THE ASSOCIATION BETWEEN NUTRITIONAL STATUS, VITAMIN AND MINERAL INTAKE AND RENAL PROFILE AMONG HAEMODIALYSIS PATIENT IN HOSPITAL PAKAR UNIVERSITI SAINS MALAYSIA (HPUSM), KELANTAN

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by

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ABSTRAK

Rawatan hemodialisis adalah rawatan biasa dalam kalangan pesakit buah pinggang kronik kerana penyakit ini boleh mengubah pilihan makanan individu serta profil buah pinggang terutamanya disebabkan oleh kesan sampingan rawatan yang mempengaruhi status pemakanan serta pengambilan vitamin dan mineral mereka. Matlamat kajian ini adalah untuk mengkaji hubungan antara status pemakanan, pengambilan vitamin dan mineral, dan profil buah pinggang dalam kalangan pesakit hemodialisis. Kajian keratan rentas telah dijalankan dalam kalangan 106 pesakit hemodialisis berumur 19 tahun ke atas menggunakan teknik pensampelan mudah di Hospital Pakar Universiti Sains Malaysia (HPUSM). Latar belakang sosial-demografi, maklumat klinikal, profil darah renal, ukuran antropometri dan pengambilan makanan (sejarah diet 3 hari) adalah parameter dalam soalan temu bual. Pengumpulan data dijalankan melalui soal selidik yang ditadbir oleh penemuduga. Majoriti pesakit hemodialisis mempunyai indeks jisim tubuh (IJT) yang berlebihan (24.24 kg/m²). Penemuan kajian ini mendapati terdapat hubungan yang signifikan antara status pemakanan dengan profil renal (tinggi dan kalium ($p = 0.004$), berat kering dengan ujian fosfat ($p = 0.044$), lilitan betis dengan fosfat ($p = 0.003$), lilitan lengan atas pertengahan dengan kreatinin ($p = 0.014$), lilitan betis dengan kreatinin ($p = 0.003$), BMI dengan magnesium ($p = 0.018$), berat kering dengan kreatinin ($p < 0.001$), BMI dengan kreatinin ($p = 0.004$), BMI dengan albumin ($p = 0.049$)) serta pengambilan

vitamin dan mineral dengan profil renal (vitamin C dan asid urik ($p = 0.020$). Walau bagaimanapun, tiada hubungan yang signifikan secara statistik ditemui antara status pemakanan dan pengambilan vitamin dan mineral dalam kalangan pesakit hemodialisis. Walau bagaimanapun, lebih banyak kajian diperlukan untuk lebih memahami faktor-faktor yang mempengaruhi profil buah pinggang dalam kalangan pesakit hemodialisis, memastikan intervensi boleh mencegah kemerosotan status pemakanan serta pengambilan vitamin dan mineral.

THE ASSOCIATION BETWEEN NUTRITIONAL STATUS, VITAMIN AND MINERAL INTAKE AND RENAL PROFILE AMONG HAEMODIALYSIS PATIENT IN HOSPITAL PAKAR UNIVERSITI SAINS MALAYSIA (HPUSM), KELANTAN

ABSTRACT

Haemodialysis treatment is common among chronic kidney disease patients as it may shift an individual's food choices as well as renal profile mainly due to the side effects of treatment which will influence their nutritional status and vitamin and mineral intake. The aim of this study was to explore the association between nutritional status, vitamin and mineral intake and renal profile among hemodialysis patients. A cross-sectional study was conducted among 106 hemodialysis patients aged 19 years old and above using convenience sampling techniques in Hospital Pakar Universiti Sains Malaysia (HPUSM) patients. Social-demographic background, clinical characteristics, laboratory data, anthropometric measurements and dietary intake (3-day diet history) were also included during the interview. Data collection carried out through interviewer-administered questionnaires. Majority of hemodialysis patients were BMI slightly overweight (24.24 kg/m²). The findings of this study found that there are significant association between nutritional status and renal profile (height and potassium ($p = 0.004$) , dry weight and phosphate test ($p = 0.044$) , calf-circumferences and phosphate ($p = 0.003$), mid-upper arm circumferences and creatinine ($p = 0.014$), calf-circumferences and creatinine , ($p = 0.003$) , BMI and magnesium ($p = 0.018$), and dry weight and creatinine tests ($p < 0.001$) , BMI and creatinine ($p = 0.004$) and BMI and albumin ($p = 0.049$)) and vitamin and mineral intake and renal profile (vitamin C and uric acid ($p = 0.020$)). However, no statistically significant association was found between nutritional status and vitamin and

mineral intake among hemodialysis patients. Hence, more studies are needed to better understand the factors affecting renal profiles in hemodialysis patients, ensuring interventions can prevent declines in nutritional status and vitamin/mineral intake.

CHAPTER 1

INTRODUCTION

1.1 Background of Study

Chronic kidney disease (CKD) is referred to a structural or functional anomaly in the kidneys (eg, glomerular filtration rate [GFR] <60 mL/min/1.73 m2 or albuminuria ≥30 mg per 24 hours) that lasts more than three months (Chen, Knicely & Grams, 2019). Hundreds of millions of people suffer from its worldwide, putting an enormous burden on the healthcare systems of low- and middle-income countries that are least prepared to deal with it (Kovesdy, 2022). Based on a systematic review and meta-analysis of 100 studies comprising 6,908,440 patients, a global prevalence of 13.4% for CKD stages 1–5 and 10.6% for CKD stages 3–5 was reported. There were 3.5% (stage 1), 3.9% (stage 2), 7.6% (stage 3), 0.4% (stage 4) and 0.1% (stage 5) prevalence rates of each CKD stage. Based on the results of studies examining the global prevalence of CKD, an estimated 843.6 million individuals worldwide are affected by CKD stages 1–5 (Hill et al., 2016).

Moreover, it has been observed that chronic kidney disease (CKD) has increased in prevalence over the last three decades, with 77.5% of end-stage kidney disease (ESKD) patients on kidney replacement therapy (KRT), with 43.1% of those patients receiving only dialysis (GBD Chronic Kidney Disease Collaboration, 2020). Haemodialysis (HD) is the most common KRT method in the world, accounting for 69% of all KRTs and 89% of all dialysis treatments as HD is the major treatment option for chronic kidney disease stage 5 patients (Bello et al, 2017). The primary goal of HD is to restore normal renal function by balancing the volume of extracellular and intracellular fluid. This is

accomplished by moving solutes (like urea) from the blood into the dialysate and vice versa (like bicarbonate) from the dialysate into the blood (Omari, 2019). Haemodialysis is more widely available and more accessible, which reduces mortality caused by ESRD. The number of ESRD patients who require haemodialysis and long-term care rises as a result of the subsequent decline in mortality, placing an increased financial strain on the healthcare systems (Habas, 2022).

The vitamin and mineral intake levels of haemodialysis patients are of paramount importance due to their special nutritional requirements and potential impact on their overall health. It is common for patients undergoing haemodialysis to experience altered metabolism, increased nutrient losses, and dietary restrictions, which can result in deficiencies in essential vitamins and minerals (Ikizler et al., 2020). Deficiencies in vitamins D, calcium, iron, and potassium can exacerbate complications associated with end-stage renal disease (ESRD), such as anaemia, bone disorders, and electrolyte imbalances (Rapa et al., 2020). Furthermore, excessive intake of certain vitamins and minerals can also pose risks to these patients. Hence, monitoring and optimizing the vitamin and mineral intake of haemodialysis patients is important to mitigate complications and enhance their overall health.

Patients with ESRD will most likely experience side effects from haemodialysis. Some of the side effects are fatigue, nausea and vomiting, infection, and muscle wasting that may lead to appetite loss, taste disturbance, food aversion, and satiety which influence the patient’s eating and drinking (Levitskaya,2022). Furthermore, haemodialysis can lead to muscle protein breakdown, leading to muscle weakness and wasting, which affects a patient's ability to consume and digest food (Kanda, 2020). A

reduction in food intake caused by partial or complete loss of appetite can also result in nutrient deficiencies, impairing nutritional status and body composition. Further, vomiting can result in nutrient malabsorption and loss due to incomplete digestion and increased food transit time (diarrhoea) that eventually will lead to poor nutritional status among haemodialysis patient (Montoro-Huguet et al., 2021). Thus, malnutrition and inflammation are common in haemodialysis patients, contributing to poor nutritional status, decreased quality of life, and higher mortality.

The renal profile of haemodialysis patients includes a comprehensive assessment of kidney function, electrolyte balance, anaemia treatment, mineral and bone health, and cardiovascular risk factors (Madhura & Jayaraj, 2021). These people face the difficult reality of end-stage renal disease (ESRD), which requires daily haemodialysis to maintain life. To assess renal function, the renal profile comprises data such as glomerular filtration rate (GFR), serum creatinine, and urine analysis (Jamal Shahwan et al., 2019).To avoid difficulties, electrolyte imbalances, particularly sodium, potassium, calcium, and phosphate levels, are meticulously monitored. Moreover, patients with CKD frequently have iron deficiency mediated through hepcidin, a peptide produced by the liver that inhibits iron absorption and release from iron stores and macrophages (Hanna et al., 2021). Hence, anaemia management is crucial for patient well-being, focusing on aspects such as iron status, erythropoietin use, and haemoglobin levels. To address mineral and bone diseases, indicators such as parathyroid hormone (PTH), vitamin D levels, and bone density are assessed. Hence, an abrupt alteration in the renal profile can signify a rapid decline in kidney function, requiring immediate medical attention. Renal profiles are also employed to monitor the status of the kidneys following a transplant surgery, ensuring the ongoing health and functionality of the transplanted organ (Gounden et al., 2023).

Consequently, the findings from the renal profile can be used to gauge the extent of CKD severity.

1.2 Problem Statement

Chronic kidney disease (CKD) is a global health concern, with a growing prevalence and significant morbidity and mortality rates, particularly in patients with end-stage renal disease (ESRD). In Malaysia, the yearly fatality rate for ESRD on haemodialysis (HD) was 13.8% in 2015. Overall, 5-year and 10-year dialysis survival rates were 52% and 27%, respectively. Over the last two decades, the death rate among HD patients has gradually increased (Ting & Adnan, 2018). According to Malaysian Society of Nephrology, by 2021, there were 49,770 dialysis patients in Malaysia, up from 29,443 in 2012. This represented a 1.5-fold increase in patients. In 2012, there were 6,695 new dialysis patients admitted; by 2021, there were 9,123 (Malaysian Society of Nephrology, 2021).

After undergo Haemodialysis, HD patients often modify their dietary intake and choices. Although HD provided many benefits to ESRD patient, it has also been associated with some adverse effects, such as malnutrition and inflammation. This is because haemodialysis procedure itself can cause infections, inflammations, or volume-related complications leading to Protein Energy Wasting (PEW). Protein and energy homeostasis are also affected by HD sessions: Amino acid and protein loss due to the session, combined with low nutrient intake, results in low nutrient availability for muscle synthesis (Carrero et al., 2023) . HD patients are more likely to experience protein-energy malnutrition because to their numerous dietary limitations and subpar appetite (Fatonah et al., 2019)Moreover, HD patients generally experience a decreased appetite as their renal disease worsens, and this often lasts even after starting dialysis.

Patients receiving haemodialysis may suffer from micronutrient deficiencies due to improper food intake, intestinal dysfunction, inflammation, dialysate/ urine loss, and abnormal metabolism (Dizdar et al., 2020). Haemodialysis patients also face a heightened risk of lacking water-soluble vitamins and minerals. Haemodialysis can result in the loss of these vitamins because of their low molecular weights (1-4 kDa) (Schwotzer et al., 2020). Besides, a common ailment in dialysis patients is iron deficiency (Fe), calcium deficiency, and zinc deficiency. A lack of iron is often a cause of anaemia in dialysis patients (Gafter-Gvili et al., 2019). In Haemodialysis patient, zinc insufficiency has been linked to immunological impairment, sexual dysfunction, hypogeusia, and depression, whereas selenium deficiency has been linked to immune dysfunction, increased oxidative stress, anaemia, and thrombocytopenia (Azevedo et al., 2023).On the other hands, sodium also reported higher among Haemodialysis patient (Borrelli et al., 2020)Dialysis patients' average daily salt intake has been found to be significantly greater. The sodium intake of chronic haemodialysis patients varies by nation, being higher in countries where the diet is abundant in processed foods (Bossola et al., 2020, Wyskida et al., 2018, Gkza et al., 2017).

Furthermore, according to the mean daily dietary intakes of vitamins A, B1, B2, B3, and C were below the recommended levels, and the distribution of patients based on daily intakes demonstrates that the majority of patients have an intake lower than that suggested for HD(As'habi et al., 2019). Vitamin deficiencies in maintenance dialysis patients are caused by the following factors: (1) reduced overall food intake due to anorexia (2) prescription of low-phosphorus, low-potassium diets that restrict intake of nutritionally valuable foods such as fresh fruits and vegetables, dairy products, and other

items high in vitamins; (3) altered metabolism, as is the case for pyridoxine and possibly folate and (4) impaired syntheses(Jankowska et al., 2016)Therefore, haemodialysis patients are more likely to have low nutritional status and poor vitamin and mineral intake due to problems and deficiencies.

Besides, proper nutrition, particularly vitamin and mineral intake is critical for preventing malnutrition and muscle wasting among haemodialysis patient with renal profile value as a biomarker. Abnormal value of eGFR, serum creatinine, urine analysis is the key marker of kidney damages. Elevated serum creatinine levels are indicative of decreased kidney function. A high serum creatinine level alone may not be sufficient for diagnosing CKD or ESRD, but it can signal the need for further evaluation. Typically, a creatinine level above the reference range (usually 0.6-1.3 mg/dL) may be a cause for concern(Fischer et al., 2018)Besides, the presence of significant proteinuria (usually defined as > 30 mg/g creatinine) in the urine is a key marker of kidney damage and can be used to diagnose CKD (Persson & Rossing, 2018).Patients with abnormal renal profile values may require further assessment and monitoring to determine the severity and underlying cause of their kidney disease.

Despite the recognized significance of nutritional factors, there exists a notable research gap regarding the association between nutritional status, vitamin and mineral intake, and the complex renal profile in haemodialysis patients. This lack of comprehensive understanding hinders the development of tailored nutritional interventions and improved patient outcomes. Hence, this study aims to investigate the relationship between nutritional status, dietary intake of essential vitamins and minerals, and the renal profile among haemodialysis patients in Kelantan population.

1.3 Research Questions

The following questions are sought to be answered at the end of the study:

i. What is the nutritional status level among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia?

ii. What is the mean of the dietary vitamin and mineral intake among haemodialysis patients in Hospital Pakar Universiti Sains Malaysia?

i. What is the renal profile level among haemodialysis patients in Hospital Pakar Universiti Sains Malaysia?

iii. Is there any association between nutritional status and dietary vitamin and mineral intake among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia?

iv. Is there any significant association between dietary vitamin and mineral intake with renal profile among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia?

v. Is there any significant association between nutritional status and renal profile among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia?

1.4 Research Objectives

1.4.1 General Objective

To determine the association between nutritional status, vitamin and mineral intake and renal profile among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia (HPUSM).

1.4.2 Specific Objectives

ii. To assess the nutritional status among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia.

iii. To determine the mean dietary vitamin and mineral intake among haemodialysis patients in Hospital Pakar Universiti Sains Malaysia.

iv. To assess the renal profile among haemodialysis patients in Hospital Pakar Universiti Sains Malaysia.

v. To assess the association between nutritional status and dietary vitamin and mineral intake among hemodialysis patients in Hospital Pakar Universiti Sains Malaysia.

vi. To assess the association between dietary vitamin and mineral intake and renal profile among hemodialysis patients in Hospital Pakar Universiti Sains Malaysia.

vii. To assess the association between nutritional status and renal profile among hemodialysis patients in Hospital Pakar Universiti Sains Malaysia.

