The Effectiveness of a Theory-based Health Behaviour Change Intervention on Waist Circumference and Kidney Function in Patients of Metabolic Syndrome with Chronic Kidney Disease: A Pilot Randomised Controlled Trial

Study Protocol and Statistical Analysis Plan

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Introduction

Metabolic syndrome (MetS) is a worldwide chronic disease mainly due to unhealthy diets and sedentary lifestyles (McCracken et al., 2018). According to the International Diabetes Federation (IDF) definition of MetS, patients must have central obesity defined by waist circumference (WC) with ethnicity-specific values, plus any two of four additional factors, namely high triglycerides (TG), low high-density lipoprotein cholesterol (HDL-C), high fasting glucose (FG), and high blood pressure (BP) (Alberti et al., 2006). IDF's definition differs from the other definition in that WC is considered a core component for MetS, which increases the specificity of the diagnosis and reduces the likelihood of over-diagnosing individuals who may have a clustering of additional risk factors (Zhu et al., 2020). The prevalence of MetS in adults has significantly increased since the 90s, with 28.2% (95% confidence interval [CI], 26.7 to 29.7) worldwide (Noubiap et al., 2022) and 25.6% (95% CI, 23.77 to 27.41) in China (Ma et al., 2020).

More recent evidence indicates that the MetS could be an independent risk factor for chronic kidney disease (CKD) (Dobrowolski et al., 2022; Rashidbeygi et al., 2019). CKD is a progressive and incurable condition with high morbidity and mortality, which manifested as an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m^2 or a urine albumin-to-creatinine ratio (UACR) $\geq$ 30 mg/g for at least three months (Delanaye et al., 2019). According to the Kidney Disease Improving Global Outcomes Clinical Practice (KDIGO) 2012 guideline, CKD is divided into five stages (stages 1, 2, 3a, 3b, 4, 5), which are based on the eGFR test result, as the stage progresses, kidney function becomes more severe, ultimately

leading to kidney failure (Delanaye et al., 2019). CKD is currently estimated to affect 10% of adults worldwide (Webster et al., 2017), with the prevalence of CKD in China being extremely high at 8.24% (95%CI: 7.84 to 8.64) (Wang et al., 2023). A recent meta-analysis involving 413,621 participants of which 93,944 had MetS showed that MetS contributed to higher risks of kidney dysfunction (risk ratio [RR] 1.50, 95% CI, 1.39 to 1.61), specifically, rapid decline in eGFR (RR 1.31, 95% CI 1.13 to 1.51), new-onset CKD (RR 1.47, 95% CI 1.37 to 1.58), as well as end-stage kidney disease (ESKD) (RR 1.55, 95% CI 1.08 to 2.22) compared with patients without MetS (Li et al., 2023). Besides, a cross-sectional study (n=383) showed a high prevalence of CKD with 25.59 % (95% CI: 21.20 to 29.98) in Chinese patients with MetS (Li et al., 2014).

Many studies have suggested that central obesity, as the core component of MetS (Alberti et al., 2006), could be one of the essential pathogenesis explaining the association between MetS and CKD (Cao et al., 2015; Tanner et al., 2012). Central obesity mainly manifests as excess abdominal adipose tissue, which directly leads to the deranged synthesis of various adipose tissue cytokines (e.g., leptin, adiponectin, resistin, and visfatin) with nephrotoxic potential to cause sustained damage or structural changes to the kidneys, as well as indirectly trigger insulin resistance, dyslipidemia and hypertension, which are the most substantial risk factors for CKD (Nashar & Egan, 2014; Nogueira & Marreiros, 2022; Zhang & Lerman, 2017). Besides, central obesity was found to be more prevalent in patients with CKD than those without CKD. A population-based study found that central obesity occurred in 29.7%, 45.2%, 40.6%, 40.2%, and 30.7% of patients with CKD stages 1, 2, 3a, 3b, and 4/5, while the rate of

central obesity in non-CKD patients was 23.4% (Evangelista et al., 2018). A recent study even showed that the raw prevalence of central obesity in Chinese adults with CKD was as high as 35.4% (Wang et al., 2023).

Patients with MetS and CKD may not only required to manage symptoms related to MetS and CKD, such as lifestyle management, monitoring of blood pressure, blood glucose levels, lipid profile and kidney function (Chadban et al., 2020; Grundy, 2016), but also face a higher possibility of needing dialysis or kidney transplantation to maintain their life, which could significantly decrease their quality of life (Kostro et al., 2016). The development of CKD is often a silent and asymptomatic process, making it difficult to detect without physical and biochemical examinations. MetS appears to be a readily identifiable target for intervention to reduce the incidence and mortality of CKD. By focusing on the core components of MetS, particularly central obesity, healthcare professionals can better identify individuals at risk and provide targeted interventions to decrease the incidence of CKD and prevent further deterioration of kidney function (Prasad, 2014). However, current limited studies have paid attention to the health needs of this population.

Current therapeutic guidelines for MetS suggest that non-pharmacological interventions (NPIs) with multifactorial lifestyle changes should be the primary treatment, including dietary modification, physical activity (PA), counselling or lifestyle modifications (Grundy, 2016). Besides, the latest studies showed that certain types of NPIs, such as mobile-based health interventions and lifestyle modification, had significantly reduced the prevalence of MetS and alleviated the severity of its components, especially in WC (Rahimi et al., 2022; Sequi-

Dominguez et al., 2020; van Namen et al., 2019). Therefore, NPIs could be an essential method for reducing WC and preserving kidney function for the target population.

