Utilising mHealth to improve health literacy on chronic kidney disease among diabetics: Malaysian Nutritional, Emotional and Physical Health literacy for optimal Renal Outcome (My-NEPHRO) randomised controlled trial protocols

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ABSTRACT

Introduction: Technology-integrated intervention approaches are considered convenient, accessible, and a more scalable way to engage a larger population. The objective of this paper is to present the protocols for a randomised controlled trial that evaluates the efficacy of a health literacy intervention module (MyNEPHRO) via a mobile application, which aims to improve health literacy, quality of life, and medical outcomes among diabetes patients with chronic kidney disease (CKD). **Methods:** This will be a randomised controlled interventional trial. MyNEPHRO module will be developed, validated, and integrated within a mobile application. The mobile app intervention is to be delivered for six months with multiple approaches. Eligible adults aged more than 18 years old with diabetes and non-dialysis chronic kidney disease will be assigned to one of the two study groups (intervention or usual care control groups) in a 1:1 ratio using simple randomisation. Repeated measures analysis of covariance (ANCOVA) will be used to examine the changes over time within and between groups. **Results:** Changes in health literacy level (primary outcomes), and changes in haemoglobin A1c (HbA1C), renal function, and quality of life (secondary outcomes) will be assessed at three and six months. **Conclusion:** This study protocol describes a digital health literacy intervention for CKD among diabetics in Malaysia, determining the effect of this intervention on health literacy, HbA1c level, renal disease progression, and quality of life in diabetics with CKD. Results from this trial will provide insights in improving health literacy regarding CKD among diabetics in Malaysia.

Keywords: chronic kidney disease, diabetes, health literacy, mhealth

INTRODUCTION

Chronic kidney disease (CKD) affects more than 10% of the world's population. This condition is characterised by persistent abnormalities in kidney structure or function lasting at least

three months, with significant health implications (KDIGO, 2024). It has emerged as one of the leading causes of mortality globally, with an increase in related deaths over the past two decades (Kovesdy, 2022). While irreversible and progressive, early correct management, including lifestyle modification, can prevent progression to end-stage renal disease (ESRD), a stage which requires dialysis (Evangelidis *et al.,* 2019). The high number of affected individuals and the significant adverse impacts of CKD signify crucial efforts for better prevention and disease progression.

CKD is a major public health concern in Malaysia, particularly among individuals with diabetes mellitus. Malaysia has one of the highest incidences of diabetes mellitus in Southeast Asia, with an estimated prevalence of 15.6% among adults (IPH, 2024). Diabetes is a leading cause of CKD in Malaysia, with almost 70% of new end-stage renal disease (ESRD) cases attributed to diabetic nephropathy (Malaysian Society of Nephrology, 2023). The total annual expenditure of ESRD by the public sector in Malaysia has grown from RM572 million in 2010 to RM1.12 billion in 2016 (Ismail *et al.*, 2019). All these factors highlight an urgent need for effective strategies that can address both prevention and management to reduce progression to ESRD and improve quality of life (QoL) among diabetes mellitus patients with CKD.

Patients with diabetes mellitus and CKD often face dilemmas as they receive conflicting advice from sources like traditional healers and supplement sellers, causing confusion, poor adherence to treatment, and improper dietary practices that worsen their condition (Ithnain *et al.*, 2020). A holistic health literacy approach can potentially address this confusion, improve practices, and lead to better disease control and QoL. Health literacy

significantly impacts health outcomes, especially in managing chronic conditions like CKD (Devraj *et al.,* 2015). It involves the ability to access, understand, evaluate, and apply health information in a way that promotes informed decision-making and self-management (IOM, 2004).

Inadequate understanding or education about CKD is one of the main factors of reported barriers to healthcare (Lo *et al.*, 2017). Low health literacy affects at least 25% of CKD patients and is associated with increased morbidity and mortality (Cavanaugh *et al.,* 2010). Limited health literacy correlates with poor disease management, higher hospitalisation rates, and reduced QoL, while higher health literacy is associated with higher or better kidney function (Devraj *et al.,* 2015). Therefore, enhancing health literacy in CKD patients with diabetes mellitus is crucial for improving their ability to make informed decisions about their health, adhere to complex treatment regimens, and actively participate in their care. A cohort study by Yu *et al.* (2021) further underscored this relationship, showing that patients with higher health literacy scores demonstrated significantly better self-care behaviour.