1.5 Research Hypothesis

1.5.1 Hypothesis

Null Hypothesis (H_0)

i.) There is no association between nutritional status and vitamin and mineral intake among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia.

ii.) There is no association between vitamin and mineral intake with renal profile among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia.

iii.) There is no association between nutritional status and renal profile among haemodialysis patient in Hospital Pakar Universiti Sains Malaysia.

Alternative Hypothesis (H_A)

i.) There is an association between nutritional status and vitamin and mineral intake among haemodialysis patient in Hospital Pakar Universiti Malaysia.

ii.) There is an association between vitamin and mineral intake with renal profile among haemodialysis patient in Hospital Pakar Universiti Malaysia.

iii.) There is an association between nutritional status and renal profile among haemodialysis patient in Hospital Pakar Universiti Malaysia.

1.6 Justification of Study

The research findings will provide insights into the correlation between the nutritional status, vitamin and mineral intake, and the renal profile of haemodialysis patients at HPUSM. Several prior studies have explored the nutritional status, including measurements like BMI, as well as vitamin (specifically vitamins D, C, B1, and folates) and mineral intakes (including zinc, copper, sodium, phosphate, calcium, and magnesium) among haemodialysis patients (Bossola et al., 2014; Mun et al., 2019; Jankowska, Rutkowski & Slizien, 2019). Many of these studies have reported abnormal levels of vitamins and minerals, which can lead to various complications and diseases, including bone disorders and anemia (Anees et al., 2021; Gaffney-Stomberg, 2019; Riaz et al., 2023).However, a notable gap exists in the emphasis on the evaluation of the renal profile in these studies. The renal profile plays a crucial role in understanding the effectiveness of haemodialysis treatment and the overall health of the patients. Key indicators such as creatinine levels, glomerular filtration rate (GFR), and urine tests offer

critical insights into the severity of kidney impairment. Patients on haemodialysis who consume inadequate intake of nutrient and minerals may experience abnormal value of renal profile like creatinine and the presence of protein in their urine as a result of their dietary intake. Additionally, the nutritional status of patients will be evaluated to determine its relationship with vitamin and mineral intake among haemodialysis patients. It is essential to investigate this relationship, as an imbalance in vitamin and mineral intake during haemodialysis may increase the risk of mortality and morbidity due to malnutrition and other risk factors. Furthermore, this study may identify the renal profile among haemodialysis patients to determine whether vitamin and mineral intake changes and poor nutritional status are associated with the value of the renal profile. Therefore, this research can provide a platform future researcher to conduct intervention study to improve dietary intake of HD patients.

1.7 Conceptual Framework

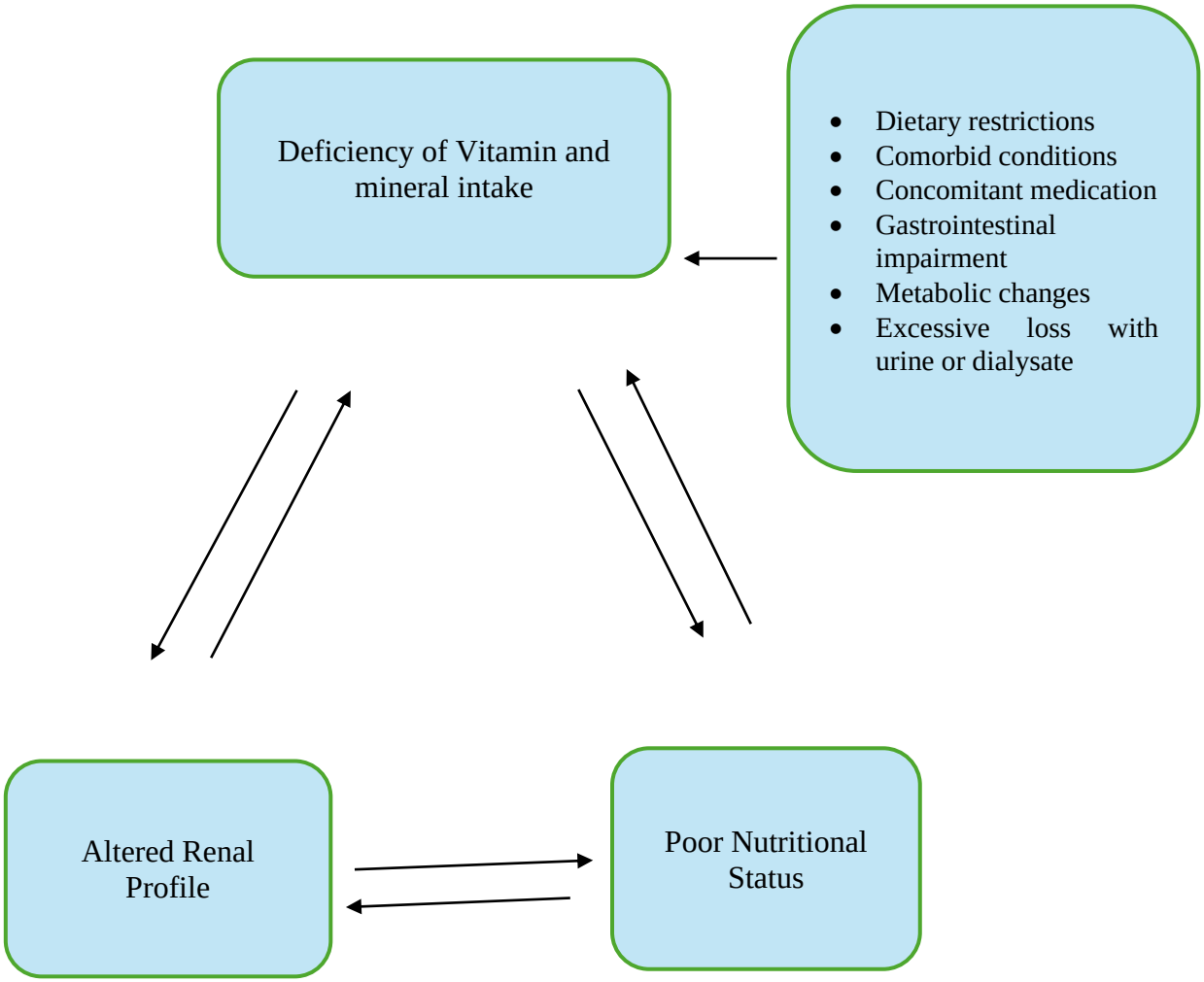


Figure 1: Conceptual Framework of Cause and effect related to the deficiency of vitamin and mineral intake, poor nutritional status and renal profile alteration.

In Malaysia, the prevalence of chronic kidney disease (CKD) is 9.07% of the total population, with 0.36% having stage 5 CKD or end-stage renal disease (ESRD) (Ismail et al., 2019). Many studies have proved that haemodialysis patients are more likely to get deficiency of vitamin and mineral intake due to several such as dietary restrictions, comorbid conditions, concomitant medication, gastrointestinal impairment, metabolic changes, and excessive loss with urine or dialysate (Jankowska, Rutkowski&Alicja,

2017). Changes in dietary restrictions and preferences may exaggerate the depletion of antioxidant defence mechanisms, such as low levels of vitamins C and E (due primarily to dietary restrictions of vegetables and fruits, malnutrition, and vitamin loss during HD procedure), decreased selenium levels, and decreased function of the GSH-scavenging mechanism. (Liakopoulos et al., 2017). This is because the supply of vitamin and minerals plays a crucial role in the optimal function of the innate immune system as well as in adaptive immunity; it involves defence mechanisms against pathogens as well as long-term balances of proinflammatory and anti-inflammatory factors. To support the immune system, a balanced diet generally provides the required balance of minerals (Weyh et al., 2022). A lack of any of these minerals may decrease immunological competence temporarily or potentially disrupt systemic inflammatory regulation in the long run. For example, Vitamin D's being used in the utility of renal bone disease. Hence, when CKD patients undergo haemodialysis, it leads to Vitamin D catabolism, as indicated by 24,25(OH)2D, declines in CKD patients. A decrease in 1,25(OH)2D leads to hypocalcaemia and SHPT, which are the primary causes of secondary osteoporosis (Jean, Souberbielle & Chazot, 2017).

Furthermore, studies also show that there are association between deficiency vitamin and mineral intake with poor nutritional status. This is because CKD patients often develop nutritional imbalance due to increased energy requirements (caused by catabolism and chronic inflammation) as well as paradoxical appetite loss(Sahathevan et al., 2020). CKD patients often have other comorbid diseases that can adversely affect their nutritional status like hypertension, diabetes mellitus and cardiovascular disease (Besides, haemodialysis patient who have inadequate dietary intake may be due to loss of appetite or some other emotional and metabolic stress may also lead to have poor

nutritional status (Maurya, Arya & Sengar, 2019).The nutritional status of the patients deteriorated steadily as their CKD progressed, and alterations in body composition were mostly evident as a drop in skeletal muscle index (SMI), with no significant changes in body fat indices. At any CKD stage, the proportion of haemodialysis patients with low phase angle (PA) and skeletal muscle index (SMI) was considerably higher than that of non-dialysis patients (Liu et al., 2022). The most prevalent nutritional issue during dialysis therapy is malnutrition. Malnutrition can occur as a result of haemodialysis treatments due to their catabolic effects, replacement therapy, dietary restrictions, and loss of nutrients through the dialysis membrane (Pawlaczyk et al., 2022). Nutrition has a substantial influence on the inflammatory systems that comprise innate immunity, and when this connection is disrupted, it can have a significant impact on disease development. Nutritional deficits are linked to poor immune response and decreased host resistance to infection (Wu et al., 2019).

In addition, there are also some significant studies that showed the association between poor nutritional status and renal profile alteration. In haemodialysis patients, a decrease in serum albumin predicts poor mortality; however, the cause of hypoalbuminemia is multifaceted and linked to inadequate diet, inflammation, and concomitant disorders(Y. Wang & Gao, 2022). Besides, CKD metabolic acidosis is one of the most common complications affecting patients living with chronic kidney disease (CKD). It causes a decrease in sodium bicarbonate levels in the blood, which aids in slowing the progression of kidney disease (Jeong, Kwon & Kim, 2014). Hence, Metabolic acidosis results in a decrease in Na–Cl levels caused by impaired kidney function. It is caused by insufficient kidney function to synthesize ammonia, regenerate bicarbonate,

and excrete hydrogen ions. Lower Na–Cl levels may contribute to poor renal outcomes and increased tubulointerstitial injury risk(Maruta et al., 2019).

CHAPTER 2

LITERATURE REVIEW

2.1 Prevalence of Haemodialysis among Chronic Kidney Disease patients in Malaysia

In Malaysia, the prevalence of CKD had rising over the last 7 years since 2011, with the prevalence 9.07% (2011) to 15.48% (2018). The main reasons accounting for this rising trend are the increasing prevalence of non-communicable disease like diabetes mellitus, hypertension, BMI, increasing age and used of nonsteroidal anti-inflammatory drugs and traditional drugs and also due to changes in population demographics (Saminathan et al., 2020). Hence, according to Surendra (2021), there are exponential growth of patients on dialysis and haemodialysis become the most preferred treatment modality for ESRD or CKD in Malaysia. As a result, ESRD had become the main issue in Malaysia as it significantly can lead to high number of mortality and morbidity among Malaysia. Estimates of the global burden of disease reported that kidney disease accounted for 1,129,000 deaths and 38,104,000 disability-adjusted life years (DALYs), making it the 12th highest cause of death (2.0% of all deaths) and the 19th cause of disability (1.4% of all DALY) (Surendra, 2019).

According to the 24th report of the Malaysian Dialysis and Transplant Registry (MDTR), 6,662 new HD patients and 1,001 new PD patients were reported in 2016 representing an acceptance rate of 216 per million population (pmp) and 32 pmp respectively. Overall, the total number of HD and PD patients increased to 35,781 patients (1,159 pmp) and 3,930 patients (127 pmp) respectively in 2016. Despite undergoing

haemodialysis as a form of treatment, there remains a low survival rate among patients. In the United States, patients with HD have a 1-year survival rate of 79% and a 5-year survival rate of 34%. In Iran, some studies had found that the overall survival rates for HD patients are 75% at 1 year, 63% at 2 years, 50% at 3 years, and 23% at 5 years (Khazaei et al., 2018; Mousavi et al., 2010).

2.2 Effect of haemodialysis on vitamin and mineral deficiency

While haemodialysis remains a crucial therapy for managing end-stage renal disease (ESRD), its impact on vitamin and mineral deficiencies is a subject of ongoing research. The process of haemodialysis is known to influence the levels of both water-soluble and fat-soluble vitamins. Water-soluble B vitamins, including thiamine (B1), riboflavin (B2), pyridoxine (B6), folate (B9), and cobalamin (B12), can be affected by the removal of water-soluble compounds during the dialysis process (Bolasco et al., 2019). Additionally, recent study emphasizes the intricate relationship between haemodialysis and vitamin D metabolism. Vitamin D deficiency is prevalent in individuals undergoing haemodialysis due to reduced synthesis in the skin, impaired activation in the kidneys, and the loss of vitamin D binding proteins during dialysis (Ramezani et al., 2021). Given the critical role of vitamin D in bone health and immune function, addressing these deficiencies is crucial for the overall well-being of individuals on haemodialysis.

The impact of haemodialysis on mineral homeostasis is also a focus of contemporary research. Imbalances in calcium, phosphorus, and potassium are common in individuals undergoing haemodialysis, and these disturbances can lead to complications such as cardiovascular disease and bone disorders (Lukowsky et al., 2014). Advanced strategies are being explored to optimize the dialysis procedure and minimize

nutrient loss, and personalized approaches are increasingly recognized as essential for addressing the diverse nutritional needs of individuals on haemodialysis (Bolasco et al., 2019). This evolving understanding underscores the importance of regular monitoring and tailored interventions to mitigate the risk of vitamin and mineral deficiencies in this vulnerable population.

2.3 Effect of haemodialysis with poor nutritional status

Haemodialysis is a life-sustaining therapy for individuals with end-stage renal disease (ESRD), but its impact on nutritional status is substantial, particularly in the context of poor nutritional status. In individuals already experiencing malnutrition, the process of haemodialysis can exacerbate protein-energy wasting (PEW), leading to further depletion of body protein and fat stores. This vicious cycle of compromised nutritional status and haemodialysis-induced protein catabolism contributes to muscle wasting, weakness, and a decline in overall physical function (Omari et al., 2019; Serón-Arbeloa et al., 2022) Moreover, electrolyte imbalances, a common consequence of haemodialysis, are intensified in the presence of poor nutritional status, amplifying the risk of complications such as muscle weakness and cardiovascular irregularities (Correa et al., 2021)

Mineral and vitamin deficiencies are also exacerbated in individuals undergoing haemodialysis with poor nutritional status. Chronic kidney disease and the dialysis process can disrupt the balance of essential nutrients, including iron, water-soluble B vitamins and fat-soluble vitamins like vitamin D. The compromised absorption and utilization of these nutrients are further aggravated when nutritional status is suboptimal (Agarwal, 2021; Jean et al., 2017; Kaczkan et al., 2023). These deficiencies contribute to a spectrum of adverse outcomes, ranging from impaired immune function and increased

susceptibility to infections to disruptions in bone and mineral metabolism, including conditions like renal osteodystrophy and anemia (Umakanth, 2018; Xie et al., 2021).

2.4 Effect of haemodialysis on renal profile alteration

In the context of renal replacement therapies, haemodialysis is a viable therapeutic option. If kidney function is impaired, body waste products like urea and creatinine are removed from the blood. This can be done as in haemodialysis, fluids and essential nutrients are balanced in the body through the use of a semi-permeable membrane and an electrochemical gradient (Albalawi et al., 2023). Hence, through this process it actually can alter the normal range of renal profile like sodium, phosphate, creatinine, albumin, blood urea nitrogen (BUN) and etc. Besides, there are high prevalence of haemodialysis patient have high phosphate level that eventually led to hyperphosphatemia(Vervloet & van Ballegooijen, 2018; Yoke Mun et al., 2019). High phosphate levels may contribute to the development and progression of secondary hyperparathyroidism (Ting et al., 2018).