Hence, this proposed study aims to develop a theoretical-based NPI for adults with MetS and CKD on the synthesised scientific evidence, and the effects on health-related outcomes will be evaluated using a randomised controlled trial (RCT) study. Before the main RCT, a pilot RCT will be conducted to examine the feasibility and acceptability of the proposed intervention. The hypothesis is (1) the theory-based health behaviour change intervention is feasible and acceptable among Chinese patients with MetS and CKD; (2) Participants in the intervention group will have lower WC, better kidney function, healthier dietary behaviour, higher PA, better exercise capacity and higher self-efficacy than those in the control group at immediate post-intervention (T1).

Findings of Systematic Review

After conducting a literature review, surprisingly limited studies focus on the effectiveness of NPIs among adults of MetS with CKD to reduce WC and preserve kidney function or decelerate the development and progression of CKD. Hence, this study expanded the search strategy of the population to adults with MetS-only to identify this relevant evidence.

Previous studies have suggested that certain types of NPIs (e.g., mobile-based health interventions, lifestyle modification) had a significant change in the reducing prevalence of MetS and alleviating the severity of its components, especially in WC (Rahimi et al., 2022; Sequi-Dominguez et al., 2020; van Namen et al., 2019). However, previously published

reviews could not determine the optimal format, type and key components of NPIs for adults with MetS in reducing WC. Moreover, limited attention has been paid to the effectiveness of NPIs for adults with MetS in preserving kidney function or even decelerating the development and progression of CKD. Evidence on the effectiveness of NPIs of adults with MetS on WC and kidney function remains scarce. Hence, this systematic review (SR) aimed to examine the effectiveness of NPIs in reducing WC and preserving kidney function in adults with MetS.

Methods

Nine electronic databases (Embase, PubMed, Scopus, Web of Science, CINAHL, PsycINFO, Cochrane, CNKI and Wanfang) were searched from inception to 26 April 2024. Randomised controlled trials of adults with MetS receiving NPIs reporting on the outcomes of WC, kidney function, MetS-related components and health-related behaviours were included. The pooled synthesis of intervention effects was reported as the standardised mean difference or mean difference (MD) and its 95% confidence interval (CI). The narrative summary was provided if a meta-analysis was not applicable.

Results

This review included 15 studies with 1,559 participants (Female: 56.9%). The NPI of included studies were categorised into dietary intervention (n=3), physical activity (PA) intervention (n=5) and multi-component intervention (n=7) including dietary and PA intervention, with psychological strategies. The multi-component intervention with psychological strategies showed the largest reduction in WC (MD: -3.45, 95% CI: -5.05 to -1.86), systolic blood pressure (MD: -4.24, 95% CI: -8.23 to -0.25), fasting glucose (MD: -0.24,

95% CI: -0.48 to -0.00), dietary behaviour and PA (all P<0.05). Besides, the PA intervention showed significant improvement in high-density lipoprotein cholesterol (Cohen's d=1.42 and 1.82). Only one of the included studies examined intervention effects on kidney function, showing that the urine albumin-to-creatinine ratio significantly decreased after the multi-component intervention compared with baseline (p<0.05).

Conclusion

The finding of SR suggested that the multi-component intervention, which includes the provision of a low-calorie (negative energy balance of 500 kcal/day) and low-carbohydrate (based on a low glycemic index) diet plan or healthy dietary education, PA education and/or supervised or unsupervised moderate-intensity PA (dosage: 1 to 2.5h/week), assisted with psychological strategies (goal setting, problem-solving, coping skills) in a group or/and individual, face-to-face, smartphone, telephone, email or/and booklet format, and provided by nurse or researcher with health education background at least three months, had strong effectiveness in improving health-related behaviours and MetS-related components, especially in reducing WC. Only one study reported the kidney function outcome, which showed that the multi-component intervention had no significant change in preserving kidney function in adults with MetS. However, the result should not draw a conclusion on the effectiveness of multi-component intervention due to the limited number of included studies. More rigorous studies are needed to confirm the effectiveness and examine a better approach to reduce WC and preserve kidney function.

However, limited information on factors influencing these behaviour change interventions was reported and identified from this SR, therefore studies are needed to explore the possible factors influencing health-related behaviours among Chinese adults of MetS with CKD. Besides, only two included studies indicated that the health belief model (Wong et al., 2023) and the transtheoretical model (Saboya et al., 2017) were used to guide the design and development of the interventions. Hence, the mechanisms behind the intervention and the factors influencing health-related behaviours (e.g., healthy dietary and PA) still need more investigation.

Findings of Qualitative Study

Based on the findings and knowledge gaps from the SR, the proposed intervention to reduce WC and preserve kidney function among adults with MetS mainly involves the most common health-related behaviours, such as regular exercise and healthy dietary (Short & Mollborn, 2015). For patients with MetS-only or comorbid with CKD, health-related behaviour such as dietary adjustment and increased exercise aimed at controlling the associated problematic health conditions (e.g., hypertension, dyslipidaemia, insulin resistance, and diabetes) are currently one of the most affordable and life-long effective interventions (Prasad, 2014).

