know who will be participating in this study as the patient's name will be disclosed, and only initial will be used.

If the patient shows signs and symptoms of depression, we will counsel the patient and refer the patient to the psychiatric clinic for further evaluation and management**.**

2. Declaration of absence of conflict of interest

One of the co-researchers is the specialist in charge of the patient in this study. However, co-researcher will not receive any benefits or incentives from this study. The participant may feel obligated to participate in this study to avoid any consequences. Thus, we will ensure during consent taking that this study is done voluntarily. We will also provide to preserve this study's integrity and prevent bias by ensuring each participant's privacy and confidentiality.

3. Privacy and confidentiality

All forms will be put on initial and number coded. The data will be saved in SPSS software. Only research team members can access the data. Data will be presented as group data, and we will not identify the participant individually.

Data will be stored in the researcher's private laptop or computer with a personal backup hard disk. Data will be discarded after ten years (after completion of study and thesis submission). As this study is part of a bigger study that may involve the participant in the intervention study, consent will be taken and informed to the participant that their data will be incorporated in the bigger study. If consented, they may participate in the intervention study as well.

4. Risks to participants

As the questionnaire involved sensitive and emotional issues, it may pose psychological risks to participants. We will inform participants verbally and also written in the consent form.

Should they feel stressed with the question, they may opt not to answer the question, or if they need further help, we may refer them to a counsellor or psychiatrist.

5. Communities sensitivities and benefits

As we identified the prevalence of burnout and associated factors, we will identify those participants who have significant burnout and may further enroll them in the next phase of research (part of the RUI). The next phase of the study will be the intervention phase; thus, the participant may benefit from this (if the participant consented). We will also inform the result of this study to participants and further management if participants have significant burnout.

We will publish the data of this study to benefit the community as a whole. Hopefully, this study's result may bring forward another study to improve the patient's holistic management.

6. Honorarium and incentives

Token of appreciation will be given to the participants after they have completed the questionnaires. However, we will not talk about it beforehand to prevent biased or influence of decision among participant. Incentives also will be given to research assistants on an hourly basis.

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UNIVERSITI SAINS MALAYSIA

JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

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20th November 2019

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JEPeM Code : USM/JEPeM/19060371
Protocol Title : Study of Burnout among Caretakers of Pediatric Patient with Chronic Kidney Disease in Hospital Universiti Sains Malaysia.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/19060371**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **20th November 2019** until **19th November 2020.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Dr. Siti Nur Haidar Hazlan
2. Dr. Muhamad Ikram Ilias
3. Assoc. Prof. Dr. Azriani Berahim @ Ab Rahman

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Participant Information Sheet and Consent Form (English version)
2. Participant Information Sheet and Consent Form (Malay version)
3. Questionnaire

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.**
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**

CERTIFIED BY:

NPRA MALAYSIA
National Pharmaceutical Regulatory Agency (NPRA)

Forum for Ethical Review Committees in Asia & Western Pacific Region

3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.