Haemodialysis patients can also develop hypoalbuminemia as a result of haemodialysis action. This can be accompanied by inflammation and malnutrition. As a result of Chronic Renal Failure (CRF), protein is lost through the urine, and it can decrease serum albumin levels or cause hypoalbuminemia. Albumin is released through urine due to increased permeability in the glomerulus, which causes proteins to pass into the glomerular filtrate(Tanan et al., 2020). Moreover, findings of the study by Singh et al (2021) indicate that haemodialysis leads to an elevation in serum sodium and calcium levels while causing a reduction in serum levels of urea, creatinine, uric acid, and potassium.

2.5 Dietary assessment

Dietary assessment encompasses the examination of food intake and individual dietary components, comparing the quantities consumed with established reference values to ascertain potential deficiencies or excesses (Kurniawan et al., 2022). To enhance precision, a thorough analysis of the chemical compositions of all ingested food is essential, considering that biochemistry plays a crucial role in understanding how the body utilizes various nutrients and identifying specific deficiency states (Templ & Templ, 2021). Despite the importance of biochemical analysis, conducting such assessments for each dietary component in clinical settings is impractical. Consequently, various dietary assessment methods, including diet records or food diaries, dietary recalls, and food frequency questionnaires (FFQ), are commonly employed. These methods vary in the duration over which dietary intake information is collected and the techniques used to measure portion sizes (WA et al., 2020).

In a food diary or diet record, subjects document every food and drink they consume, providing details such as ingredients, preparation methods, and the amount of food ingested during a specific timeframe. Diet records can be categorized into two types: estimated and weighted diet records. In a weighted diet record, subjects are instructed to weigh the items (food or beverages) using a scale both before and after consumption (Dao et al., 2019). The 24-hour diet recall involves participants recalling and detailing all food and beverage consumption over the past day, providing a snapshot of immediate dietary patterns. Extending this concept, the 3-day and 7-day diet recalls offer a broader perspective by including a more extended timeframe, allowing for a more comprehensive understanding of short-term dietary habits(Chandrashekarappa et al., 2019). These methods are particularly useful for capturing variations in daily food intake. On the other

hand, the Food Frequency Questionnaire (FFQ) takes a different approach, focusing on habitual dietary patterns over an extended period, often several months. The FFQ involves participants responding to questions about the frequency and quantity of specific food items consumed regularly(Mumu et al., 2020).

CHAPTER 3

METHODOLOGY

3.1 Research Design

This study applied the cross-sectional study design, which involved the utilization of anthropometric measurements, laboratory data, and dietary intake for data collection. The laboratory data were used to determine the dry weight and renal profile of haemodialysis patients in Hospital Pakar Universiti Malaysia, Kubang Kerian, Kelantan. A cross-sectional study was preferred because it collected information on specific populations based on data gathered at a single point in time without influencing any variables, as it was an observational study. Besides, it was also cost-effective and relatively quick to perform.

3.2 Study Location

This study was carried out in Hospital Pakar Universiti Malaysia (HPUSM), Kubang Kerian, Kelantan. This location was chosen because it was the best place to conduct clinical research and the most suitable location for data collection among haemodialysis patients. The specific locations chosen were the outpatient setting: haemodialysis centre, dietetics outpatient clinic, Klinik Rawatan Keluarga (KRK), Klinik Pakar Perubatan (KPP), and the inpatient setting: medical ward (7 Utara), surgical wards, High Dependency Unit, and orthopaedic wards.

3.3 Study Population

Reference population

Haemodialysis patients in Hospital Pakar Universiti Malaysia (HPUSM), Kubang Kerian, Kelantan. Haemodialysis patients were chosen from both inpatient and outpatient settings.

Target population

Haemodialysis patients in the outpatient clinic setting and haemodialysis patients who had been admitted into the wards at HPUSM.

Source population

Haemodialysis patients who attended the outpatient clinic and who stayed in specific wards at HPUSM.

Sampling frame

Registration lists for haemodialysis patients in the outpatient clinic and admission lists for haemodialysis patients in specific wards at HPUSM, Kubang Kerian, Kelantan.

3.4 Research Subjects

3.4.1 Inclusion and Exclusion Criteria

Inclusion criteria :

a) Male and female adults
b) Adults from the age of 19 to 60 years old
c) Undergoing Haemodialysis patients in either outpatient or inpatient setting in HPUSM (3 times per week)
d) Patients diagnosed with CKD for at least 6 months
e) Patients' absence from psychological disorder
f) Able to understand Bahasa Melayu and/or English

Exclusion Criteria

a) Children and pregnant mother

b) Patients with serious hearing or vision problem

c) Bedridden patient

3.5 Sample Size Calculation

The sample size needed for the research was calculated according to three research objectives. According to Wan (2013), one mean calculation was used to determine the estimated sample size required for the research objective. The formula for calculating one mean was as follows:

$n = (Z \times \frac{\sigma}{\Delta})$

Next, one proportion calculation was also used to estimate the sample size (Wan, 2013). The formula for one proportion calculation was as shown below:

$$n = \left[\frac{Z}{\Delta}\right]^2 p\,(1-p)$$

Lastly, a two proportion calculation was also used to estimate the sample size (Wan, 2013). The formula for two proportion calculation was as follows:

$$n = \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2}(Z_a + Z_\beta)^2$$

$n =$ sample size	$Z =$ value representing the desired confidence level
$\Delta =$ precision	$p =$ anticipated population proportion
σ = population standard deviation	α = level of statistical significance
Z_β = power of the study	

Sample Size for the first objective:

For the first objective, which was to explore the nutritional status among haemodialysis patients in Hospital Pakar Universiti Malaysia, one proportion calculation was used to estimate the sample size. The formula for one proportion calculation was as shown below:

$$n = \left[\frac{Z}{\Delta}\right]^2 p\,(1-p)$$

$n =$ sample size

$Z =$ value representing the desired confidence level

$\Delta =$ absolute precision

$p =$ anticipated population proportion

Using a Δ value of 0.1 and a confidence level of 95% for the study, the Z-score was 1.96. According to the first objective, the prevalence of haemodialysis patients who had poor nutritional status in Malaysia was used as the anticipated population proportion. Yoke Mun et al. (2019) reported that a high proportion of haemodialysis patients were malnourished (64.4%). Thus, the anticipated population proportion was 0.644.

$$n = \left[\frac{1.96}{0.1}\right]^2 0.644\,(1-0.644)$$

$$= 88\ subjects$$

To account for potential dropouts, extra respondents were required to be enrolled in the study. A higher dropout rate was chosen because the study population was a high-risk population who were ill and sickly. Therefore, a 20% dropout rate was applied to the sample size:

Sample size, $n = \left[\frac{1.96}{0.1}\right]^2 0.644\,(1-0.644) + 20\%$

$$= 88 + 17.6$$

$$= 105.6 \sim 106\ subjects$$

Sample size calculation for the objective 2:

For objective 2, which was to determine the mean vitamin and mineral intake among haemodialysis patients in Hospital Pakar Universiti Malaysia, the mean (SD) score, 0.5 ± 0.23 for vitamin B1 among 67 regular haemodialysis patients, was used to determine the estimated sample size required for this study. The precision (true value) was estimated to fall within 5 percentage points (Nurul Zulaikha et al., 2023). Thus, the sample size for the study was calculated using a Δ value of 0.1, a confidence level of 95%, and a Z-score of 1.96. Therefore,

$$\text{Sample size, } n = \left(1.96 \times \frac{0.23}{0.1}\right)^2$$

$$= 20\ subjects$$

To account for potential dropouts, extra respondents were required to be enrolled in the study. Therefore, a 20% dropout rate was applied to the sample size:

$$\text{Sample size, } n = \left(1.96 \times \frac{0.23}{0.1}\right)^2 + 20\%$$

$$= 24.38 \sim 24 \text{ subjects}$$

Sample size calculation for the objective 3:

Meanwhile, the third objective was to identify the renal profile among haemodialysis patients in Hospital Pakar Universiti Malaysia. According to Masyeni et al. (2020), it was reported that haemodialysis patients tended to have high levels of phosphate, with a prevalence of 69% out of 100 CKD patients who underwent haemodialysis, and the mean phosphate level was 44.59 (SD ± 32.40). Thus, the anticipated population proportion was 0.69. Using a Δ value of 0.1 and a confidence level of 95% for the study, the Z-score was 1.96. Therefore,

Sample size, $n = \left[\frac{1.96}{0.1}\right]^2 0.69\ (1 - 0.69)$

$= 82.17 \sim 82\ subjects$

To account for potential dropouts, a 20% dropout rate was applied to the sample size:

Sample size, $n = \left[\frac{1.96}{0.1}\right]^2 0.69\ (1 - 0.69) + 20\%$

$= 82.17 + 16.43$

$= 98.6 \sim 99\ subjects$

Sample size calculation for objective 4:

According to the fourth objective, which was to assess the association between nutritional status and vitamin and mineral intake among haemodialysis patients in Hospital Pakar Universiti Malaysia, the prevalence of underweight among haemodialysis patients was used as P1. According to Bramania et al. (2021), 16.9% out of 160 participants were classified as underweight, making the anticipated population proportion 0.169. Meanwhile, for P2, the prevalence of deficient intake of zinc was used. According to Garagarza et al. (2023), out of 582 patients, 53.6% of haemodialysis patients presented a deficient intake of zinc, making the anticipated population proportion 0.536. The sample size was calculated using a Zβ value of 0.84 (80% power), a confidence level of 95%, and a Z-score of 1.96. Therefore,

$$n = \frac{0.169\ (1 - 0.169) + 0.536(1 - 0.536)}{(0.169 - 0.536)^2}(1.96 + \ 0.84)^2$$

= 22.65 ~ 23 subjects

To account for potential dropouts, extra respondents were required to be enrolled in the study. Therefore, a 20% dropout rate was applied to the sample size:

Sample size, $n = 23 + 20\%$

= 27.6 ~ 28 subjects

The sample size was calculated according to the objectives. The final sample sizes obtained for the study were 106 subjects for objective 1, 24 subjects for objective 2, 99 subjects for objective 3, and 28 subjects for objective 4. Therefore, the highest value, which was 106 subjects, was chosen.

3.6 Sampling method

The sampling method used in this research to recruit participants was convenience sampling through posters. Participants who met the inclusion criteria were chosen for the study. However, all subjects were recruited voluntarily. Prior to their participation in the study, informed consent was obtained from all participants. This approach was inexpensive, and the subjects were generally easy to access.

3.7 Research Instrument

3.7.1 Data Collection Form

Data collection was conducted using interviewer-administered questionnaires. The data collection form consisted of five sections (Part A, B, C, D, and E). Part A included sociodemographic data of subjects such as gender, age, ethnicity, marital status, education, and income. Part B focused on subjects' clinical data, which included the date of admission, duration of haemodialysis, comorbidities (hypertension, stroke, diabetes mellitus, hyperlipidemia, lung disease, gastrointestinal issues, cancer, gout, arthritis, vision and hearing problems), types of medications, dosages, and supplements taken. Part C covered laboratory data, including renal profiles (sodium, potassium, magnesium, blood urea nitrogen (BUN), phosphate, uric acid, creatinine, albumin) extracted from blood test results taken at admission. The patients' dry weight and laboratory data were also extracted from their medical records. Part D involved anthropometric measurements (dry weight, height, mid-upper arm circumference, calf circumference, and BMI) to

assess the nutritional status of the patients. Finally, Part E consisted of dietary intake information based on a 3-day diet history (2 dialysis days and 1 non-dialysis day).

3.7.2 Laboratory test (Renal Profile)

Laboratory assessments involved obtaining retrospective data on serum albumin, creatinine, sodium, potassium, phosphate, blood urea nitrogen (BUN), magnesium, chloride, and uric acid from patients' medical records within the past 3 months.

3.7.3 Anthropometric Measurement

In this study, the mean dry weight was obtained from the patients' dialysis records, while height was measured directly using a stadiometer. During the height measurement, patients were required to remove their shoes and either stand or recline flat. Height measurements were taken before the dialysis process. The patients' BMI was calculated after obtaining the height and dry weight. Patients with a BMI between 23 and 27.5 kg/m² were categorized as overweight, while those with a BMI below 18.55 kg/m² were classified as underweight, and those above 27.5 kg/m² were considered obese (MaHTAS, 2023; Somasundaram et al., 2019). Additionally, the mid-upper arm circumference (MUAC) and calf circumference (CC) were also measured. MUAC was measured at a non-vascular access site, and CC was measured at the widest point of the calf, both using a measuring tape accurate to the nearest 0.1 cm. MUAC was taken between the acromion of the scapula at the posterior shoulder region and the olecranon process of the ulna at the elbow, while CC was measured around the widest part of the calf (Aksoy et al., 2019).

3.7.4 3-Days Diet History

The 3-day diet history, focusing on dietary intake over two dialysis days and one non-dialysis day, employed a systematic approach to data collection. This was conducted through interviews to establish the participants’ usual dietary habits during both dialysis

and non-dialysis days. A structured template was used, which included sections for mealtimes, food items, portion sizes, and descriptions of cooking methods. Participants were encouraged to note any snacks, condiments, or additives consumed. The dosage of any supplements taken before, during, or after haemodialysis within the 3-day period was also recorded, as this could influence the total intake of vitamins or minerals.

Emphasis was placed on accurate reporting, and participants were provided with guidance on estimating portion sizes to improve the precision of the recorded data. To minimize recall bias, participants were asked to document their dietary information shortly after each meal. Additionally, reminders were sent to ensure compliance and completeness of the recorded information.

For the estimation of macronutrient and micronutrient intake, the data from the 3-day diet history were analyzed using the Nutritionist Pro software (version 2.2, 2005, Axxya Systems-Nutritionist Pro, Stafford, TX). The software's food database was expanded to include analyses of locally processed foods as well as traditional Malaysian dishes and recipes. Energy density was calculated by dividing the total energy intake by the total weight of food consumed (kilocalories per gram). Special attention was given to ensure that all liquids reported by participants, including water, beverages, and soups, were accurately included.

3.8 Data Collection Method

Data collection began after receiving ethical approval from the Human Research Ethics Committee of USM and obtaining permission from the Director of HPUSM. Data were collected at HPUSM.