Previous studies have shown that self-efficacy (Taha et al., 2022), social support (Kim & Park, 2023), perceived barriers and benefits (Wu et al., 2016) could be these factors influencing health-related behaviours among adults with MetS. However, few studies focus on factors

influencing health-related behaviours and needs related to these behaviour changes among adults with MetS and CKD. A deep understanding of the possible factors influencing the identified health-related behaviours (dietary behaviour and PA) from the SR among adults of MetS with CKD is critical to engage these health-related behaviours and ultimately improve patients' health management and overall health outcomes.

The Health Action Process Approach (HAPA) is a commonly used theory in health behaviour change research among patients with chronic diseases. The HAPA suggests that engagement in healthy behaviour is comprised of two main processes: the motivational phase, which involves forming an intention, and the volitional phase, which includes planning to act and taking action (Schwarzer, 2016). Such interventions may include behaviour change techniques specifically designed to increase an individual's motivation to change, facilitate the translation of intentions into action, or both. Besides, motivation (e.g., self-efficacy, intention) and volition (e.g., planning, action control) have been shown to uniquely predict various health behaviours including dietary behaviours (Duan et al., 2022; Ranjbaran et al., 2022) and PA (Dillon et al., 2022; Rollo & Prapavessis, 2020). The latest study has also shown that HAPA-based intervention was effective in modifying health behaviours among patients with CKD (Hu et al., 2023).

Based on these considerations, this proposed study aims to explore the factors influencing healthy dietary behaviour and PA and needs related to these behaviours changes among the Chinese adults of MetS with CKD guided by the HAPA.

Methods

A total of 36 semi-structured, audio-recorded interviews were conducted with adults with MetS, or comorbid with CKD (female: 33.3%, mean age: 39.8 ± 12.5) who volunteered to be interviewed from Sichuan Province. A sociodemographic data collection form was used to collect the sociodemographic and clinical characteristics. 10 open-ended questions guided by HAPA were used to explore patients' perceived barriers, facilitators, experiences and needs among the targeted population. SPSS version 26.0 will be used for quantitative data analyses, and content analysis will be used for qualitative data analysis. Besides, credibility, transferability, dependability and confirmability were employed to establish the trustworthiness of the current study (Anney, 2014).

Results

The interview revealed that the vast majority of patients have a positive attitude towards managing diseases through healthy dietary behaviour and PA, and believe that the main motivation for them to adhere to these health-related behaviours is to stay healthy. secondly, the lack of disease-related knowledge and professional guidance on healthy dietary and PA are the main obstacles they face. Therefore, the provision of such knowledge is most needed at present. However, the reliability and authority of information sources were also emphasized. Thirdly, the importance of advice or inspiration from others and the companionship of family or friends in maintaining health-related behaviours is also emphasized. Finally, unlike MetS-only patients, patients with MetS and CKD needed more professional treatment based on their health condition, and almost all of these patients chose walking or brisk walking as their daily exercise routine.

Conclusions

Dietary behaviour and PA change intervention is feasible and acceptable to people with MetS, or comorbid with CKD in managing health conditions. Interventions could mainly be achieved by providing MetS and CKD knowledge, dietary and PA guidance through healthcare professionals, dietitians or physicians. Also, using group discussions to increase social support. Besides, brisk walking could be an aerobic exercise form for the targeted population as this is commonly performed by the study population.

Methodology

Study design

This pilot study will adopt a 2-arm, pretest-posttest, and assessor-blind RCT design to examine the feasibility and acceptability of a theory-based health behaviour change intervention and examine its effects on WC (primary outcome), kidney function (eGFR, UACR, primary outcome), dietary behaviour, PA, exercise capacity and self-efficacy of diet behaviour and PA among Chinese adults with MetS and CKD.

Settings and participants

Settings

This study will be conducted in the ward and outpatient departments of the nephrology unit of West China Hospital of Sichuan University, and one community hospital.

Inclusion criteria and exclusion criteria

Inclusion criteria. (1) Participants are 18 years old and above; (2) Participants have both diagnoses of MetS based on IDF clinical diagnostic criteria (WC for Chinese: ≥ 90 cm in men and ≥ 80 cm in women, and fulfils two items of the following: TG ≥ 1.7 mmol/L or treatment for hypertriglycerides, HDL-C<1.03 mmol/L in men or <1.29 mmol/L in women or treatment for low HDL-C, FG ≥5.6 mmol/L or previously diagnosed type 2 diabetes, and BP ≥ 130/85 mmHg or treatment for hypertension) (Alberti et al., 2006). and CKD (eGFR < 60 mL/min/1.73 m^2 or a UACR ≥ 30 mg/g for at least three months) (Delanaye et al., 2019); (3) No medical contraindications to exercise, including walking; (4) Participants are capable of understanding and providing informed consent; (5) Own a smartphone for accessing WeChat; (6) Being able to communicate in Chinese; (7) Stay in Chengdu during the study period.