The QoL of patients was found to decrease in all stages of kidney disease. Reductions in physical functioning, physical role functioning, and in the physical component summary were also observed progressively in the different stages of kidney disease (Kefale *et al.*, 2019). Therefore, for CKD patients with diabetes mellitus, a holistic approach to health literacy is essential, given the complex and multifactorial nature of these conditions.

Problem statement and study rationale

Health literacy is consistently linked to better self-management in CKD patients,

though its impact on patient outcomes remains less clear and incompletely understood, with a scarcity of studies in developing countries (Billany *et al.*, 2023). Since cultural and local contexts of the disease and illness are very important in a holistic health literacy model, the development of health literacy modules in the local context is crucial. Intervention approaches using digital therapy, such as mobile application technology and websites, enable a wider reach and are more scalable. Thus, mobile application in the utilisation of this module may improve the delivery of the module.

For diabetic CKD patients in Malaysia, a mobile application is uniquely positioned to deliver tailored, culturally relevant information in a format that supports consistent engagement and active participation in health management. Mobile health (mHealth) applications have gained traction as accessible, scalable tools for health education and disease management. In Malaysia, smartphone usage is high, with over 94% of adults owning a smartphone (MCMC, 2021). This high rate of mobile phone usage among Malaysians provides an ideal platform for interventions, enabling widespread dissemination of health information and facilitating self-management support. In addition, previous studies have shown that mHealth interventions can improve health literacy and QoL among patients with chronic diseases. A study by Logan *et al.* (2019) demonstrated that mobile applications significantly enhance patients' self-efficacy and adherence to treatment protocols, ultimately contributing to improved health outcomes.

Providing accessible, real-time educational resources and self-management tools not only support patients in managing their health but also aligns with Malaysia's broader public health objectives to reduce the burden of non-communicable diseases through digital innovation. The digitalised module will not just be a mobile application but a critical intervention for improving health literacy, empowering CKD patients with diabetes to achieve better health outcomes and enhancing their QoL.

The purpose of this paper is to present the protocol for a randomised controlled trial that evaluates the efficacy of a health literacy intervention module (MyNEPHRO) via a mobile application. The MyNEPHRO app aims to improve health literacy, QoL, and medical outcomes among diabetes patients with CKD. This study aims to develop a digitalised holistic health literacy module for CKD in diabetes mellitus in Phase 1 and analyse its effectiveness among non-dialysis CKD patients with diabetes mellitus in Phase 2. The study objectives of Phase 2 are (1) to compare differences in health literacy scores between intervention and control groups at pre-, post-3 and 6 months; (2) to compare differences in QoL scores between intervention and control groups at pre-, post-3 and 6 months; (3) to compare differences in renal function using estimated glomerular filtration rate (eGFR) and haemoglobin A1c (HbA1C) between intervention and control groups at pre- and post-6 months.