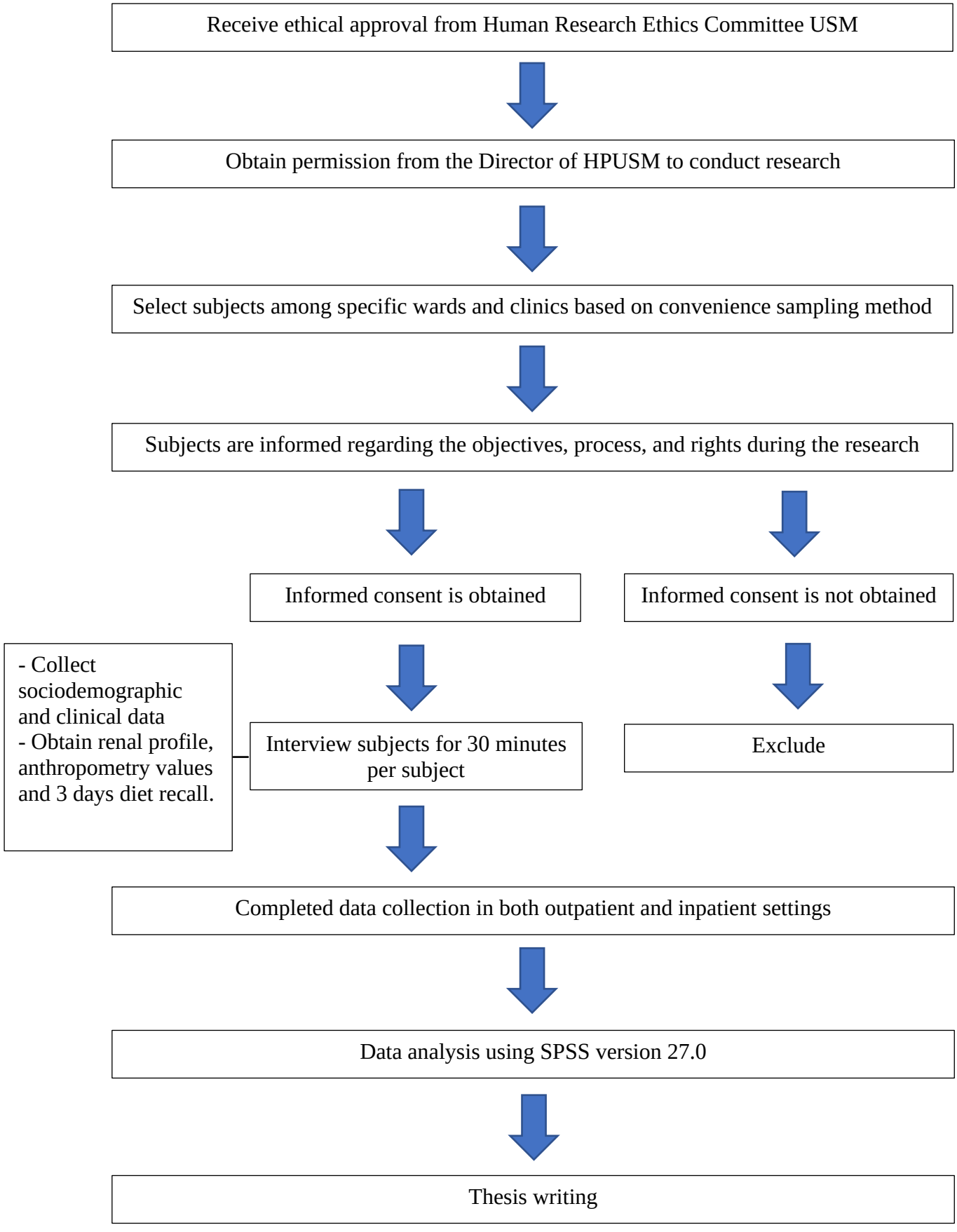
Firstly, potential subjects who met the inclusion criteria were selected and approached by distributing posters. All subjects were recruited voluntarily. Each subject was briefed on the study's introduction, objectives, procedures, advantages, and possible risks, including their right to refuse participation. The subjects were given full freedom to decide whether they wanted to participate, with their rights protected. Written informed consent was obtained from the subjects prior to their recruitment once they agreed to participate. Subjects who agreed were interviewed for approximately 30 minutes each. They were informed that they could withdraw from the study at any time without penalty or loss of benefits. Conversely, reluctant subjects or those who refused to provide consent were excluded and were not obliged to participate.

Subjects' sociodemographic data (age, gender, ethnicity, marital status, education, income), clinical data (date of admission, comorbidities such as hypertension, stroke, diabetes mellitus, hyperlipidemia, lung disease, gastrointestinal issues, cancer, gout, arthritis, vision and hearing problems, and duration of haemodialysis), supplement intake, and renal profile (sodium, potassium, magnesium, blood urea nitrogen (BUN), phosphate, uric acid, creatinine, and albumin) were collected from their medical folders, as consent had been obtained. Each subject was then interviewed, and two sets of measurements were taken: anthropometric measurements and the 3-day diet history (2 days of dialysis and 1 non-dialysis day).

Throughout the interview session, subjects were informed that they might feel disturbed, annoyed, mentally burdened, or uncomfortable. If they felt tired, disturbed, or uncomfortable during the interview, they had the right to request a break or withdraw from the study at any time without penalty, as they were given full freedom to do so.

Additionally, subjects were assigned unique numerical codes such as “001,” “002,” or “003” for confidentiality purposes. These codes were used to identify them on the questionnaires. All data were kept anonymous and were entered into the Statistical Package for Social Sciences (SPSS) version 26.0 for analysis. The data were presented as grouped data, ensuring that no individual subject was identified, protecting their privacy. The collected data were stored in a secure folder, accessible only by the researcher, to ensure the confidentiality of each subject.

3.9 Flow Chart



3.10 Research Variables

3.10.1 Independent Variable

i. Vitamin and mineral intake among haemodialysis patients in HPUSM

ii. Anthropometry measurement among haemodialysis patients in HPUSM

3.10.2 Dependent Variable

i. Renal profile among haemodialysis patients in HPUSM

3.11 Data Analysis

Data were analysed using IBM SPSS Statistics for Windows, Version 27.0. The summary of the sociodemographic, clinical data (comorbidities, duration of haemodialysis, renal profile), anthropometric data and vitamin and mineral intake will use descriptive statistics. According to the normality distribution, numerical data will be presented as mean with standard deviation (SD) or median with interquartile range (IQR) while categorical data will be presented as frequency and percentage (%). The association between nutritional status and renal profile will be tested using Pearson's Correlation or Spearman's Correlation depending on their normality of distribution. A one-way ANOVA test was run to find the significant mean differences between each renal profile and BMI. Independent t-test was applied to find the mean difference in renal profile between males and females. A p-value of <0.05 was considered significant.

CHAPTER 4
RESULTS

4.1 Socio-Demographic and Duration of Hemodialysis of Hemodialysis Patients in HPUSM.

In this study, there were a total of 106 hemodialysis patients in HPUSM participated in this study. Out of 106 subjects, 49 subjects (46.2%) were men while 57 subjects (53.8%) were women. Majority of the subjects were from Malay (96.2%), ethnicity with ages ranging from 18 to 60 years old. Most subjects were married (85.8%), with secondary education level (60.4%) and without salary (47.2%). As stated in Table 4.1. 77 subjects were inpatient (72.6%) that came from different Inpatient wards while 29 subjects (27.4%) were outpatients that were mostly being collected from the Hemodialysis Unit. Most respondents (54.7%) had been receiving haemodialysis treatment for one to five years. In contrast, only 2 respondents (1.9%) had been living with End Stage Renal Disease and undergoing haemodialysis treatment for 11 to 15 years.

Table 4.1: Sociodemographic data of the respondents and duration of haemodialysis.

Variables	Frequency (n)	Percentage (%)
Gender		
Men	49	46.2
Women	57	53.8
Age		
18-30 years	1	0.9
31 - 40 years	13	12.3
41 - 50 years	16	15.1
>50 years	76	71.7
Ethnicity		
Malay	102	96.2
Chinese	4	3.8
Marital Status		
Single	6	5.7
Married	91	85.8

Table 4.1 , continued

Variables	Frequency (n)	Percentage (%)
Marital Status		
Divorced / Widower	9	8.5
Educational Status		
Primary	17	16
Secondary	64	60.4
Tertiary	22	20.8
Illiterate / No Schooling	3	2.8
Income (RM) per month		
No Salary	50	47.2
< RM2,500	26	24.5
RM 2,500 - 4,999	18	17
RM 5,000 - 10,000	11	10.4
>RM 10,000	1	0.9
Hospitalization		
Inpatient	77	72.6
Outpatient	29	27.4
Duration of Haemodialysis		
< 1 Year	24	22.6
1 - 5 Years	58	54.7
6 - 10 Years	16	15.1
11 - 15 Years	2	1.9
> 15 Years	6	5.7

4.2 Comorbidities, Medication Adherence and Supplement taken among Hemodialysis patients in HPUSM.

Among the respondents, hypertension was the most prevalent comorbidity, affecting 95 respondents (89.6%), while cancer was the least common with only 1.9% and these 2 patients already received cancer treatment before and during hemodialysis period. In terms of medication adherence, hypertension also had the highest rate at 89.6%, whereas none of the respondents were on medication for stroke, gastrointestinal issues, arthritis, or breathing problems despite the presence of these conditions in some individuals. Hyperlipidemia was the second most common comorbidity at 73.6% (70 respondents), lung disease and gout were among the least common at 6.6%.

Table 4.2 : Comorbidities and Medication.

Variables	Yes	No
	n (%)	n (%)
Presence of Co-morbidity		
Hypertension	95 (89.6)	11(10.4)
Stroke	9 (8.5)	97 (91.5)
Diabetes Mellitus	70 (66.0)	36 (34.0)
Hyperlipidaemia	78 (73.6)	28 (26.4)
Heart Disease	29 (27.4)	77 (72.6)
Lung Disease	7 (6.6)	99 (93.4)
Gastrointestinal	58 (54.7)	48 (45.3)
Cancer	2 (1.9)	104 (98.1)
Gout	7 (6.6)	99 (93.4)
Arthritis	10 (9.4)	96 (90.6)
Breathing Problem	15 (14.2)	91 (85.8)
Vision Problem	64 (60.4)	42 (39.5)
Hearing Problem	19 (17.9)	87 (82.1)
Medication of Comorbidities		
Hypertension	95 (89.6)	11 (10.4)
Stroke	0 (0)	106 (100)
Diabetes Mellitus	70 (66.0)	36 (34.0)
Hyperlipidaemia	78 (73.6)	28 (26.4)
Heart Disease	29 (27.4)	77 (72.6)
Lung Disease	7 (6.6)	99 (93.4)
Gastrointestinal	0 (0)	106 (100)
Cancer Treatment	2 (1.9)	104 (98.1)
Gout	7 (6.6)	99 (93.4)
Arthritis	0 (0)	106 (100)
Breathing Problem	0 (0)	106 (100)

4.3 The Average Value of Renal Profile and Anthropometric Measurements of Hemodialysis Patients in HPUSM.

From the renal profile and anthropometric data of haemodialysis patients, serum sodium, potassium and magnesium were in the normal range with mean 134.93 ± 17.37 mmol/L, median 4.2 ± 0.95 mmol/L and 0.96 ± 0.97 mmol/L respectively. However, Blood Urea Nitrogen (BUN), phosphate, uric acid and creatinine level were markedly higher compared reference range with mean increase of 7.00 ± 4.63 mmol/L for BUN, 16.28 ± 145.44 mmol/L for phosphate, 359.33 ± 139.65 μmol/L for uric acid and 896.23

± 364.52 µmol/L for creatinine. Meanwhile, albumin was below the normal range with a mean 36.03 ± 6.70 g/L.

In terms of anthropometric measurements, the study revealed a median dry weight of 60.70 kg (IQR 18.05). Analysis of both MUAC and CC indicated that, on average, haemodialysis patients exhibited normal muscle mass, meeting the standard cutoff points for MUAC (>23 cm) and CC (>30.1 cm). The mean Body Mass Index (BMI) was 24.24 kg/m² (SD 4.47), suggesting that a majority of the haemodialysis patients were slightly overweight (23–27.49 kg/m$^{2)}$. It is demonstrated by the fact that out of 106 respondents, 43 (40.6%) are overweight, 33 (31.1%) are normal, 22 (20.8%) are obese, and only 8 (7.5%) are underweight.

Table 4.3: Renal Profile and anthropometric measurements

Characteristics	**Mean (SD)/ Median (IQR)**
Renal Profile	
Sodium (mmol/L) [a]	134.93 (17.37)
Potassium (mmol/L) [b]	4.2 (0.95)
Magnesium (mmol/L) [b]	0.96 (0.97)
Blood Urea Nitrogen (BUN) (mmol/L) [a]	7.00 (4.63)
Phosphate (mg/dL) [a]	16.28 (145.44)
Uric acid (umol/L) [a]	359.33 (139.65)
Creatinine (umol/L) [a]	896.23 (364.52)
Albumin (g/L) [a]	36.03 (6.70)
Anthropometric	
Dry Weight (kg) [b]	60.70 (18.05)
Height (cm) [a]	160.03 (8.30)
Mid upper arm circumferences (cm) [b]	26.38 (4.46)
Calf circumferences (cm) [b]	31.77 (6.06)
BMI (kg/m^2) [a]	24.24 (4.47)
BMI Range	**Total n (%)**
Underweight (<18.5 kg/m$^{2)}$	8 (7.5)
Normal (18.5 -22.9 kg/m$^{2)}$	33 (31.1)
Overweight (23–27.49 kg/m^2)	43 (40.6)
Obese (≥27.5 kg/m^2)	22 (20.8)

[a] Mean (SD)

[b] Median (IQR)

BMI : Body mass index

4.4 Dietary Vitamin and Mineral Intake.

Vitamin and mineral intake among the 106 hemodialysis patients revealed significant deficiencies when compared to the recommended nutrient intake (RNI) for adults. The median intake for Vitamin A (23.77 μg/day), Vitamin D (<0.001 μg/day), Vitamin E (1.55 mg/day), Vitamin B1 (0.81 mg/day), Vitamin B2 (0.71 mg/day), Vitamin B6 (0.55 mg/day), Vitamin B12 (1.49 μg/day), folates (187.95 μg/day), and Vitamin C (15.87 mg/day) were all substantially below the recommended levels. Similarly, intake of minerals such as sodium (907.11 mg/day), potassium (934.47 mg/day), calcium (169.37 mg/day), magnesium (90.26 mg/day), zinc (3.16 mg/day), and copper (0.37 mg/day), were lower than the RNI. Iron intake (9.00 mg/day) was adequate for men but insufficient for menstruating women. Furthermore, 37.7% took supplements.

Table 4.4: Average content of selected vitamin and mineral intake and supplement taken.

Characteristics	Total (N=106) Median (IQR)
Vitamin	
Vitamin A (μg/day)	23.77 (121.32)
Vitamin D (μg/day)	<0.001 (0.62)
Vitamin E (mg/day)	1.55 (1.56)
Vitamin B1 (mg/day)	0.81 (0.56)
Vitamin B2 (mg/day)	0.71 (0.37)
Vitamin B6 (mg/day)	0.55 (0.45)
Vitamin B12 (μg/day)	1.49 (3.02)
Folates (μg/day)	187.95 (205.21)
Vitamin C (mg/day)	15.87 (21.69)

Table 4.4, continued

Characteristics	Total (N=106) Median (IQR)
Mineral	
Sodium (mg/day)	907.11 (1108.36)
Potassium (mg/day)	934.47 (506.47)
Phosphorus (mg/day)	800.03 (617.67)
Calcium (mg/day)	169.37 (106.22)
Iron (mg/day)	9.00 (5.64)
Magnesium (mg/day)	90.26 (65.38)
Zinc (mg/day)	3.16 (2.62)
Copper (mg/day)	0.37 (0.21)
Supplement taken	**n (%)**
Yes	40 (37.7)
No	66 (62.3)

4.5 Correlation between Dietary Vitamin and Mineral Intake with Renal Profile.

The correlation between dietary vitamin and mineral intake with renal profile was investigated using Spearman's correlation as presented in Table 4.5. It was found that there was a significant, moderate and negative relationship between vitamin C and uric acid among hemodialysis patients in HPUSM (r = -0.358, p = 0.020), with higher vitamin C intake resulted in lower uric acid. There were no other significant relationships between dietary vitamin and mineral intake with the renal profile.