Exclusion criteria. (1) Participants who cannot perform brisk walking exercise; (2) Participants who have already started dialysis or kidney transplant; (3) Current participation in another clinical trial related to health behaviour change or medical trial; (4) Participants who have doctor-diagnosed psychiatric illness ; (5) Participants who have a cognitive impairment, which will be screened by the abbreviated mental test with a score lower than seven (Chan et al., 2013); (6) Adjustment of medication within half a year; (7) Participants who have performed regular planned exercise (Defined as at least 150 minutes of moderate-intensity aerobic activity or 75 minutes of high-intensity aerobic activity per week, or a combination of moderate-intensity and high-intensity aerobic activity) (Olson et al., 2023) within the past month.

Sample Size Calculation

The sample size for the pilot study is identified according to the general rule of thumb (Lancaster et al., 2004), and 40 adults of MetS with CKD will be recruited, each group will have 20 participants. The sampling method will adopt the convenience sampling method.

Randomisation

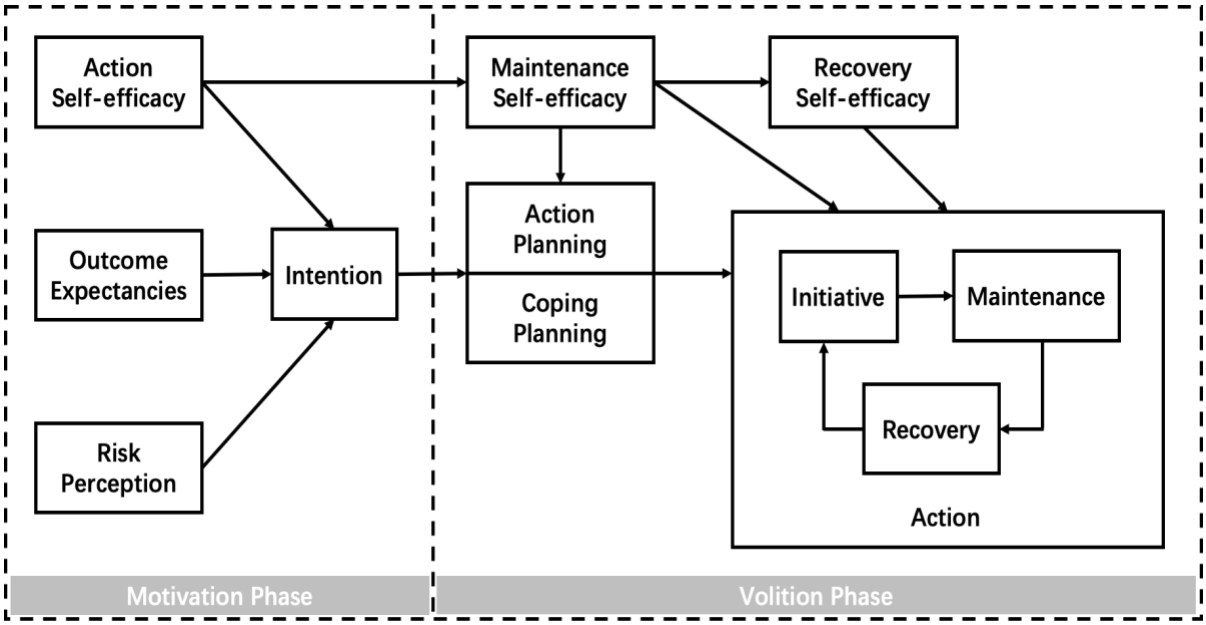
Participants will be 1:1 randomised (blocks of random size of 8) to the intervention and control group, stratified by stage of CKD. Blinded allocation of the participants will be based on computer-generated random numbers with sealed, opaque, sequentially numbered allocation envelopes. The envelopes will be opened by the participants after the baseline assessment. Assessors for all outcomes were blinded to the group assignment of participants. All outcome data remained blinded until the end of the study.

Theoretical framework

The Health Action Process Approach (HAPA) will be adopted to guide this study. Previous studies with the effectiveness in changing health behaviours guided by the HAPA showed that the available dosage of intervention ranged from eight to 12 sessions for each week in eight to 12 weeks (Dillon et al., 2022; Duan et al., 2022; Ranjbaran et al., 2022; Rollo & Prapavessis, 2020). Figure 1 displays the variables associated with each phase, along with hypothesised relationships among the variables.

Figure 1

The Health Action Process Approach



Intervention procedures

Theory-based health behaviour change intervention group

For the intervention group, participants will be enrolled via WeChat and undergo 8 intervention sessions over 12 weeks. WeChat is one of the most popular social media platforms worldwide, and it has been used on a large scale since its release. The latest statistics show that in 2023, there are 827.2 million WeChat users in China, which accounts for 58.9% of the total population (China Internet Watch, 2023).

The 8 intervention sessions contain three parts. The first part will consist of two online individual education sessions related to MetS, CKD, healthy dietary and PA, displaying in the form of texts and pictures, and online instant conversations via WeChat, two online group (6 to 8 participants) music-paced brisk walking training, two group discussions (6 to 8 participants) related to current health status, recommended and dietary regimens and exercise and personal goals, two telephone follow-ups after group discussions to reinforce the predetermined goals and the practice of healthy dietary and music-paced brisk walking, and to provide opportunities

for answering any questions related to the practice of healthy dietary and music-paced brisk walking. All the education sessions' contents are based on a well-structured health handbook. An overview of the intervention sessions is shown in Table 1.