MATERIALS AND METHODS

Study design

This will be an open-label randomised controlled interventional trial. MyNEPHRO modules will be developed and integrated within a mobile application (app) in Phase 1. In Phase 2, the mobile app intervention will be delivered for six months in the intervention group, while the control group will receive usual care. Eligible adults aged more than 18 years old with diabetes and non-dialysis CKD will be assigned to either the intervention or the control group in a 1:1 ratio using
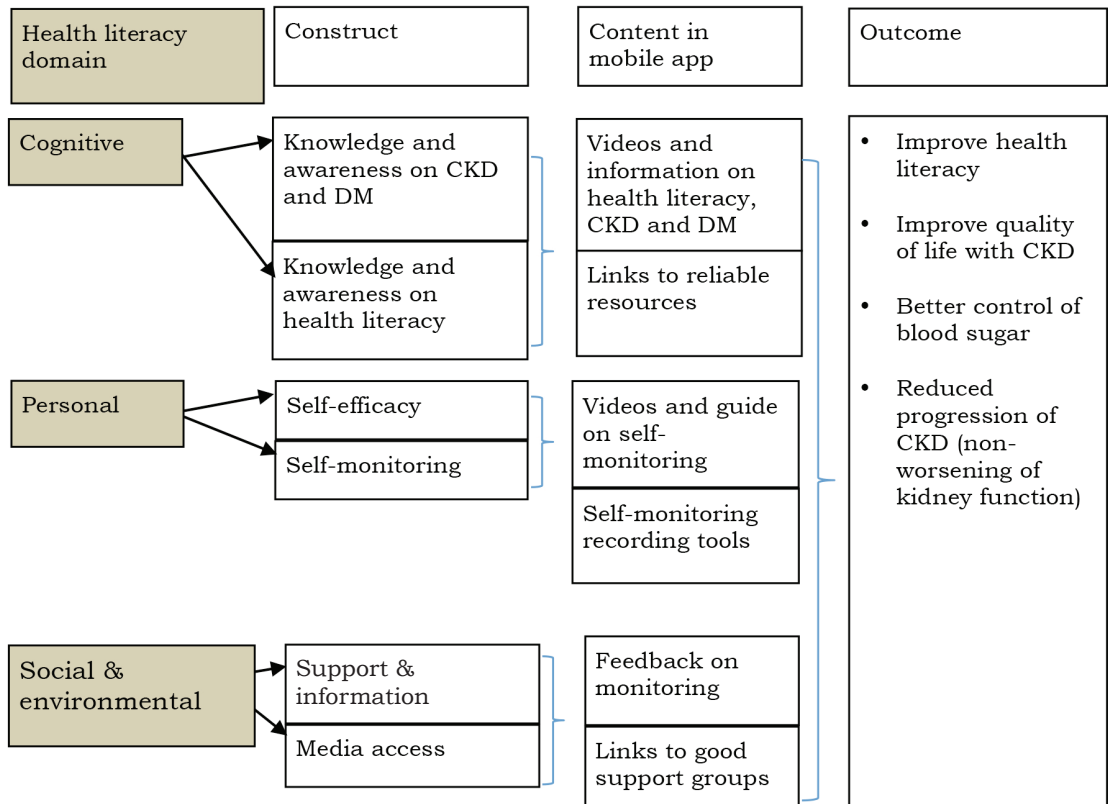
Figure 1. Conceptual framework of the module
CKD: Chronic kidney disease; DM: Diabetes mellitus

simple randomisation. The design, conduct, and reporting will follow the consolidated standards of reporting trial (CONSORT) guidelines. The trial will be carried out in the district of Kuala Terengganu, Malaysia.

Development and validation of the MyNEPHRO module and mobile app

The programme's main aim is to increase the holistic health literacy and self-management of the intervention group, improve blood sugar control, and retard the progression of CKD. Therefore, the programme focuses on the aspects of health literacy and will develop the constructs and contents based on the health literacy domains (Figure 1) and theoretical framework for health literacy (Figure 2).

The module content will be adapted from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) website, where content is copyright-free and can be freely reproduced (NIDKK, 2017). Videos will be produced by the research team based on the content. Adjustments of content and the design of the mobile application will be done based on results of a qualitative inquiry among 12 diabetic patients with CKD on the learning needs and features of a user-friendly mobile application and educational features for education regarding CKD. Thematic analysis will be used to come up with the themes for the mobile application module.