Table 4. 5 : Correlation between dietary vitamin and mineral intake with renal profile

Characteristics	Sodium (mmol/L)		Potassium (mmol/L)		Magnesium (mmol/L)		BUN (mmol/L)		Phosphate (mg/dL)		Uric Acid (mg/dL)		Creatinine (mg/dL)		Albumin (mg/dL)	
	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value
Vitamin A	0.132	0.178	0.086	0.386	-0.121	0.429	0.096	0.329	0.018	0.855	-0.047	0.768	-0.034	0.727	0.157	0.124
Vitamin D	0.074	0.452	0.044	0.656	-0.033	0.832	0.136	0.165	-0.030	0.762	-0.139	0.378	-0.038	0.702	0.122	0.235
Vitamin E	-0.041	0.680	0.003	0.978	0.054	0.727	0.079	0.419	0.136	0.171	-0.277	0.076	0.185	0.057	0.063	0.538
Vitamin B1	0.064	0.519	-0.023	0.813	-0.253	0.094	0.096	0.330	0.063	0.526	-0.165	0.298	0.027	0.782	0.033	0.748
Vitamin B2	0.100	0.311	0.130	0.188	-0.112	0.465	0.196	0.440	0.020	0.842	-0.032	0.842	-0.01	0.916	-0.084	0.413
Vitamin B6	0.116	0.240	-0.063	0.528	-0.206	0.174	0.062	0.527	0.041	0.682	-0.081	0.611	0.018	0.857	0.068	0.505
Vitamin B12	-0.065	0.512	-0.059	0.551	0.041	0.787	0.013	0.898	0.075	0.451	-0.097	0.542	0.121	0.216	0.049	0.631
Folates	0.096	0.330	-0.035	0.722	-0.237	0.117	0.074	0.450	0.032	0.746	-0.208	0.185	-0.042	0.669	0.052	0.614
Vitamin C	-0.034	0.734	0.011	0.909	-0.041	0.791	0.150	0.125	-0.057	0.566	-0.358	0.020*	-0.118	0.227	-0.093	0.365
Sodium	0.076	0.440	0.190	0.054	-0.223	0.141	0.166	0.089	0.106	0.287	-0.058	0.713	0.022	0.824	-0.014	0.890
Potassium	0.004	0.969	0.109	0.270	-0.231	0.127	0.031	0.754	0.117	0.238	0.142	0.368	0.039	0.694	0.082	0.427
Phosphorus	0.003	0.975	0.115	0.245	-0.124	0.418	0.057	0.563	0.102	0.306	0.022	0.890	0.037	0.706	0.059	0.568

Table 4.5, continued

Characteristics	Sodium (mmol/L)		Potassium (mmol/L)		Magnesium (mmol/L)		BUN (mmol/L)		Phosphate (mg/dL)		Uric Acid (mg/dL)		Creatinine (mg/dL)		Albumin (mg/dL)	
	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value
Calcium	0.127	0.197	0.070	0.481	-0.031	0.842	-0.020	0.840	-0.103	0.299	0.074	0.641	-0.066	0.499	0.03	0.774
Iron	0.046	0.641	0.123	0.212	-0.148	0.333	0.113	0.248	0.000	0.997	-0.029	0.853	-0.072	0.461	-0.028	0.788
Magnesium	0.028	0.775	-0.058	0.557	-0.241	0.111	0.103	0.294	0.101	0.311	-0.107	0.501	0.074	0.45	0.104	0.309
Zinc	0.124	0.208	-0.084	0.398	-0.228	0.133	0.047	0.633	0.06	0.549	-0.113	0.478	0.042	0.67	0.043	0.672
Copper	-0.013	0.898	-0.066	0.508	-0.261	0.083	0.162	0.097	0.021	0.833	-0.161	0.309	-0.034	0.728	0.012	0.904

*p - value of < 0.05 was considered as significant

* BUN : Blood Urea Nitrogen

4.6 Correlation between Nutritional Status and Renal Profile.

The correlation between nutritional status with renal profile was tested using Pearson's Correlation and Spearman's Correlation. Our results revealed that increasing dry weight was significantly correlated to higher blood phosphate (p-value = 0.044, r = 0.199) and creatinine (p < 0.001, r = 0.348). Higher BMI was significantly correlated with increasing blood creatinine (p-value = 0.004, r = 0.279), albumin (p - value = 0.049, r = 0.200) and magnesium (p-value = 0.018, r = 0.35). On the other hand, calf circumference was positively correlated with higher renal phosphate (p – value= 0.003, r = 0.289) and creatinine (p-value = 0.003, r = 0.287). Besides, mid-upper circumferences were significantly correlated with higher creatinine (p-value =0.014, r-value = 0.238).

Table 4.6 : Correlation between nutritional status and renal profile

Characteristics		Dry Weight	Mid-Upper Arm Circumferences	Calf Circumferences	BMI
Sodium	r-value	-0.027[b]	-0.030[b]	-0.012[b]	-0.181[a]
	p-value	0.787[b]	0.761[b]	0.905[b]	0.065[a]
Potassium	r-value	0.100[b]	-0.074[b]	-0.020[b]	-0.055[b]
	p-value	0.314[b]	0.456[b]	0.844[b]	0.577[b]
Magnesium	r-value	-0.280[b]	-0.262[b]	-0.244[b]	0.350[b]
	p-value	0.062[b]	0.082[b]	0.106[b]	0.018[b]*
BUN	r-value	0.233[b]	0.111[b]	0.135[b]	0.168[a]
	p-value	0.787[b]	0.257[b]	0.169[b]	0.085[a]
Phosphate	r-value	0.199[b]	0.101[b]	0.289[b]	0.096[a]
	p-value	0.044[b]*	0.309[b]	0.003[b]*	0.335[a]
Uric Acid	r-value	0.214[b]	0.115[b]	0.218[b]	0.076[a]
	p-value	0.173[b]	0.469[b]	0.166[b]	0.633[a]
Creatinine	r-value	0.348[b]	0.238[b]	0.287[b]	0.279[a]
	p-value	0.000[b]*	0.014[b]*	0.003[b]*	0.004[a]*
Albumin	r-value	0.199[b]	0.199[b]	0.180[b]	0.200[a]
	p-value	0.050[b]	0.051[b]	0.077[b]	0.049[a]*

[a]Tested using Spearman Correlation

[b]Tested using Pearson Correlation

*BUN : Blood urea nitrogen

* p-value < 0.05 was considered as significant

4.7 Correlation between nutritional status and dietary vitamin and mineral intake

Correlation between dietary vitamin and mineral intake with nutritional status was tested using Spearman's correlation as presented in Table 4.7. There was no significant relationship between nutritional status and dietary vitamin and mineral intake among hemodialysis patients in HPUSM.

Table 4.7 : Correlation between nutritional status and dietary vitamin and mineral intake

Characteristics		Dry Weight	Mid-upper Arm Circumferences	Calf Circumferences	BMI
Vitamin A	r-value	-0.058	-0.084	-0.018	0.004
	p-value	0.553	0.390	0.854	0.969
Vitamin D	r-value	0.052	-0.019	0.017	0.093
	p-value	0.600	0.849	0.860	0.344
Vitamin E	r-value	0.171	0.025	0.124	0.108
	p-value	0.079	0.802	0.205	0.269
Vitamin B1	r-value	0.043	0.100	0.074	0.122
	p-value	0.661	0.310	0.450	0.213
Vitamin B2	r-value	0.000	-0.066	-0.039	0.090
	p-value	1.000	0.500	0.695	0.359
Vitamin B6	r-value	0.006	0.066	0.100	0.059
	p-value	0.952	0.499	0.310	0.547
Vitamin B12	r-value	0.075	0.043	0.059	0.119
	p-value	0.445	0.658	0.548	0.226
Folates	r-value	-0.011	0.058	0.039	0.057
	p-value	0.914	0.554	0.692	0.561
Vitamin C	r-value	-0.028	0.005	0.024	0.066
	p-value	0.773	0.958	0.807	0.503

Table 4.7, continued

Characteristics		Dry Weight	Mid-upper Arm Circumferences	Calf Circumferences	BMI
Sodium	r-value	0.121	0.110	0.161	0.118
	p-value	0.216	0.262	0.099	0.228
Potassium	r-value	0.030	0.091	0.075	0.144
	p-value	0.761	0.355	0.443	0.141
Phosphorus	r-value	0.061	0.117	0.075	0.144
	p-value	0.536	0.232	0.444	0.142
Calcium	r-value	0.023	0.002	-0.028	0.106
	p-value	0.817	0.980	0.774	0.279
Iron	r-value	0.084	0.088	0.058	0.129
	p-value	0.390	0.372	0.556	0.187
Magnesium	r-value	0.052	0.068	0.109	0.114
	p-value	0.594	0.487	0.267	0.246
Zinc	r-value	0.003	0.003	0.071	0.042
	p-value	0.978	0.978	0.472	0.670
Copper	r-value	-0.003	-0.035	0.082	0.049
	p-value	0.973	0.718	0.402	0.619

*BMI : Body mass index

CHAPTER 5

DISCUSSION

5.1 Socio-Demographic and Duration of Hemodialysis of Hemodialysis Patients in HPUSM.

In this study, socio-demographic characteristics included gender, age, ethnicity, marital status, educational status and respondents' income per month. The current study included higher percentage of women as compared to men. Besides, this is being supported by a recent study that stated increasingly, women constitute a larger proportion of the global haemodialysis population, attributed to the phenomenon where women commence dialysis at lower estimated renal function levels compared to men ((Weigert et al., 2019). Besides, Shah et al. (2018) reported similar findings among 1247 haemodialysis patients in Portugal and Poland, showing a greater representation of women receiving HD treatment compared to men. Moreover, women generally exhibit greater health awareness and a proactive approach to seeking medical care and adhering to treatment recommendations compared to men (Dluhos-Sebesto et al., 2021).

Furthermore, patients aged 50 years old and above were the major age group recruited in this study. It aligns with the study of Malaysian Dialysis and Transplant Registry 2015, as it discovered a higher demand for hemodialysis treatment among patients diagnosed with chronic kidney disease (CKD) under the age of 65. The higher prevalence of hemodialysis treatment among people above 50 years old can be attributed to the natural decline in kidney function with age and the late diagnosis of chronic kidney

disease (CKD)(Jeele et al., 2021; Lee & Son, 2021). As individuals age, their kidneys gradually lose their ability to efficiently filter waste and maintain electrolyte balance, a process that can begin as early as in their 30s and 40s. This age-related decline in kidney function can lead to the development of CKD, which may progress to end-stage renal disease (ESRD) if not managed effectively. Furthermore, CKD is often asymptomatic in its early stages, making it difficult for individuals to notice or seek medical attention until the disease has significantly advanced(Avila et al., 2023). This late diagnosis means that many older adults discover their condition only when their kidney function is critically low, necessitating the immediate initiation of hemodialysis to perform the vital functions their kidneys can no longer manage(Shlipak et al., 2021). Consequently, the combination of natural ageing processes and the silent progression of CKD leads to a higher incidence of hemodialysis treatment among the older population. A study by Saminathan et al (2020) revealed that in Malaysia the awareness of CKD diagnosis was still low (5%) as compared to like China (12.5%), India (7.9%), Canada (5.3%) and Thailand (1.9%) (Saminathan et al., 2020).

Moreover, in the current study, more than half of the respondents (60.4%) had an educational background at the secondary levels (n = 64). As discussed by Zajacova & Lawrence (2018) in their study on the relationship between education and heath, it stated that there is evidence for a strong association between education and health outcomes over the following decades. Less educated adults reported worse general health, more chronic conditions, and more functional limitations and disabilities (Zajacova & Lawrence, 2018).Moreover, education level is recognized as a significant predictor of health outcomes due to its association with enhanced employment prospects, resulting in more reliable income and improved socioeconomic conditions. Educated individuals

generally demonstrate a deeper understanding of diseases and greater awareness of treatment options and lifestyle modifications (Ravindran et al., 2020).

A total of 91 respondents (85.8%) in this study were married. This result is also being supported by other studies who found that most of their study samples are married. (Al-Baghdadi & Rajha, 2018; Z. F. Wang et al., 2021).This is because marriage provides substantial emotional and social support, crucial for managing the demanding regimen of hemodialysis. Spouses often assist with transportation to dialysis sessions, help manage medications, and encourage adherence to dietary restrictions, thereby improving treatment outcomes (Safi et al., 2024). Consistent with our findings, Kiajamali et al. (2017), identified a strong and significant correlation between social support and self-efficacy among hemodialysis patients ($r = 0.592$, $p < 0.001$). Additionally, married individuals generally report better mental health and lower levels of stress, which can positively impact their physical health and ability to cope with chronic illnesses .Unmarried individuals with CKD, particularly men and those with higher than college education levels, were more prone to experiencing depression compared to their married counterparts ((Z. F. Wang et al., 2021).

In terms of monthly income, the majority of the respondents ($n = 50$) in the present study had no salary as most respondents were either housewives, retirees or no longer working. This result is supported by a study that revealed Malaysian households with HD patients more than three-quarters (n=100, 93%) were in the B40 income brackets. While a significant number of hemodialysis patients originate from low-income families, the majority of hemodialysis treatment costs (63.1%) are covered by the public sector. This includes funding from various governmental entities such as the Ministry of Health

(MOH) and other federal or state-owned organizations. Interestingly, 79% of new dialysis patients under 20 years old received their treatment through government-funded dialysis programs (Malaysian Society of Nephrology, 2016).

Moreover, the majority of the respondents that were collected were inpatients, indicating that they were receiving their dialysis treatment while hospitalized under continuous medical supervision either in a hospital setting or at the private healthcare facilities(Crews et al., 2010). The high number of inpatient respondents from HPUSM (Hospital Pakar Universiti Malaysia) for hemodialysis treatment can be attributed to several operational factors of the hemodialysis unit. Firstly, the unit is equipped to accommodate approximately 45 patients per week, including both outpatient and inpatient services. Outpatient services involve a rotational schedule where the same patients return three times a week for dialysis sessions(Ashby et al., 2019). In contrast, inpatient services allow patients to be admitted for dialysis and then discharged, without necessarily staying in the hemodialysis unit or hospital for extended periods. This flexibility in admission and discharge patterns facilitates a larger pool of respondents from the inpatient category, reflecting the operational dynamics and capacity management of the hemodialysis unit at HPUSM.

5.2 Comorbidities, Medication Adherence and Supplement taken among Hemodialysis patients in HPUSM.

In the current study, the most reported comorbidity was hypertension affecting 95 individuals (89.6%) followed by hyperlipidemia (73.6%) and diabetes mellitus (66 %).This finding aligns with several studies indicating that hypertension impacts approximately 50-60% of hemodialysis patients, with some studies suggesting that the prevalence could be as high as 80-90% in this population (Kim et al., 2023; Sarafidis et al., 2008). Besides, the three risk factors; (35.3%), diabetes mellitus (17.5%), hyperlipidemia (47.7%) have high prevalence among the Malaysian population (Chia & Kario, 2020). These conditions are not only the risk factors for the development of CKD but contribute to its progression. Moreover, type 2 diabetes mellitus (T2DM) is the primary cause of end-stage renal disease (ESRD) in many developed countries and is a common comorbidity among dialysis patients. Most individuals are diagnosed with T2DM prior to starting dialysis, though some may develop new-onset diabetes afterward (Ou et al., 2021)

In terms of medication adherence, most respondents with comorbidities such as hypertension, hyperlipidemia, and diabetes mellitus adhered to their prescribed medications as directed by their doctors. This adherence is crucial, as managing these conditions helps to reduce the risk of cardiovascular complications and slow the progression of kidney disease (Ali et al., 2020). Studies have shown that effective management of these comorbidities can significantly improve the quality of life and outcomes for patients undergoing hemodialysis (Dasari et al., 2014; Pugh et al., 2019; Wilhelmsen & Eriksson, 2019). Regular monitoring and patient education are key factors in ensuring medication adherence and optimizing treatment regimens. Although,

gastrointestinal complaints such as constipation, indigestion, abdominal pain and acid reflux (GERD) were frequent in patients with ESRD (54.7%), but many respondents reported not taking medications for gastrointestinal issues, as these occurred infrequently (Cano et al., 2007; Golper & Friedman, 2021; Mortazavi et al., 2022). It's agreed by some studies that reported the prevalence of irritable bowel syndrome (IBS), gastroesophageal reflux disease (GERD) and dyspepsia among hemodialysis patients was significantly greater compared to healthy control participants (Mortazavi et al., 2022; Shirazian & Radhakrishnan, 2010). Moreover, study showed that gastrointestinal symptoms occur in 32–79% of dialysis patients and more than 90% of CKD patients (Karahan & Şahin, 2022)

5.3 Renal Profile and Anthropometric Measurements of Hemodialysis Patients in HPUSM.

The current study demonstrated that the mean sodium level was 134.93 mmol/L (SD 17.37) which is within the normal range of 130-145 mmol/L, which indicates adequate sodium management. However, these results are in disagreement with previous studies that stated, common haemodialysis patients faced hyponatremia due to low serum sodium level which was associated with greater risk of mortality. The most significant factors associated with lower serum sodium concentrations included receiving higher ultrafiltration volumes, having diabetes as an underlying condition, and elevated serum glucose levels(Liu et al., 2024; Rhee et al., 2019).