Table 1

Intervention sessions based on the Health Action Process Approach

Session One: Strengthen understanding of MetS, CKD, health dietary, PA and management related to these behaviours		
Format: Individual **Delivery mode:** Online		
Week	**Phase**	**Detail**
1	Motivation phase	a. Briefly self-introduction and study introduction.
		b. Provide knowledge about MetS, CKD, health dietary, PA and management related to these behaviours
		c. Introduce music-paced brisk walking
		d. Ask participants if they have any question about the MetS, CKD, different types of health dietary and PA and their management.
		e. Ask patients to set goals for a healthy dietary and PA, reflecting in waist circumference, weight, exercise time and frequency.
Session Two: Music-paced brisk walking practice		
Format: Group **Delivery mode:** Online		
Week	**Phase**	**Detail**
2	Motivation phase	a. Perform the group music-paced brisk walking.
		b. Ask participants did they make specific action plans of when, where and how to perform healthy dietary and music-paced brisk walking.
Session Three: Get to Know other health-related lifestyle management and self-monitoring methods		
Format: Individual **Delivery mode:** Online		
Week	**Phase**	**Detail**
3	Motivation phase	a. Provide knowledge about tobacco and alcohol consumption, mental health, medicine management and self-monitoring methods.
		b. Strength training, flexibility and balance training recommendations
		c. Ask participants if they have any question tobacco and alcohol consumption, mental health, medicine management and self-monitoring methods.
		d. Ask participants to evaluate their execution of music-paced brisk walking plans and adjust music-paced brisk walking plans if necessary.

Session Four: Music-paced brisk walking practice		
Format: Group **Delivery mode:** Online		
Week	**Phase**	**Detail**
4	Motivation phase	a. Re-emphasis on the importance of exercise in MetS and CKD management.
		b. Perform the group music-paced brisk walking.
		c. Encourage participants to complete training and achieve their goal.
Session Five: Discuss current health status and personal goal		
Format: Group **Delivery mode:** Online		
Week	**Phase**	**Detail**
6	Volition Phase	a. Briefly introduce this discussion content.
		b. Provide information about the reference standards for various indicators and height and weight correspondence table
		c. Guide participants to discuss their health changes and personal goals since participating in the study.
Session Six: How to solve the difficulties and challenges faced during conducting the healthy dietary and music-paced brisk walking.		
Format: Group **Delivery mode:** Online		
Week	**Phase**	**Detail**
8	Volition Phase	a. Briefly introduce this discussion content.
		b. Guide participants to discuss their difficulties and challenges and how they solve them.
Session Seven: Telephone follow-ups about current healthy dietary status and music-paced brisk walking		
Format: Individual **Delivery mode:** Telephone		
Week	**Phase**	**Detail**
10	Volition Phase	a. Briefly introduce this telephone follow-up.
		b. Guide participants to reinforce the practice of conducting healthy dietary and music-paced brisk walking.
Session Eight: Telephone follow-ups to congratulate participants' achievements		
Format: Individual **Delivery mode:** Telephone		
Week	**Phase**	**Detail**
12	Volition Phase	a. Celebrating achievements and providing positive reinforcement.
		b. Guide participants to reinforce the practice of conducting healthy dietary and music-paced brisk walking.

Note. PA: physical activity; MetS: metabolic syndrome; CKD: chronic kidney disease.

Besides, participants in the intervention group will be required to perform moderate-intensity PA at least 150min/week. Brisk walking (refer as 3000 steps in 30 minutes, or 100 steps per minute) has been well-reported as a safe moderate-intensity exercise (O'Brien et al.,

2018; Tudor-Locke et al., 2020). Walking with appropriate music tempo is one of the simple and easy-to-master methods of brisk walking, and it has been shown to be a useful regulatory tool to prompt the free-living individual to reach an appropriate stride rate to achieve a walking pace that is at least moderate-intensity PA (Faulkner et al., 2021). Previous studies also showed that after considering the different heights and weights, the optimal walking tempo for synchronisation with music was 100 to 120 beats per minute (bpm) (Etani et al., 2018; Styns et al., 2007).

Participants can choose nine songs (each song is about three minutes long) suitable for themselves from our song list with the music tempo ranging from 100 to 120 beats/minute. Participants will be required to perform music-paced brisk walking, including a 5-minute warm-up, 30-minute music-paced brisk walking and 5-minute stretching exercises to promote cool-down five days per week. Besides, participants will be required to send their daily walking record, which can be obtained from WeRun (a mini monitoring program in WeChat) to the researcher via WeChat. If the daily walking record of the participants is less than 3000 or has not been sent for two consecutive days in a week, the researcher will remind the participants separately through WeChat.

Control group

The participants in the control group will follow the routine care provided by the hospitals. In addition to providing the contact number of the nephrology unit in case they have medical needs, any other additional support during the intervention period will not be provided. After the 12-week intervention ends, the control group will be provided with the same information

given to the intervention group to raise the awareness of its members regarding the need for healthy dietary, daily exercise and disease care after the entire study is completed.

In order to maximise the retention rate, some reminder strategies will be implemented. For example, WeChat messages will be sent to the participants before each intervention session to remind them to participate in the intervention or group discussion, and also will be sent to participants to confirm the time for telephone follow-up the next day. Besides, exercise reminders will also be conducted.