Thereafter, this study will adopt the systematic approach for face and content validity. For content validity,
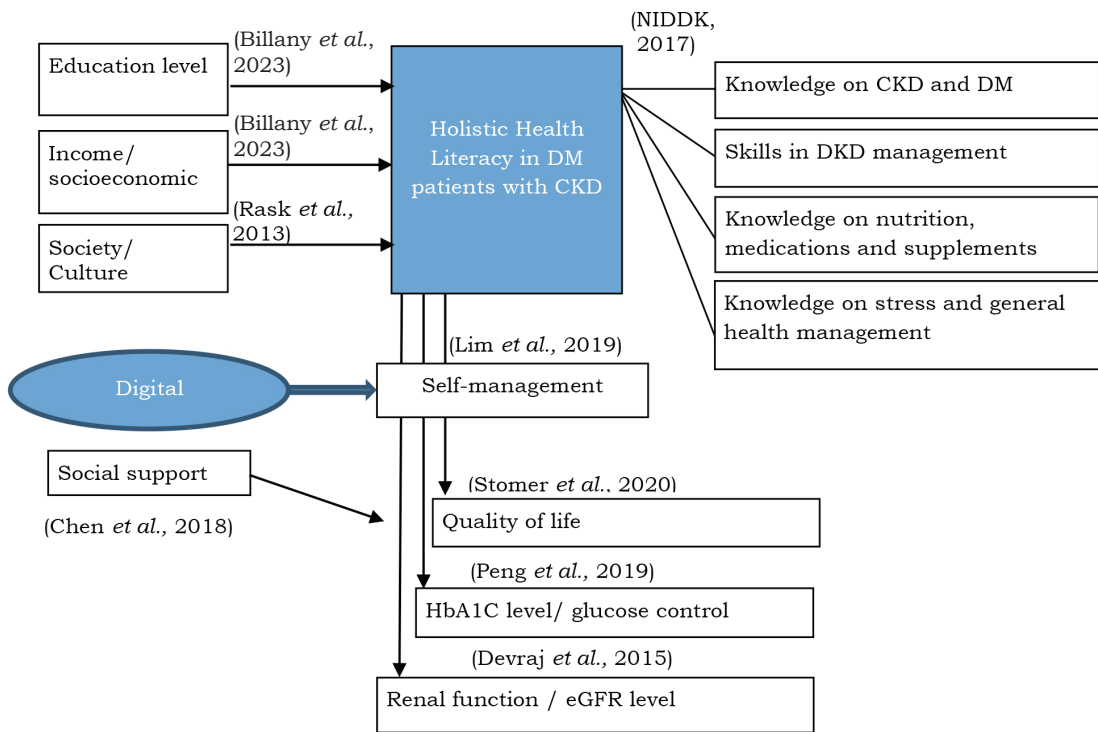
Figure 2. Theoretical framework on health literacy

the study will apply the procedures used by Yusoff (2019) as follows: (1) Preparation of a content validation form - the Educational Content Validation Instrument in Health (ECVIH) by Leite *et al.* (2018) will be used. It has three domains: objectives (five items), structure/presentation (10 items), and relevance (three items). ECVIH demonstrates good internal consistency (0.87) and reliability. Responses will be scored on a 10-point Likert scale from 1 (strongly disagree) to 10 (strongly agree). (2) Selecting a review panel of experts - eight experts will be selected based on their expertise in nephrology, dietetics, and pharmacology (Kuzel, 1999). Their input will establish the validity of the module. (3) Conducting content validation - experts will review the first draft to ensure the content is suitable, clear, and unambiguous. (4) Reviewing domains and items - submodules will serve as the domains and topics within the module as items. Experts will provide oral or written feedback to enhance the relevance and clarity of the items. (5) Providing scores for each item - experts will independently rate each item on a 10-point Likert scale (1 = strongly disagree, 10 = strongly agree). The scores will reflect the perceived relevance and clarity of each item. (6) Calculating Content Validity Index (CVI) - CVI will be calculated using these formulas: (1) I-CVI = (agreed item count) / (number of experts), (2) S-CVI/Ave = (sum of I-CVI scores) / (number of items), and (3) S-CVI/UA = (sum of universal agreements) / (number of items). A minimum CVI value of 0.78 is required. If unmet, feedback will be used to guide module revision and re-evaluation.

Following the development of the mobile application, face validity will be done with five doctors and five patients

to confirm their understanding of the education materials for refinement of the mobile application. The process will follow the face validity process outlined by Yusoff (2019), consisting of preparation of a response process validation form, selecting a panel of raters, assessing the response process, reviewing items for clarity and comprehension, item rating using a clarity and comprehensibility scale, and calculating the Face Validity Index (FVI).

Study participants

Participants are considered eligible for the randomised controlled trial if they: (1) are more than 18 years old and live, work, or study in Kuala Terengganu, Terengganu, Malaysia; (2) have diabetes mellitus with CKD (Stages I - IV) as diagnosed by their physician; (3) own an Android smartphone; (4) are fluent in the Malay language; and (5) are willing to participate in the programme. The exclusion criteria include those: (1) having comorbid conditions affecting the kidney, such as nephrolithiasis; (2) participating in additional health education programmes or interventional research; (3) who are already using a mobile application for self-management; (4) who had been admitted for any renal problems in the past one month; (5) who cannot read due to vision problems.

Sample size was calculated for all objectives with available published parameters using PS software. The largest sample size is 102 - 51 for intervention group and 51 for control group; including a 20% increase to consider loss to follow-up. The following equation was used (Florey, 1993):

n (sample size for each group) = 2 [(a + b)2 x σ2] / (μ1 - μ2)2

where: a = conventional multiplier for alpha (0.05) = 1.96 and b = conventional multiplier for power (0.80) = 0.842.