However, there were parameters that were elevated among Haemodialysis patients which were Blood Urea Nitrogen (BUN), phosphate, uric acid and creatinine. Phosphate level reported to be higher (16.28 mg/dL) as compared to the reference range (3.5-5 mg/dL) which may indicate that hemodialysis patients may experience hyperphosphatemia(Shaman & Kowalski, 2016). Phosohate elevation can be due to the

conventional dialysis that removes phosphorus in the range of 1,800-3,600 mg three times per week, which is insufficient to clear the daily amount of phosphorus taken to maintain balance. This is related to the kinetics of phosphorus removal during hemodialysis, in which blood phosphorus levels plateau after an initial drop within the first 2 hours of treatment, followed by a rebound, resulting in an up to 40% increase in serum phosphorus levels after dialysis(Umeukeje et al., 2018).

Other than phosphate, uric acid and creatinine were higher than the normal range in this study which resulted 359.33 µmol/L and 896.23 µmol/L respectively. The normal range for uric acid and creatinine according to the HPUSM normal range is 142.8-339.2 µmol/L and 58-127 µmol/L respectively. Blood Urea Nitrogen (BUN) level was significantly elevated 7.00 mmol/L compared to the reference range of 0.65-3.36 mmol/L, which is typical in hemodialysis patients due to impaired renal function. BUN is a primary nitrogenous waste from the breakdown of proteins and amino acids, while creatinine results from the degradation of creatine phosphate in muscles, both of which are eliminated by the kidneys. BUN indirectly assesses renal function by measuring urea nitrogen in the blood, reflecting the kidneys' excretory capacity(JM & S, 2021; Salazar, 2014). Elevated levels of BUN, creatinine, and uric acid in these patients indicate kidney damage. These results are similar with the finding from Al Jameil, 2019) that reported the serum levels of BUN, uric acid and creatine significantly increased ($P<0.05$) as patients progressed from mild to moderate CKD to ESRD. Besides, it is also in line with Mahmood et al., (2014) that revealed CKD patients undergoing dialysis had higher serum creatinine level than the normal range due to several factors such as age, sex, and physical condition. It’s common for haemodialysis patients to undergo creatinine clearance or

glomerular filtration rate (GFR) assessment, as it is the primary method for estimating kidney function.

Meanwhile, albumin levels, with a mean of 36.03 g/L (SD 6.70), were below the normal range of 39.7-49.4 g/L, indicating potential malnutrition or chronic illness. A study found that there was no significant difference in serum albumin levels between pre-hemodialysis (3.07 ± 0.63 g/dL) and post-hemodialysis (3.05 ± 0.54 g/dL) patients. This suggests that hemodialysis patients tend to have low serum albumin level(Tanan et al., 2020). Low serum albumin is a strong predictor of mortality and morbidity in hemodialysis patients. Each 1 g/dL decrease in serum albumin is associated with a 13.7% increase in mortality rate and 8.9% increase in morbidity (JM & S, 2021). Patients with low albumin level will experience hypoalbuminemia which is associated with lower residual kidney function(Alves et al., 2018).

In terms of anthropometric measurements, the result of MUAC and CC showed a normal range which means patients exhibited normal muscles mass, as it meets the standard of cut-off point for MUAC (>23 cm) and CC (>30.1 cm). In a study of hemodialysis patients, the mean MUAC was 26.3 ± 3.1 cm, which is considered within the normal range. Patients with longer durations of hemodialysis tended to have lower MUAC values, indicating greater muscle wasting(Sultan et al., 2021). Another study found the mean MUAC was 26.50 ± 4.09 cm in hemodialysis patients, which was lower than healthy controls. A MUAC below the normal range was associated with factors like hypoalbuminemia, hyperphosphatemia, and inflammation(Moussa et al., 2016). The mean CC in hemodialysis patients was 29.7 ± 3 cm, which is also within the normal range. CC was not found to be abnormal in the majority of patients studied(Sowtali et al., 2021).

The mean body mass index (BMI) was 24.24 kg/m² (SD 4.47), suggesting that a majority of the hemodialysis patients were slightly overweight (23–27.49 kg/m$^{2)}$. It is demonstrated by the fact that out of 106 respondents, 43 (40.6%) are overweight. A cross-sectional study in Tunisia found that 24 out of 120 hemodialysis patients (20%) had a BMI > 25 kg/m², indicating overweight or obesity. The mean BMI was 24.24 ± 4.47 kg/m², suggesting a majority of patients were slightly overweight (Gorsane et al., 2015). Besides, according to Rabbani et al., (2022) study showed that obese patients on hemodialysis have relatively lower blood pressure readings when compared with underweight patients on hemodialysis (Rabbani et al., 2022). Another study found that patients with obesity had the lowest mean post-hemodialysis systolic and diastolic blood pressure. Compared to normal weight, overweight and obese patients had a protective effect on post-hemodialysis hypertension(Abdullah Bawazir et al., 2020).

5.4 Dietary Vitamin and Mineral Intake and Supplement Taken

The research results indicate that hemodialysis patients have significant deficiencies in the intake of several vitamins and minerals compared to the recommended nutrient intake (RNI) for adults. The median intake for Vitamin A (23.77 μg/day) was lower as compared to recommended intake (600 μg RE/day) based on RNI 2017. The low vitamin A intake in hemodialysis patients is likely due to dietary restrictions and poor absorption of vitamin A in this population(Fusaro et al., 2017). Vitamin A is a critical nutrient for maintaining the integrity and function of epithelial tissues, as well as for supporting the proper development and activity of key immune cells, such as macrophages. Adequate vitamin A intake is essential for overall health and immune system function (Huang et al., 2018) . However, this finding is in contrast to other study, as hemodialysis patients commonly have increased serum vitamin A levels, rather than

low vitamin A intake. Vitamin A is commonly increased in patients with advanced chronic kidney disease (CKD), maintenance hemodialysis (MHD), and chronic peritoneal dialysis (CPD)(Chazot et al., 2023)

The intake of vitamin D in this study was reported to be lower (<0.001 μg/day) than the recommended intake 15μg/day for both men and women. It aligns with several studies that found similarly high rates of vitamin D deficiency in dialysis patients compared to the general population (Shahidi et al., 2023; Stark et al., 2011; Zahideen et al., 2022). Besides, another study among 182 hemodialysis patients, the mean serum 25(OH)D level was only 16.30±8.92 ng/mL, with 70.4% of the subjects having 25(OH)D deficiency (<20 ng/mL), 22.4 % having insufficiency (20-29 ng/mL), and 7.2% of the subjects having sufficient 25(OH) D (ε30 ng/mL) levels (Gupta, 2022) This deficiency may result from decreased vitamin D synthesis in the skin due to less sun exposure and impaired metabolism in the kidneys. As people age, the conversion of 25(OH)D to the active form 1,25(OH)2D declines.

Vitamin B1 or thiamine of this study showed deficiency (0.81 mg/day), compared to the recommended intake with 1.1 mg/day (women), 1.2 mg/day (men). A previous study had shown the prevalence of thiamine deficiency in dialysis patients can range from 30-80%(Jankowska et al., 2017). This is due to several factors - dialysis patients have increased thiamine requirements but also experience increased losses of thiamine during the dialysis process(Moradi & Said, 2016). Thiamine is an essential vitamin required for energy metabolism, and deficiency can lead to serious complications like Wernicke's encephalopathy(Oudman et al., 2024). One study found that 30% of hemodialysis patients had thiamine deficiency, which was associated with increased mortality risk. Dialysis

patients require higher thiamine intake, but often have dietary restrictions that make it difficult to meet these needs(Hung et al., 2001; Oudman et al., 2024).

The current study found that vitamin B2 also reported to have low dietary intake (0.71 mg/day) compared to the recommended intake (1.1 mg/day (women), 1.3 mg/day (men)). Although results indicate vitamin deficiencies are common in patients with chronic kidney disease (CKD) and on dialysis, there are no clear clinical trials evaluating the need for riboflavin supplementation in this population (Clase et al., 2013). This is because the other research has been more focused on other water-soluble vitamins where deficiencies appear to be more common like vitamin B1, B6, B12 and vitamin C(Cardoso & Pereira, 2019; Juszczak et al., 2023; Steiber & Carrero, 2016). Besides, there a study that disagreed with this result as Vitamin B2 status in hemodialysis patients is generally adequate (Clase et al., 2013). A study on peritoneal dialysis patients found that riboflavin availability, as measured by alpha-EGR, is a determinant of riboflavin status in these patients (Kosmadakis et al., 2014).

Vitamin B6 of this study reported to be lower (0.55 mg/day) than the recommended intake which is 1.3 mg/day for both men and women. Studies have shown the prevalence of vitamin B6 deficiency in dialysis patients to be between 24% and 56%(Corken & Porter, 2011; Ying et al., 2018). Dialysis has been found to reduce plasma levels of vitamin B6 by 28-48% depending on the dialyzer used (Wu et al., 2023). Patients on dialysis are at risk of vitamin B6 deficiency due to dietary restrictions, increased losses during dialysis, and metabolic disturbances associated with kidney disease(Juszczak et al., 2023). Vitamin B6 deficiency was found in 40% of the overall population. It is

common in hemodialysis patients and may contribute to anemia and abnormal bone metabolism (Obi et al., 2016).

The current study showed deficiencies of vitamin B12 (1.49 μg/day) compared to the recommended intake (4.0 μg/day). One study found a 58% prevalence of B12 deficiency in ESRD patients on maintenance hemodialysis, as defined by elevated methylmalonic acid (MMA) levels and positive blood smears (Saifan et al., 2013). Other studies reported that approximately 20% of chronic hemodialysis patients had vitamin B12 deficiency (Alkrush & Mahmood, 2023; Capelli et al., 2019). Additionally, dialysis patients may have a defect in their ability to convert vitamin B12 into its active form, hydroxylcobalamin, which is needed for homocysteine metabolism. Transcobalamin II, which is necessary for the entry of vitamin B12 into tissues, may also be impaired in end-stage renal disease (ESRD)(Amini et al., 2015).

Folate intake for the current study was at 187.95 μg/day, below the recommended 400 μg/day..Studies have shown that folate deficiency is common in hemodialysis patients, with over 80% of patients having low red blood cell folate levels despite normal serum folate (Chazot et al., 2021; X. Yang et al., 2021). This suggests that serum folate may not accurately reflect tissue folate stores in this population.To address folate deficiency, folic acid supplementation is widely recommended for hemodialysis patients. The optimal dosage appears to be 5 mg of folic acid per day, as this has been shown to reduce the risk of arteriovenous access thrombosis compared to weekly supplementation(Tu et al., 2022). Other benefits of folic acid supplementation in hemodialysis patients may include improved homocysteine levels and potentially reduced cardiovascular risk (Y. Wang et al., 2019).

Vitamin C among hemodialysis patient in HPUSM also recorded low dietary intake (15.87 mg/day) than its recommended intake 70 mg/day. Vitamin C deficiency is common among hemodialysis patients, with 10-25% having plasma vitamin C levels below 10 μM. This is due to dietary restrictions, losses during dialysis, and accelerated catabolism (Chaghouri et al., 2021; Zhang, 2014). In one study, 15% of hemodialysis patients exhibited a severe vitamin C deficiency (<10 μM)(Bashardoust et al., 2018; Zhang, 2014). Higher plasma vitamin C levels were linked to lower plasma parathyroid hormone (PTH) levels. In dialysis patients, dietary intake of vitamin C is often insufficient. Foods rich in vitamin C, such as fruit juice and broccoli, also contain high levels of potassium, which is restricted for these patients. Consequently, vitamin C deficiency can easily occur, exacerbated by significant losses of vitamin C during hemodialysis (Y. L. Kim, 2012).

Other than vitamin intake, the current study found that mineral intake such as sodium, potassium, calcium, magnesium, zinc and copper among hemodialysis patients also showed deficiencies as it substantially below the recommended levels.

The study found that potassium intake is significantly lower at 934.47 mg/day compared to the recommended intake of 4.7 g/day. Patients on hemodialysis often struggle to adhere to dietary recommendations for restricted potassium intake. Several studies have found that the dietary intake of potassium among hemodialysis patients is frequently inconsistent with recommended intake(de Rooij et al., 2022; Wouda et al., 2021). Saglimbene et al. (2021) found that only 25% of patients' dietary intakes of phosphate and potassium adhered to the guidelines. This may be due to the restrictive and complex nature of the "renal diet" which can negatively impact quality of life (Rhee et

al., 2023). Narasaki et al. (2021) discovered that a lower dietary potassium intake was linked to an increased risk of mortality in hemodialysis patients. The researchers suggest that excessive dietary potassium restriction may be deleterious in this population. However, a study by Ramos et al. (2021) found no correlation between dietary potassium intake and serum potassium levels or the prevalence of hyperkalemia in hemodialysis patients.

The current study showed that calcium intake among hemodialysis patient is lower (169.37 mg/day) compared to recommended intake 1000mg/day. Dietary calcium intake is often inadequate in adults on hemodialysis compared to recommended guidelines. A study found that only 53% of hemodialysis patients reported calcium intake consistent with guidelines(Saglimbene et al., 2021). Another study compared dietary calcium intake between hemodialysis patients in the UK and China. It found the median calcium intake was 618 mg/day in UK patients and 360 mg/day in Chinese patients, both below the recommended intake (Song et al., 2022). The combination of dietary restrictions, the complexity of the "renal diet", lack of individualized guidance, and patient distrust in the recommendations all contribute to the low calcium intake observed in the hemodialysis population(Kalantar-Zadeh et al., 2015).

The current study showed that magnesium intake (90.26 mg/day) is lower in hemodialysis patients than the recommended intake (<310 – 420 mg/day). Although the kidney plays a vital role in magnesium homeostasis, this ability deteriorates as kidney function declines (Cunningham et al., 2012). In more advanced chronic kidney disease, the compensatory mechanisms to maintain normal magnesium levels become inadequate, leading to frequent hypermagnesemia in patients with very low kidney function (Van De

Wal-Visscher et al., 2018). The dialysate magnesium concentration is a major determinant of magnesium balance in hemodialysis patients, but nutrition and medications can also play an important role(Bargnoux et al., 2024).

The current study showed that the dietary zinc intake is significantly low (3.16 mg/day) than the recommended intake (4.6 mg/day (women), 6.5 mg/day (men)). This is because hemodialysis patients are at risk of zinc deficiency due to several factors, including elimination by dialysis, dietary restrictions, hypoproteinemia, and decreased absorption (Garagarza et al., 2022). The causes of zinc deficiency in this population include insufficient dietary intake, impaired absorption, and excess loss through dialysis. Zinc supplementation is often required to correct deficiencies in hemodialysis patients(Tokuyama et al., 2021).A study by Elgenidy et al., (2023) found that there is high prevalence of zinc intake below recommended values in hemodialysis patients, which was linked to higher mortality risk.

5.5 Correlation between Dietary Vitamin and Mineral Intake with Renal Profile.

The current study found that there was a significant, moderate and negative relationship between vitamin C and uric acid among hemodialysis patients in HPUSM. This suggests that higher levels of vitamin C are associated with lower levels of uric acid in this population. However, no prior research has been conducted to evaluate the relationship between dietary vitamin C and serum uric acid.