The feasibility of the intervention will be assessed by the recruitment rates, attrition rates and attendance rates for the intervention. In addition, reasons for exclusion, refusal to participate, incompletion and dropout will be recorded.

The acceptability of the intervention will be assessed through semi-structured interviews with participants in the intervention group within one week of completion of the intervention. The theoretical framework of acceptability is used to identify the interview outline (Sekhon et al., 2022). The outline of the semi-structured interview is presented in Appendix I, and the principal investigator (PI) will conduct the interviews via Tencent Meeting. All the interviews will be audio-recorded, transcribed verbatim and analysed using direct content analysis.

Content validation

An expert panel review will be invited to read and provide comments to examine the validity and acceptability of the information provided in the intervention using the Content Validity Index (CVI) (Almanasreh et al., 2019). The expert panel will be composed of one

experienced physician, one experienced dietitian, two senior nurses who take care of MetS or CKD patients, and one academic professor in nursing.

Treatment fidelity

The intervention will be delivered in accordance with a standardised protocol. The PI will conduct all the intervention sessions in the daily outpatient clinic and ward rounds to ensure the consistency of the intervention. A checklist will be used for audit checking on the intervention provision, and the dose of each session will be recorded.

Outcome measures

Waist circumference

WC will be measured at the midpoint between the lower rib and the top of the iliac crest with the relaxed abdomen with a non-stretchable plastic measuring tape with an accuracy of 0.1 cm (Ness‐Abramof & Apovian, 2008).

Kidney function

Blood samples will be obtained in the morning after fasting for at least 12 hours, and they will be refrigerated immediately after phlebotomy and centrifuged within 2 hours of collection (Sun et al., 2016). Blood Samples will be analysed for eGFR. The eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation for Chinese individuals (Kong et al., 2013). Venipuncture will be performed by doctors or nurses in the department of clinical laboratory in the hospital or the ward of the nephrology unit. Morning urine samples will be collected in the refrigerator immediately to measure the levels of urine albumin and

creatinine; then, the UACR will be calculated. All blood samples and urine samples will be sent to the department of clinical laboratory at the research hospital for investigation.

According to the KDIGO and IDF guidelines of frequent assessment of CKD (KDIGO, 2012), if the participant has done the eGFR test in the hospital within three months of any data collection time point, this blood result will be used.

PA

The Chinese version of the short form of the International Physical Activity Questionnaire (IPAQ-SF) will be used to evaluate the amount of weekly PA. IPAQ was developed by the WHO in 1998 to access PA (Bassett Jr, 2003). The IPAQ-SF records PA with nine questions, including vigorous, moderate-intensity, walking, and sitting. The simplified Chinese version of IPAQ-SF has shown good internal reliability and test-retest stability (total intraclass correlation coefficient [ICC]=0.84, 95%CI 0.76 to 0.89) (Lou & He, 2019). Besides, the IPAQ-SF records self-reported physical activity in the last seven days, and the responses were converted to Metabolic Equivalent Task minutes per week (MET-min/wk). Total minutes over the last seven days spent on vigorous activity, moderate-intensity activity, and walking were multiplied by 8.0, 4.0, and 3.3, respectively, to create MET scores for each activity level.

Exercise capacity

6MWT is an assessment to measure the distance a person is capable of walking on a flat, hard surface in 6 minutes, and will be performed according to the American Thoracic Society's guideline (Laboratories, 2002). It has been validated in MetS or CKD population (Heubel et al., 2018; Wilkinson et al., 2019). Participants will be asked to walk back and forth in 6 minutes

at their usual speed along a straight 30-meter hospital corridor with marks every 5 meters. Throughout the test, patients will be permitted to slow down, pause, or take breaks as needed, but also be expected to resume walking when they feel ready. Give encouragement using standard phrases from the guide (Holland et al., 2014). Dyspnea and fatigue during the walk will be graded by the 10-scale Borg scale (Shariat et al., 2018). Heart rate, oxygen saturation, BP and total distance covered will be measured immediately before and after the 6MWT.

Dietary behaviour

The diet control subscale of the Chinese version of Chronic Kidney Disease Self-care (CKDSC-DC) and the nutrition domain of Health Promoting Lifestyle Profile-II (HPLP-II-N) will be used to measure dietary behaviour. The CKDSC scale is a 16-item questionnaire designed to measure self-care behaviour for people with CKD with five subscales, one of which is diet control (4 items). Based on the Likert scale, responses ranged from 1 (almost never) to 5 (almost always), and the higher scores indicate better CKD self-care behaviours in diet control. A total score of 14 or more is considered healthy dietary behaviour. The overall validity and reliability of the Chinese version of CKDSC were satisfactory, with Cronbach's α of 0.83. For the diet control subscales, Cronbach's α was 0.83 (Wang et al., 2016).

HPLP-II has 52 items, covering six domains: health responsibility, physical activity, spiritual growth, nutrition, interpersonal relations and stress management. The Chinese version of HPLP-II has a good internal consistency with an overall Cronbach’s alpha of 0.95, and the Cronbach’s alpha of each domain is: health responsibility (0.81), physical activity (0.83), nutrition (0.72), spiritual growth (0.84), interpersonal relations (0.84), stress management

(0.80). In this study, only the domain of nutrition will be used, and the participants will be required to rate on a 4-point Likert scale from 1 (not at all) to 4 (always). A total score of 22.5 or greater is considered healthy dietary behaviour (Zhou et al., 2022).