Considering a difference of 0.5% in the change of % HbA1c between groups and 0.8 standard deviation (*SD*) of change in % HbA1c (Seangpraw *et al.,* 2023), a sample size of 41 adults per group will give 80% power at 0.05 significance level.

Recruitment and study flow

The target sample will comprise 102 adults with diabetes mellitus and CKD stages I - IV living in Kuala Terengganu, Terengganu, Malaysia. The study flow is as outlined in Figure 3. Health campaigns regarding diabetes will be done targeting patients attending the medical clinic in a university hospital. Potential subjects will be recruited during the programmes by identifying them using a Google form for inclusion and exclusion criteria. Those fulfilling the inclusion and exclusion criteria will be contacted via phone and the study will be explained to them accordingly.

Randomisation will be performed by the co-investigator (SWW) in this trial once the baseline data collection is completed. Each participant will be assigned either to the intervention or the control group by a 1:1 ratio simple randomisation. The Research Randomizer software will generate random numbers using the "Math.random" method with JavaScript programming for the intervention group. The group assigned will be inserted in envelopes according to the number generated. The co-investigator will select the envelope sequentially and contact each participant to inform him/her of the allocated group (intervention or control) and instruct on the next processes according to the group assigned.

This study uses a single-blind approach. Assessments will be done at baseline, 3 months, and 6 months by the main researcher (NH), who will remain blinded to group allocations throughout the study (Figure 3). Participants will be instructed to get a copy of their blood investigation report during the
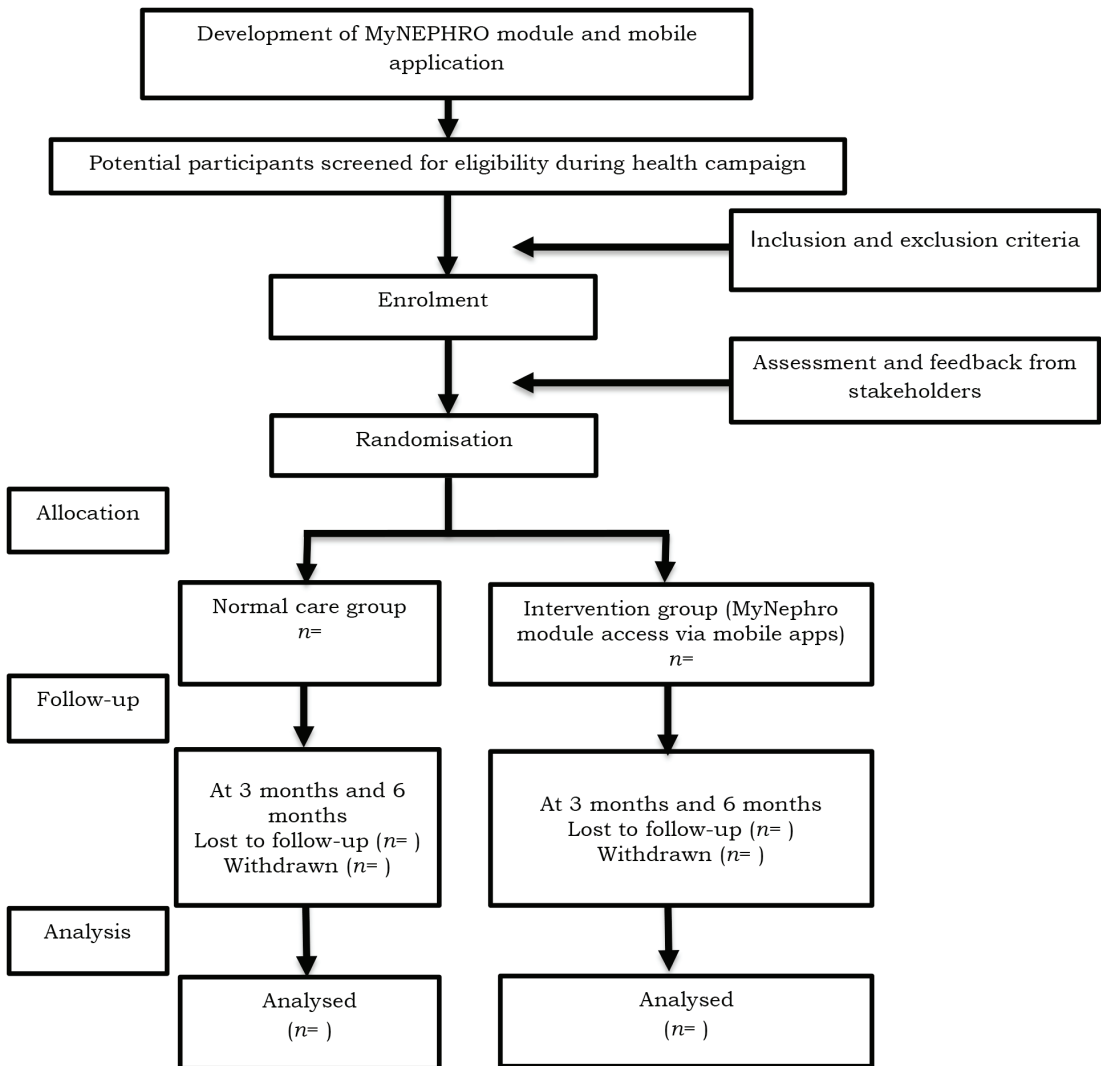
Figure 3. Study flowchart