5.6 Correlation between nutritional status and renal profile

The current result indicate that calf-circumferences are significantly positive and directly associated with phosphate levels in hemodialysis patients. However, this is in contrast with the previous study that found that in the normal range of serum phosphate, higher quartiles of phosphate were correlated with lower calf circumference (CC) in hemodialysis patients. The fully adjusted β coefficient for serum phosphate with CC was -1.12 (95%CI = -1.78, -0.47, P < 0.001), indicating that subjects with higher normal range serum phosphate tended to have lower CC(Chen et al., 2018). This suggests that hemodialysis patients with higher serum phosphate tend to have smaller calf circumferences.

Additionally, our study found a direct relationship between body mass index (BMI) and serum magnesium levels in dialysis patients. In contrast, a multi-center study involving 1,222 hemodialysis patients reported a negative correlation between serum magnesium and BMI ($r = -0.085$, $p = 0.003$) (Y. Zhang et al., 2022). This discrepancy may be due to differences in dietary intake, absorption, and metabolic needs.

Additionally, the current study found that there is direct relationship between mid-upper arm circumference and creatinine in dialysis patients. A study of 792 maintenance hemodialysis patients found that mid-arm muscle circumference (MAMC), a measure related to MUAC, was correlated with serum creatinine concentration ($r=+0.148$, $p<0.01$). This is because lower MUAC, reflecting reduced muscle mass, is associated with higher malnutrition-inflammation scores, increased mortality risk, and impaired creatine homeostasis in hemodialysis patients (Bint Harun et al., 2024; Post et al., 2021; Y. Yang et al., 2024)

The current study found that there was direct correlation between BMI and serum creatinine (p-value = 0.004, r = 0.279). Besides, numerous studies have found a paradoxical correlation between higher BMI and better outcomes in hemodialysis patients(Kittiskulnam & Johansen, 2019; Molnar et al., 2011; Stenvinkel et al., 2016). Patients with higher BMI tend to have higher serum creatinine levels, which is an indicator of greater muscle mass (Ertilav et al., 2019). This suggests that serum creatinine can modify the association between BMI and mortality/morbidity in hemodialysis patients. (Park et al., 2018; Sakao et al., 2016).

Besides that, results indicated that higher BMI is associated with higher albumin levels in hemodialysis patients. However, this finding contrast with other studies that found inverse correlation between serum albumin and BMI (Powers Carson & Arora, 2023; Shimizu et al., 2024). Besides, there is a study that mentioned obesity could reflect malnutrition and deficiency in various nutritional factors, which might result in hypoalbuminemia(Boaz et al., 2021). This implies that higher BMI (obesity) is associated with lower albumin levels.(Mun, 2021).

Our study found a positive correlation between dry weight and creatinine among hemodialysis patients. However, this finding contrasts with other studies that report a statistically significant negative correlation between dry weight and serum creatinine (Germain et al., 2021; H. R. Kim et al., 2021). A previous study found that a significant inverse correlation between interdialytic weight gain percentage (IDWG%) and serum creatinine ($r = -0.200$, $p < 0.001$) in hemodialysis patients (Jalalzadeh et al., 2021) . This

suggests that higher serum creatinine levels are associated with lower interdialytic weight gain, which can be an indicator of lower dry weight.

Our finding contrasts with previous studies that reported no correlation between dry weight and phosphate levels, identifying dietary phosphorus intake, parathyroid hormone, and fibroblast growth factor 23 (FGF23) as the key factors influencing serum phosphate levels (Garagarza et al., 2024; Mahdavi et al., 2019; Tsai et al., 2021; Yamada et al., 2016). Therefore, more focused research is needed to definitively determine whether a relationship exists between dry weight and serum phosphate in this patient population.

The current study found that increasing calf circumference was significantly correlated to higher creatinine. Mairini et al., (2024) found that calf circumference was positively correlated with serum creatinine levels in hemodialysis patients. Specifically, the study reported a Spearman's correlation test between skeletal muscle mass index (SMMI) and creatinine. Another study also examined the relationship between nutritional parameters and dialysis adequacy (Kt/V urea) in hemodialysis patients. It found that calf circumference was positively correlated with Kt/V urea in the group with Kt/V urea ≥1.4, suggesting an association between calf circumference and serum creatinine levels (Kaya et al., 2016).

5.7 Correlation between nutritional status and dietary vitamin and mineral intake

Our study found no significant correlation between nutritional status and dietary vitamin and mineral intake among hemodialysis patients at HPUSM, which contradicts the findings of Bukhari et al. (2022). Their study identified a positive significant

correlation between nutritional status and dietary vitamin and mineral intake, noting that higher blood copper levels and lower blood zinc and selenium levels are associated with increased nutritional risk in maintenance hemodialysis patients.

5.8 Strength and Limitation of Study

To our knowledge, limited research was done to study the association between nutritional status, vitamin and mineral intake with renal profile among hemodialysis patients in Kelantan. Hence, this study might provide new insights that relate with the impact of HD on nutritional status and vitamin and mineral intake among HD patients in Malaysia although the findings might be in contrast with the previous study. Besides, the findings can be used as fundamental data to future research studies. Moreover, this study was also conducted through interview-administered questionnaires where researchers collect data by asking participants questions directly and responses will be recorded. This method allows for clarification of questions, ensures that the participants understand what is being asked, and can lead to higher quality data especially when the participants have literacy issues. Moreover, interviews were generally conducted while patients were undergoing dialysis, so asking the questions directly, rather than having participants fill in questionnaires, made the process more convenient and minimized any discomfort during the interview.

Furthermore, this study faces several limitations that warrant consideration. Firstly, the accuracy of measuring Mid-Upper Arm Circumference (MUAC) and Calf Circumference (CC) may be compromised by various factors. For instance, participants wearing clothing during measurements can introduce measurement errors, potentially affecting the reliability of the results. Additionally, inpatient participants often encounter challenges in adhering to measurement protocols, particularly for CC, due to limited

mobility. This restriction can complicate the standardized measurement process and result in less precise data. Moreover, variability in treatment regimens could impact the study outcomes. Differences in dialysis protocols, including variations in duration and frequency among patients, may introduce inconsistencies that complicate the interpretation of the results. Lastly, this study also faced high refusal rates from patients as patients undergoing dialysis may experience fatigue and may be less inclined to participate in additional research activities due to their health condition and treatment regimen. Hence, it can impact the overall sample size and potentially introduce selection bias.

CHAPTER 6

CONCLUSION

6.1 SUMMARY OF FINDINGS

In summary, the results of this study demonstrated that majority of the hemodialysis patients in HPUSM have significant deficiencies when compared to the recommendation nutrient intake (RNI) for adults. All types of vitamin and mineral showed lower intake of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, folates, Vitamin C, sodium, potassium, calcium, magnesium, zinc and copper except phosphate. Moreover, the renal profile and nutritional status of HD patients also out of range as Blood Urea Nitrogen (BUN), phosphate, uric acid and creatinine level were markedly higher compared reference range. Meanwhile, albumin recorded below than normal range. It was also found that average of HD patients is having normal MUAC and CC, but BMI is slightly overweight (24.24 kg/m^2). The present study concludes that there was no significant association between nutritional status and dietary

vitamin and mineral intake among hemodialysis patients. There is significantly inverse relationship between vitamin C and uric acid among the subjects. Besides, there is significantly direct relationship between dry weight and phosphate test, calf-circumferences and phosphate, mid-upper arm circumferences and creatinine, calf-circumferences and creatinine, BMI and magnesium, dry weight and creatinine, BMI and creatinine and BMI and albumin. Although this finding found the association within each variable, but there's not enough evidence to support this finding. Hence, further studies are required to provide clearer understanding on the association of renal profile with vitamin and mineral intake and nutritional status among hemodialysis patients in Malaysia.

6.2 RECOMMENDATIONS

Hemodialysis patients are prone to decline in nutritional status due to the side effects of treatment and kidney function that influenced the dietary intake of patients. Healthy changes in dietary intake are important in order to ensure healthful choices are made to improve or maintain patients' nutritional status at diagnosis. Proper dietary changes must be encouraged and educated to patients by physicians or dietitians through consultation or printed materials on proper food choices. Besides, it is worth highlighting that hemodialysis patients' vitamin and mineral intake and renal profile are likely poor and proper approach by multidisciplinary team should be encouraged to avoid poor prognosis among hemodialysis patients.

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APPENDICES

Appendix 1: Data Collection Form

SCHOOL OF HEALTH SCIENCES
UNIVERSITI SAINS MALAYSIA
2023/2024

The Association Between Nutritional Status, Vitamin and Mineral Intake and Renal Profile Among Haemodialysis Patient In Hospital Pakar Universiti Malaysia (HPUSM), Kelantan

STUDY QUESTIONNAIRE FORM

RESPONDENT CODE	
CLINIC / WARD	
DATE	
TIME	

Prepared by:
Nur Amirah Zahida Binti Zakaria
3rd Year Dietetics Student
School of Health Sciences, Health Campus USM
Tel: 014-2909929
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Checked by:
Dr. Divya a/p Vanoh
Nutrition and Dietetics Lecturer
School of Health Sciences, Health Campus USM
Tel: 013-7790208
Email:divyavanoh@usm.my

Part A: SOCIODEMOGRAPHIC DATA

This part consists of 6 questions.

1. **Gender**

☐ Male ☐ Female

2. **Age**

____ years old

3. **Ethnicity**

☐ Malay ☐ Chinese ☐ Indian ☐ Others: _____

4. **Marital status**

☐ Single ☐ Married ☐ Divorced / Widower

5. **Educational status**

☐ Primary ☐ Secondary ☐ Tertiary ☐ No schooling/ illiterate

6. **Monthly Household Income**

RM _____

Part B : CLINICAL DATA

1. **Date of admission: _____**

2. **Duration of haemodialysis : _____**

3. **Co-morbidity:**

- ☐ **Hypertension**
- ☐ **Stroke**
- ☐ **Diabetes Mellitus**
- ☐ **Hyperlipidaemia**
- ☐ **Lung Disease**
- ☐ **Gastrointestinal**
- ☐ **Cancer**
- ☐ **Gout**
- ☐ **Arthritis**
- ☐ **Vision and hearing problem**
- ☐ **Other: _____**

4. **Medication type, dosage:**

_____

5. **Dietary supplement type, dosage:**

_____

6. **If patient has cancer, state type of cancer and treatment received:**

7. _____

Part C : RENAL PROFILE Date:

Characteristics	Reading
Renal Profile	
Sodium (mmol/L)	
Potassium (mmol/L)	
Magnesium (mmol/L)	
Blood Urea Nitrogen (BUN) (mmol/L)	
Phosphate (mg/dL)	
Uric acid (mg/dL)	
Creatinine (mg/dL)	
Albumin (mg/dL)	

Part D: ANTHROPOMETRIC MEASUREMENT

	1st Reading	2nd Reading	3rd Reading	Average
Dry weight (kg)				
Height (cm)				
BMI (kg/m²)				
Mid-upper arm circumference (cm)				
Calf Circumference (cm)				

Formula

BMI: $\frac{\text{weight (kg)}}{\text{height (m}^2\text{)}}$

Part E: 3-day Diet History

DAY: **DATE:**

TIME	FOOD/BEVERAGES	QUANTITY	PLACE / COOKING METHOD
BREAKFAST			
MID-MORNING			
LUNCH			
TEA-TIME			
DINNER			
SUPPER			

Appendix 2 : Borang Pengumpulan Data

PUSAT PENGAJIAN SAINS KESIHATAN

UNIVERSITI SAINS MALAYSIA

2023/2024

PERKAITAN ANTARA STATUS NUTRISI, KADAR PENGAMBILAN VITAMIN DAN MINERAL DENGAN RENAL PROFILE DALAM KALANGAN PESAKIT HEMODIALISIS DI HOSPITAL PAKAR UNIVERSITI MALAYSIA (HPUSM).

BORANG SOAL SELIDIK

KOD RESPONDEN	
KLINIK / WAD	
TARIKH	
MASA	

Disediakan oleh :

Nur Amirah Zahida Binti Zakaria

Pelajar tahun 3 Dietetik

Pusat Pengajian Sains Kesihatan, Kampus Kesihatan USM

Tel: 014-2909929

Email: amirahzahida12@gmail.com

Disemak oleh:

Dr. Divya a/p Vanoh

Pensyarah Nutrisi dan Dietetik

Pusat Pengajian Sains Kesihatan, Kampus Kesihatan USM

Tel: 013-7790208

Email:divyavanoh@usm.my

Bahagian A: DATA SOSIODEMOGRAFI

Bahagian ini terdiri daripada 6 soalan.

1. **Jantina**

   ☐ **Lelaki** ☐ **Perempuan**

2. **Umur**

   ____ years old

3. **Etnik**

   ☐ **Melayu** ☐ **Cina** ☐ **India** ☐ **Lain-lain: _____**

4. **Status Perkahwinan**

   ☐ **Bujang** ☐ **Berkahwin** ☐ **Bercerai/ duda/janda**

5. **Tahap Pendidikan**

   ☐ **Sekolah Rendah** ☐ **Sekolah Menengah** ☐ **Institut Pengajian Tinggi** ☐ **Tidak bersekolah/ buta huruf**

6. Pendapatan Isi Rumah Bulanan

RM _____

Bahagian B : Data Klinikal

7. Tarikh Kemasukan : _____

8. Tempoh Hemodialisis : _____

9. Komorbiditi:

☐ **Hypertensi**

☐ **Strok**

☐ **Diabetes Mellitus**

☐ **Hyperlipidaemia**

☐ **Lung Disease**

☐ **Gastrointestinal**

☐ **Kanser**

☐ **Gout**

☐ **Arthritis**

☐ **Masalah penglihatan dan pendengaran**

☐ **Lain – lain : _____**

10. Jenis ubat, dos:

_____

11. Jenis makanan / supplemen tambahan, dos:

_____

12. Jika pesakit mempunyai kanser, sila nyatakan jenis kanser dan rawatan yang diterima:

_____

Bahagian C : Profil Renal **Tarikh :**

Ciri-ciri	Bacaan
Renal Profile	
Sodium (mmol/L)	
Potassium (mmol/L)	
Magnesium (mmol/L)	
Blood Urea Nitrogen (BUN) (mmol/L)	
Phosphate (mg/dL)	
Uric acid (mg/dL)	
Creatinine (mg/dL)	
Albumin (mg/dL)	

Bahagian D : PENGUKURAN ANTROPOMETRIK

	Bacaan Pertama	**Bacaan Kedua**	**Bacaan Ketiga**	**Purata**
Berat kering (kg)				
Tinggi (cm)				
BMI (kg/m²)				
Lilitan lengan pertengahan atas (cm)				
Lilitan betis (cm)				

Formula

BMI: $\frac{\text{Berat(kg)}}{\text{Tinggi (m}^2\text{)}}$

Bahagian E : Sejarah Diet 3 Hari

HARI : **TARIKH :**

MASA	MAKANAN / MINUMAN	KUANTITI	TEMPAT/ CARA PENYEDIAAN
SARAPAN PAGI			
PERTENGAHAN PAGI			
MAKAN TENGAHARI			
MINUM PETANG			
MAKAN MALAM			
SUPPER			

Appendix 3 : Poster

Appendix 4 : Informed Consent Form

LAMPIRAN A

MAKLUMAT KAJIAN

Tajuk Kajian : **Perkaitan antara status nutrisi, kadar pengambilan vitamin dan mineral dengan renal profile dalam kalangan pesakit hemodialisis di Hospital Pakar Universiti Malaysia (HPUSM).**

Nama Penyelidik : **Nur Amirah Zahida Binti Zakaria**
: **Dr. Divya a/p Vanoh**

PENGENALAN

Anda adalah dipelawa untuk menyertai satu kajian penyelidikan secara sukarela. Kajian ini adalah berkaitan Hubungan antara status nutrisi, kadar pengambilan vitamin dan mineral dengan renal profile dalam kalangan pesakit haemodialysis di Hospital Pakar Universiti Malaysia (HPUSM).