The CKDSC-DC provides a disease-specific measure of dietary behaviour in the context of CKD (Wang et al., 2016). While, the HPLP-II-N evaluates various aspects of healthy dietary practices, such as consuming a balanced diet, limiting unhealthy food choices, and following dietary recommendations. It provides a broader perspective on overall health-promoting behaviour, including nutrition, among individuals with Mets or CKD (Zhou et al., 2022). Therefore, combining the CKDSC-DC and HPLP-II-N allows for a more comprehensive understanding of disease-specific dietary behaviours and general health-promoting dietary behaviours among patients with MetS and CKD.

Self-efficacy of dietary behavior and physical activity

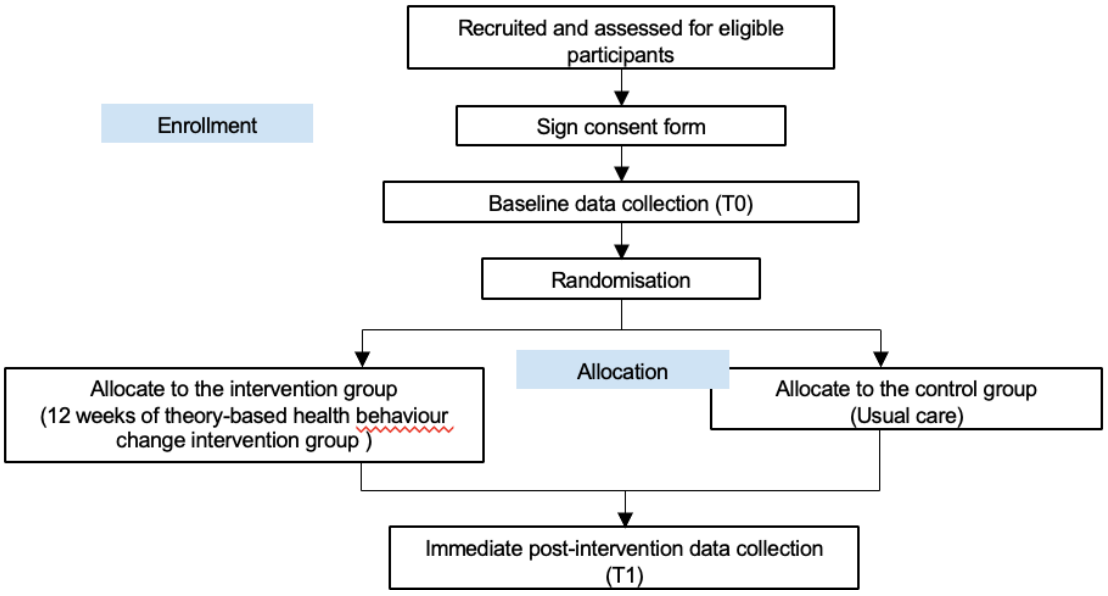
The Chinese version of Health-Related Diet and Exercise Self-Efficacy Scale - simplified version (HRDESES) included 8 items under 2 dimensions: diet subscale and exercise subscale. Response options are rated on a 5-point scale: 0 (I'm not sure), 1 (mostly I cannot), 2 (don't know), 3 (mostly I can), or 4 (I'm sure I can). The total score ranges from 0 to 32, with a higher score indicating higher levels of health-related diet and exercise self-efficacy. HRDESES showed good internal consistency with a Cronbach's α of 0.87 for the total scale, 0.86 for the diet subscale and 0.91 for the exercise subscale (Mao et al., 2022).

Data collection procedures

The PI and one trained RA will recruit potential participants previously diagnosed with MetS and CKD in the nephrology unit. If the patients meet the inclusion criteria for recruitment, they will be given an information sheet to explain the study. If they agree to participate, written informed consent will be obtained. After completing baseline questionnaires, eligible participants will be randomly assigned to the intervention or control groups. Besides, the researchers will add participants' WeChat accounts for the coming intervention. The participant recruitment flow is shown in Figure 2.

Figure 2

Participant recruitment flow



group allocation to reduce the detection bias. Before data collection, the intraclass correlation coefficient will assess inter-rater reliability, with a value greater than 0.75 indicating good inter-rater reliability (Koo & Li, 2016). The schedule of data collection is shown in Table 2.

Table 2

Schedule of data collection

Outcomes	Measurements	T0	T1
Sociodemographic characteristics	Self-reported questionnaire	✓	
WC	Anthropometric measure	✓	✓
Kidney function	Biochemical measures	✓	✓
PA	IPAQ-SF	✓	✓
Exercise capacity	6MWT	✓	✓
Dietary behaviour	CKDSC-DC, HPLP-II-N	✓	✓
Self-efficacy of dietary behaviour and PA	HRDESES	✓	✓

Note. T0: baseline; T1: immediate post-intervention; T2: one-month post-intervention; WC: waist circumference; PA: physical activity; IPAQ-SF: the simplified Chinese version of the short form of the International Physical Activity Questionnaire; 6MWT: Six-Minute Walk Test; CKDSC-DC: the diet control subscale of the Chinese version of Chronic Kidney Disease Self-care Scale; HPLP-II-N: the nutrition domain of Health Promoting Lifestyle Profile-II; HRDESES: the Chinese version of Health-Related Diet and Exercise Self-Efficacy Scale - simplified version