course of the study. HbA1C and serum creatinine levels will be taken from the blood investigation results during their regular follow-up and baseline investigation should be within one month of recruitment into the intervention or control group. The intervention group will receive the mobile application, while the control group will continue their usual care. The intervention is self-accessed by the user of the mobile app, with monthly reminders to access the app biweekly and use the self-monitoring features. Those who do not access the app at least monthly will be considered as dropouts from the intervention group.

Ethical consideration

Participation of subjects in this study will be voluntary and it is possible to withdraw from the study at any time without penalty or jeopardising their care. All participants will provide their

Table 1. Participants' timeline

	Study Period			
	Enrolment	Allocation	Follow-Up	
Time-Point	*At inclusion*	*t0*	*t3*	*t6*
Enrolment:				
Eligibility screening	X			
Informed consent	X			
Allocation	X			
Interventions:				
Intervention group		X		
Control group		X		
Assessments:				
Baseline sociodemographic assessment		X		
HbA1c		X		X
Renal function		X		X
Health literacy questionnaire		X	X	X
QoL questionnaire		X	X	X

informed consent. A small gift will be given to the participants as a token of appreciation. Pre-test and post-test questionnaires will be linked with the use of participants' e-mail addresses. Responses will be treated confidentially and results will be reported anonymously. Participants' study information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law. Data with no individual identification will be published in scientific journals for academic purposes. Participants' original research data records will only be accessible to the researchers, as well as the Ethical Review Board and regulatory authorities if needed, for the purpose of verifying the study procedures and/or data. The study has been granted ethical approval by the UniSZA Human Research Ethics Committee (UniSZA/UHREC/2024/739) and was prospectively registered with Clinical Trial Registry on 6 September 2024.

Data collection and management
The participants' timeline is presented in Table 1.

Assessment of health literacy
The self-administered Health Literacy Survey Malaysian Questionnaire 18 (HLS-M-Q18) will be used. This questionnaire was adapted and compressed from the Health Literacy Survey European Questionnaire 47 (HLS-EU-Q47) and was pre-tested and validated in Malaysia. Instrument reliability showed all major domains in HLS-M-Q18 had a Cronbach's alpha value greater than 0.7 (Mohamad *et al.*, 2020).

Assessment of quality of life (QoL)
The World Health Organization (WHO) has developed an instrument called the World Health Organization Quality of Life (WHOQOL) to measure various subjective aspects of QoL. Among these instruments, the World Health Organization Quality of Life Brief Version (WHOQOL-BREF) is widely recognised for its applicability in cross-cultural comparisons of QoL and it is available in over 40 languages. The WHOQOL-BREF is a 26-item instrument consisting of four domains: physical health (seven items), psychological health (six items),

social relationships (three items), and environmental health (eight items); it also contains QOL and general health items.

Baseline sociodemographic assessment

Sociodemographic variables encompass age, sex, race, education level (primary, secondary, or tertiary), and household income.