Adalah penting bagi anda membaca dan memahami maklumat kajian sebelum anda bersetuju untuk menyertai kajian penyelidikan ini. Sekiranya anda menyertai kajian ini, anda akan menerima satu salinan borang ini untuk simpanan anda.

Penyertaan anda di dalam kajian ini dijangka mengambil masa 30 minit. Seramai 106 orang dijangka akan menyertai kajian ini.

TUJUAN KAJIAN

Kajian ini bertujuan untuk mengenal pasti status nutrisi, kadar pengambilan vitamin dan mineral serta renal profile dalam kalangan pesakit Haemodialysis di HPUSM. Kajian ini juga dapat menentukan sama ada status nutrisi, kadar pengambilan vitamin and mineral dan renal profile pesakit haemodialysis HPUSM mempunyai perkaitan antara satu sama lain atau tidak

KELAYAKAN PENYERTAAN

Salah seorang kakitangan kajian akan membincangkan kelayakan untuk menyertai kajian ini. Adalah penting anda berterus terang kakitangan tersebut [Jika berkaitan boleh ditambah “termasuk sejarah kesihatan anda].

Kajian ini akan melibatkan individu yang:

a) Orang dewasa berumur 19 tahun dan ke atas
b) Pesakit yang sedang menjalani hemodialisis yang merupakan pesakit luar atau pesakit dalam di HPUSM (3 kali seminggu)
c) Pesakit yang didiagnos dengan penyakit kronik buah pinggang (CKD) sekurang-kurangnya 6 bulan
d) Bebas daripada sebarang gangguan mental (psikologi)
e) Memahami Bahasa Melayu atau Bahasa Inggeris

Kajian ini tidak akan melibatkan individu yang:

a) Pesakit kanak-kanak dan ibu mengandung
b) Pesakit dengan masalah pendengaran atau penglihatan yang serius

c) Pesakit yang terbaring dan terlantar

PROSEDUR-PROSEDUR KAJIAN

Pertama sekali, borang persetujuan akan diberikan kepada anda sekiranya anda bersetuju untuk menyertai dalam kajian ini. Data sosiodemografi (jantina, umur, bangsa, status perkahwinan, taraf pendidikan dan jumlah pendapatan) akan dikumpul serta sejarah kesihatan anda (tarikh kemasukan ke klinik atau wad, tempoh menjalani hemodialisis, komorbiditi (hipertensi, strok, diabetes mellitus, hyperlipidemia, lung disease, gastrointestinal, gout, arthritis, masalah penglihatan dan pendengaran) akan direkod oleh fail rekod kesihatan dan dicatat. Selain itu, anda juga akan ditanya berkaitan dengan jenis pengambilan ubat dan supplement beserta dos ubat serta data klinikal lain yang relevan dengan kajian. Maklumat renal profile pesakit akan diambil terus daripada sistem USM. Segala maklumat akan dicatatkan dalam borang soal selidik yang disediakan.

Kemudian, pengukuran antropometri akan dibuat ke atas anda, termasuk pengukuran tinggi, ukur lilit lengan dan ukur lilit betis. Pengiraan BMI akan dibuat setelah telah mendapat data berkaitan tinggi dan berat kering pesakit. Berat kering (dry weight) pesakit akan diambil daripada rekod medikal pesakit. 2 bacaan bagi setiap pengukuran akan diambil bagi mengurangkan ralat. Bacaan ketiga akan diambil sekiranya perbezaan antara bacaan pertama dan kedua melebihi 10%. Setelah bacaan ketiga dibuat, bacaan purata akan diambil. Seterusnya, anda akan ditanya berkaitan 3 hari sejarah diet (2 hari dialisis, 1 hari bukan dialisis) yang memerlukan anda merekod secara terperinci tentang masa, jenis hidangan, kuantiti hidangan serta tempat hidangan dan kaedah masakan. Sesi pertanyaan (interview) ini akan berlangsung dalam anggaran 20 hingga 25 minit.

RISIKO

Sekiranya anda menyertai kajian ini, anda mungkin mengalami beberapa risiko. Anda mungkin akan berasa terganggu, letih dan beban emosi sepanjang sesi temuduga dijalankan. Jika situasi ini berlaku, anda berhak untuk meminta masa untuk berehat atau menarik diri dari kajian ini pada bila-bila masa tanpa sebarang hukuman atau denda.

Sila maklumkan kepada kakitangan kajian sekiranya anda menghadapi sebarang masalah atau mempunyai sebarang maklumat penting yang mungkin mengubah persetujuan anda untuk terus menyertai kajian ini.

MELAPORKAN PENGALAMAN KESIHATAN (Jika Kajian Melibatkan Kesihatan SAHAJA)

Sila hubungi kakitangan berikut pada bila-bila masa sekiranya anda mengalami sebarang masalah kesihatan, samada berkaitan atau tidak berkaitan dengan kajian ini.

Nur Amirah Zahida Binti Zakaria di talian 014-2909929 atau
Dr. Divya a/p Vanoh di talian 013-7790208 secepat mungkin.

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak untuk menyertai kajian ini atau menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh kakitangan kajian ini tanpa persetujuan anda sekiranya anda didapati tidak sesuai untuk meneruskan kajian ini berdasarkan protokol kajian. Kakitangan kajian akan memaklumkan anda sekiranya anda perlu diberhentikan dari menyertai kajian ini.

MANFAAT YANG MUNGKIN [Manfaat terhadap Individu, Masyarakat, Universiti]

Prosedur kajian ini akan diberikan kepada anda tanpa kos. Anda akan menerima maklumat melalui panggilan telefon tentang status keadaan terkini (BMI, ukur lilit lengan dan ukur lilit betis) sama ada berada dalam lingkungan normal atau tidak. Kajian ini juga membolehkan peserta mengenal pasti tabiat pemakanan (pengambilan vitamin dan mineral) serta status renal profile mereka.Di samping itu, anda akan dapat mengetahui maklum balas secara terus berkaitan dengan keputusan kajian.

Hasil kajian ini diharapkan, dapat memberi manfaat kepada masyarakat umum untuk menentukan hubungkait antara status nutrisi , renal profile serta kadar pengambilan vitamin dan mineral dalam kalangan pesakit hemodialisis HPUSM. Malah, kajian ini juga dapat memberi manfaat kepada profesional kesihatan mengenai jenis komorbiditi dalam kalangan pesakit hemodialisis yang seterusnya dapat memberi impak negatif terhadap pejagaan pesakit di masa akan datang.

Anda tidak akan menerima sebarang pampasan atau honorarium kerana menyertai kajian ini.

PERSOALAN

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Nur Amirah Zahida Binti Zakaria
Pelajar Dietetik Tahun 3
Pusat Pengajian Sains Kesihatan
Kampus Kesihatan Universiti Sains Malaysia
No. Tel: 014-2909929
Email: amirahzahida12@gmail.com

ATAU

Dr. Divya a/p Vanoh
Pensyarah Program Pemakanan dan Dietetik
Pusat Pengajian Sains Kesihatan
Kampus Kesihatan Universiti Sains Malaysia
No. Tel: 013-7790208
Email: divyavanoh@usm.my

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Bahagian Penyelidikan dan Inovasi (P&I)
USM Kampus Kesihatan.
No. Tel: 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

KERAHSIAAN

Maklumat yang anda berikan akan dirahsiakan oleh kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian ini tidak akan mengenalpasti anda secara perseorangan. Hasil kajian mungkin akan diterbitkan untuk tujuan perkongsian ilmu.

Semua borang kajian dan data yang anda berikan termasuk rekod perubatan anda yang asal mungkin akan disemak oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori bagi tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat anda akan disimpan dalam komputer dan hanya kakitangan kajian yang dibolehkan sahaja dibenarkan untuk mendapatkan dan memproses data tersebut.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemprosesan data seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan (Lihat contoh Borang Keizinan Peserta di **LAMPIRAN S** atau **LAMPIRAN P**).

LAMPIRAN S

Borang Keizinan Peserta
(Halaman Tandatangan)

Tajuk Kajian : **Perkaitan Antara Status Nutrisi, Kadar Pengambilan Vitamin Dan Mineral Dengan Profil Renal Dalam Kalangan Pesakit Haemodialysis Di Hospital Pakar Universiti Malaysia (HPUSM).**

Nama Penyelidik : **Nur Amirah Zahida Binti Zakaria**

: **Dr. Divya a/p Vanoh**

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

_____

Nama Peserta

_____

No. Kad Pengenalan Peserta

_____ _____

Tandatangan Peserta atau Wakil Sah | **Tarikh** (dd/MM/yy) (Masa jika perlu)

_____ _____

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan | **Tarikh** (dd/MM/yy)

_____ _____

Nama Saksi dan Tandatangan | **Tarikh** (dd/MM/yy)

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

LAMPIRAN P

Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Peserta Kajian
(Halaman Tandatangan)

Tajuk Kajian : **Perkaitan Antara Status Nutrisi, Kadar Pengambilan Vitamin Dan Mineral Dengan Profil Renal Dalam Kalangan Pesakit Haemodialysis Di Hospital Pakar Universiti Malaysia (HPUSM).**

Nama Penyelidik : **Nur Amirah Zahida Binti Zakaria**

: **Dr. Divya a/p Vanoh**

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks – contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

_____ _____

Nama Peserta

_____ _____ _____

No. Kad Pengenalan Peserta T/tangan Peserta **Tarikh** (dd/MM/yy)

_____ _____

Nama & Tandatangan Individu yang Mengendalikan **Tarikh** (dd/MM/yy)

Perbincangan Keizinan

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

ATTACHMENT B

RESEARCH INFORMATION

Research Title : The Association Between Nutritional Status, Vitamin And Mineral Intake And Renal Profile Among Haemodialysis Patient In Hospital Pakar Universiti Malaysia (HPUSM), Kelantan.

Name of Researcher : Nur Amirah Zahida Binti Zakaria
and Co-Researcher : Dr. Divya a/p Vanoh

INTRODUCTION

You are invited to take part voluntarily in a research. This research is about The Association Between Nutritional Status, Vitamin And Mineral Intake And Renal Profile Among Haemodialysis Patient In Hospital Pakar Universiti Malaysia (HPUSM), Kelantan.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to be about 30 minutes. This study is estimated to include up to 106 participants.

PURPOSE OF THE STUDY

The purpose of this study are to determine and assess nutritional status, vitamin and mineral intake and renal profile of haemodialysis patients in Hospital Pakar Universiti Malaysia. This study is also expected to assess the association between nutritional status and renal profile, nutritional status and vitamin and mineral intake, vitamin and mineral intake and renal profile among haemodialysis patients in Hospital Pakar Universiti Malaysia.

PARTICIPANTS CRITERIA

The research team members will discussed your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history.

This study will include individual who are:

a) Adults aged 19 years old and above
b) Undergoing Haemodialysis patients in either outpatient or inpatient setting in HPUSM (3 times per week)
c) Patients diagnosed with CKD for at least 6 months
d) Patients' absence from psychological disorder
e) Able to understand Bahasa Melayu and/or English

This study will not incude individual who are:

a) Children and pregnant mother
b) Patients with serious hearing or vision problem
c) Bedridden patient

STUDY PROCEDURES

Firstly, informed consent will be given to you if you are allowed and volunteered to take part in this study. Sociodemographic details, encompassing gender, age, ethnicity, marital status, educational background, and monthly income, will be collected, along with clinical information

including hospitalization date of admission, haemodialysis duration, and prevalent comorbidities (hypertension, stroke, diabetes mellitus, hyperlipidemia, lung disease, gastrointestinal conditions, gout, arthritis, vision, and hearing problems). Medication and supplemet intake with dosage, and other relevant clinical data will also be documented using a structured data collection form. Concurrently, laboratory results for the renal profile will be extracted from admission blood tests via the USM system.

Anthropometric measurements, including height, mid-upper arm circumference, calf circumference, and the subsequent calculation of BMI, will be performed, with two initial readings recorded and a third taken if there is a discrepancy exceeding 10%. The final average value will be considered. Additionally, dietary assessment will involve a 3-day diet history (2 days dialysis, 1 day non-dialysis), where respondents will record in detail the timing, type of food, details, quantity,cooking method and location of food consumption. The interview session for each participant is anticipated to take approximately 20 to 25 minutes.

RISKS

There may be risks to you if you participate in this study. You may feel disturbed, tired and emotional burden throughout the interview session. If these situations arise during the interview session, subjects have the right to request for rest or be withdrawn from this research at any time without any penalty.

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

Nur Amirah Zahida Binti Zakaria at 014-2909929 or
Dr. Divya a/p Vanoh at 013-7790208.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discussed with you if the matter arises.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

From participating in this study, participant is able to know about his/her current nutritional status (BMI, MUAC and CC) made by them after the interview session. Subjects will gain benefit by obtaining feedback from the researcher about their study findings. This will be done via phone call.

This study finding may benefit the community by identifying the association between nutritional status and renal profile as well as the vitamin and mineral intake among haemodialysis patients in HPUSM. Moreover, this study also provide information to healthcare professionals regarding the type of comorbidities among haemodialysis patients which can further effect haemodialysis patients' care management in the future.

You will not recieve any compensation or honorarium from this study.

QUESTIONS

If you have any question about this study or your rights, please contact;

Nur Amirah Zahida Binti Zakaria
3rd Year Dietetics Student
School of Health Sciences
Health Campus Universiti Sains Malaysia
No. Tel: 014-2909929
Email: amirahzahida12@gmail.com

OR

Dr. Divya a/p Vanoh
Lecturer of Nutrition and Dietetics Programme
School of Health Sciences
Health Campus Universiti Sains Malaysia
No. Tel: 013-7790208
Email: divyavanoh@usm.my

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page **[ATTACHMENT S or ATTACHMENT G (for genetic sample only) or ATTACHMENT P]**

ATTACHMENT S

Subject Information and Consent Form (Signature Page)

Research Title : **The Association Between Nutritional Status, Vitamin And Mineral Intake And Renal Profile Among Haemodialysis Patient In Hospital Pakar Universiti Malaysia (HPUSM), Kelantan.**
Name of Researcher : **Nur Amirah Zahida Binti Zakaria**
and Co-Researcher : **Dr. Divya a/p Vanoh**

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____
Participant Name

_____
Participant I.C No

_____ _____
Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____
Name of Individual
Conducting Consent Discussion

_____ _____
Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____
Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ATTACHMENT P

Participant's Material Publication Consent Form
Signature Page

Research Title : **The Association Between Nutritional Status, Vitamin And Mineral Intake And Renal Profile Among Haemodialysis Patient In Hospital Pakar Universiti Malaysia (HPUSM), Kelantan.**

Name of Researcher : **Nur Amirah Zahida Binti Zakaria**

and Co-Researcher : **Dr. Divya a/p Vanoh**

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

Participant Name

_____ _____ _____

Participant I.C No. **Participant's Signature** **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

APPENDIX 5 : ETHICS APPROVAL

Note: Note: i) All participants who are involved in this study will not be covered by insurance.

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

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16150 Kubang Kerian, Kelantan. Malaysia.
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www.usm.my

19th March 2024

Miss Nur Amirah Zahida Zakaria
Undergraduate Student (Dietetics)
School of Health Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/KK/24010038
Protocol Title: The Association Between Nutritional Status, Vitamin and Mineral Intake and Renal Profile Among Haemodialysis Patient in Hospital Universiti Sains Malaysia (HUSM), Kelantan.

Dear Miss.,

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/KK/24010038**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **19th March 2024** until **18th March 2025.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:
1. Dr. Divya Vanoh

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

In addition to the abovementioned documents, the following technical documents were included in the review on which this approval was based:
1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Data Collection Form

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 45 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2022: 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) 2022: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2022: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2022: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2022.**
6. Any event which may have ethical significance.

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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) 2022: Final Report Form.**

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

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.