Data analysis

Descriptive statistics such as frequency, percentage, mean and SD (normal data), median and interquartile range (non-normal data) will be used to summarise the outcomes and other variables. The data distribution will be examined for normality using skewness and kurtosis statistics. Two-sample independent T-test, Mann-Whitney U test (continuous variables with or without normal distribution), Pearson's Chi-Square (categorical variables) and Fisher's exact test (if the minimum expected frequency in the contingency table is less than 5) will be used to compare outcome variables between the two groups. The data will be analysed under the

intention-to-treat principle (Hollis & Campbell, 1999). The missing data imputation will be performed based on the observed data and the assumed missing data mechanism. The between-group intervention effects across time were examined using the generalised estimation equations model (Zeger & Liang, 1986). The two-sided level of significance will be set at 0.05 (Lann, 1959), and IBM SPSS 26.0 will be used for statistical analysis.

Ethical consideration

Participation in the study will be voluntary, and all potential participants will be assured that they have the right to refuse or withdraw from the study at any time without penalty. A trained researcher will solicit written informed consent from each participant after the eligibility assessment. No any form of incentives will be provided to the participants. Although there will be no unexpected risks in this study, participants will still be encouraged to seek medical support or any other additional support for their medical needs.

All data will be coded by study identification numbers with no identifying personal information, and will remain confidential and stored on a password-protected computer for six years. In order to protect participants' privacy, the personal information of participants will be collected only once during baseline data collection and then deidentified with participant code (instead of name). Since there are WeChat group discussions in the intervention, relevant principles (e.g., using pseudonyms and hiding personal information) will be informed when establishing WeChat groups to avoid the leakage e of participants' personal information. All collected data will be destroyed after the six-year storage period.

Ethics approval will be obtained from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee and West China Hospital Sichuan University Ethics Committee. The study protocol conforms to the ethical guidelines of the Declaration of Helsinki and will be registered at www.ClinicalTrials.gov.

Fundings

None.

Conflicts of interest

None declared.

Significance of the study

To the best of my knowledge, this is the first study to develop a prospective, single-blinded, two-arm RCT design with repeated measures to evaluate the effectiveness of a theoretical-based dietary and PA behaviour change intervention in WC and kidney function among adults of MetS with CKD in Chinese population. From a scientific perspective, the results will also help increase the knowledge base for applying a dietary and PA behaviour change intervention to reduce WC and preserve kidney function among the target population.

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Appendix I

Intervention Acceptability Interview

The entire interview involved a total of 8 topics and lasted 20 minutes. You can refuse to answer if any of the questions make you uncomfortable. The entire interview will be recorded for later verbatim transcription and analysis.

1. Let's start with "How you feel about the intervention".

- Did you like or dislike this multi-component behaviour change intervention? From 1 to 5, "1" is "Strongly dislike", "3" is "No opinion", while "5" is "Strongly like". What number do you choose? Can you tell me why?

2. The second topic is related to "The amount of effort required for you to participate in the intervention".

- How much effort did it take to engage with this multi-component behaviour change intervention? From 1 to 5, "1" is "No effort at all", "3" is "No opinion", while "5" is "Huge effort". What number do you choose? Can you tell me why?

3. The third topic is related to "The extent to which the intervention has a good fit with your value system".

- Are there moral or ethical consequences to engage with this multi-component behaviour change intervention? From 1 to 5, “1” is “Strongly disagree”, “3” is “No opinion”, while “5” is “Strongly agree”. What number do you choose? Can you tell me why?

4. The fourth topic is related to “The extent to which the intervention has achieved its intended purpose”.

- Has this multi-component behaviour change intervention improved your health-related behaviours and clinical condition? From 1 to 5, “1” is “Strongly disagree”, “3” is “No opinion”, while “5” is “Strongly agree”. What number do you choose? Can you tell me why?

5. The fifth topic is related to “The extent to which you understand the intervention works”.

- Is it clear to you how this multi-component behaviour change intervention will help improve your health-related behaviours and clinical condition? From 1 to 5, “1” is “Strongly disagree”, “3” is “No opinion”, while “5” is “Strongly agree”. What number do you choose? Can you tell me why?

6. The sixth topic is related to “Your confidence that you can perform behaviours required to participate in the intervention”.

- How confident did you feel about engaging with this multi-component behaviour change intervention? From 1 to 5, “1” is “Very unconfident”, “3” is “No opinion”, while “5” is “Very confident”. What number do you choose? Can you tell me why?

7. The seventh topic is related to “The benefits, profits or values that were given up to engage in the intervention”.

- Did engaging in this multi-component behaviour change intervention interfere with your other priorities? From 1 to 5, “1” is “Strongly disagree”, “3” is “No opinion”, while “5” is “Strongly agree”. What number do you choose? Can you tell me why?

8. The last topic is related to “The general acceptability of the intervention”.

- How acceptable was this multi-component behaviour change intervention to you? From 1 to 5, “1” is “Completely unacceptable”, “3” is “No opinion”, while “5” is “Completely acceptable”. What number do you choose? Can you tell me why?