Statistical analysis

Statistical analyses will be conducted using the IBM SPSS Statistics for Windows version 25.0 (IBM Corp., Armonk, New York, USA). Descriptive statistics will be used to characterise the overall respondents. For numerical outcomes: independent *t*-test (between group comparison), paired *t*-test (within group comparison), and repeated measure analysis of covariance (ANCOVA) will be used for parametric testing for comparing the intervention and control groups and/or by time, respectively. A *p*-value of 0.05 and less is considered statistically significant.

The time points of repeated measures, at which data will be collected at baseline, 3- and 6-month intervals, serve as within-subject independent variables. On the other hand, the number of groups in the study, which consists of the intervention group and the control group, serves as between-subject independent variables. The dependent variables of the study are mean changes in health literacy score, creatinine, eGFR, HbA1c level, and QoL score.

RESULTS

Results of the randomised controlled trial will be reported for specific objective 1: changes in health literacy scores between intervention and control groups at pre-, post-3 and 6 months; specific objective 2: changes in QoL scores between intervention and control groups at pre-, post-3 and 6 months, and changes in renal function (eGFR) and HbA1C at pre- and post-6 months between intervention and control groups.

DISCUSSION

Health literacy programmes are designed to enhance patients' self-management skills and health outcomes. Effective self-care is crucial in managing chronic diseases, with self-management being a key factor in reducing risk and improving disease control. Unlike traditional educational initiatives, which may not always translate into behavioural changes, self-management interventions focus on empowering patients to actively engage in their health. This approach necessitates a shift from passive learning to active participation, where patients assume responsibility for their well-being rather than merely receiving information. Self-management interventions aim to provide patients with the skills and strategies necessary for better self-care in managing chronic conditions.

One method to improve patient self-care is through health education, which enhances health literacy. Disease-specific knowledge is critical for effective self-management of chronic conditions such as CKD. Patient education programmes, health literacy assessment tools, clear communication strategies, and shared decision-making all contribute to building a foundation of health literacy. Moreover, the integration of mobile applications into the healthcare landscape provides a dynamic and accessible platform for ongoing education, self-management, and support. As technology continues to evolve, the role of mobile applications in improving health literacy for individuals with CKD and diabetes mellitus is poised to expand, offering

innovative solutions to bridge gaps in understanding, empowering patients, and ultimately improving the holistic management of these chronic conditions, especially through improvement of self-management.

Systematic reviews of interventional studies have demonstrated that self-management interventions can lead to lower blood pressure and reduced C-reactive protein (CRP) levels compared to usual care. However, these interventions did not show significant differences in HbA1c or total cholesterol levels. Additionally, studies focusing on behavioural risk factors revealed that patients who participated in exercise management programmes could cover greater distances in the same amount of time compared to the control group, though there was no effect on body weight (Peng *et al.,* 2019). Ishani *et al.* (2016) found that telehealth provided by an inter-professional team achieved similar outcomes to standard care for patients with CKD. In contrast, Campbell *et al.* (2008) reported that individualised nutritional counselling improved QoL, cognitive functioning, vitality, and kidney disease symptoms among pre-dialysis patients compared to standard care.

These findings indicate a gap in evidence regarding the effectiveness of holistic health literacy delivered via mobile applications in improving outcomes for CKD. Therefore, this interventional study will explore the use of a holistic health literacy approach specifically for CKD.

CONCLUSION

This study protocol describes a digital health literacy intervention for CKD among diabetics in Malaysia, determining the effect of this intervention on health literacy, HbA1c level, renal disease progression, and QoL in diabetics with CKD as compared to a standard care follow-up group. Results from this trial will provide insights regarding health literacy among diabetics with CKD in Malaysia.

Authors' contributions

Hassan NM, principal investigator, conceptualised and designed the study, prepared the draft of the manuscript, and reviewed the manuscript; Yusop YM, leads the module validation, advise on data analysis, and reviewed the manuscript; Wafa SWWSST, contributes to the module and reviewed the manuscript; Jamil AKAA, contributes to the module and reviewed the manuscript; Daud N, contributes to the module and reviewed the manuscript; Juhari SN, contributes to the module and reviewed the manuscript; Yunus NI, contributes to the module and reviewed the manuscript; Idris NA, contributes to the module and reviewed the manuscript; Yusof NA, advise on data analysis and reviewed the manuscript.

Conflict of interest

Authors declare no conflict of interest.

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