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

Informed Consent Form

Investigator Information

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Investigator Official Title: Principal Investigator

Investigator Affiliation: The Chinese University of Hong Kong

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Consent Form

Dear Madam/Sir:

You are cordially invited to join the study entitled "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". The study is undertaken by YAN Linjia, a PhD student at the Nethersole School of Nursing, Faculty of Medicine, the Chinese University of Hong Kong. Her academic supervisor is Professor CHENG Ho Yu from the Nethersole School of Nursing, Faculty of Medicine, the Chinese University of Hong Kong.

Please read the informed consent form carefully before you decide to participate in the study. You can raise any questions or concerns if there is anything you don't understand, and researchers will explain it individually until you fully understand it. Before participating in this study, you can discuss this with your family or friends. If you are participating in another study, please tell your researchers.

1. Why is the study needed?

This study aims to examine the feasibility and acceptability of a theory-based health behaviour change intervention for improving waist circumference and kidney function among adults of metabolic syndrome with chronic kidney disease.

2. Who will be invited to participate in the study?

(1) Participants are 18 years old and above;

(2) Participants have both diagnoses of metabolic syndrome based on the International Diabetes Federation clinical diagnostic criteria (waist circumference for Chinese: ≥ 90 cm in men and ≥ 80 cm in women, and fulfils two items of the following: triglycerides ≥ 1.7 mmol/L or treatment for hypertriglycerides, high-density cholesterol < 1.03 mmol/L in men or < 1.29 mmol/L in women or treatment for low high-density cholesterol, fasting glucose ≥ 5.6 mmol/L or previously diagnosed type 2 diabetes, and blood pressure ≥ 130/85 mmHg or treatment for hypertension) and chronic kidney disease (eGFR < 60 mL/min/1.73 m^2 or a UACR ≥ 30 mg/g for at least three months);

(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.

3. How many people will participate in the study?

The study is expected to involve 40 participants.

4. Study Procedure

This is a three-month pilot randomised controlled trial. If you volunteer to participate in the study, you will be randomly assigned to one of two groups. The intervention group will participate in the theory-based health behaviour change intervention mainly via WeChat. The intervention will include a total of 8 online sessions. Besides, you will be required to conduct 30 minutes of music-paced brisk walking five days a week. The control group will only receive health recommendations via WeChat.

During the study, you will complete two time points (baseline and immediate post-intervention) online questionnaires on a smartphone with the assistance of a researcher for around 20 minutes. We will collect your clinical characteristics from the hospital information system, including diagnosis, blood test results, history of the present illness and past medical history. Besides, the questionnaire will collect the following information: sociodemographic characteristics, the short form of the International Physical Activity Questionnaire, Six Minute Walking Test, the Diet Control Subscale of the Chronic Kidney Disease Self-care, the nutrition domain of Health Promoting Lifestyle Profile-II and the Health-Related Diet and Exercise Self-Efficacy Scale - simplified version.

The acceptability of the intervention will be assessed through semi-structured interviews with intervention group participants within one week of intervention completion.

5. Potential Risks

Participating in the study will not cause any risk. You may feel slightly short of breath or tired while participating in the intervention, which is normal. In addition, you may feel some

discomfort or pain during the physical health assessment or blood collection, but these will be brief and mild. If you feel uncomfortable with specific questions in the questionnaire, you can refuse to answer them.

6. Potential Benefits

If you agree to participate in the study, all the results will be directly reported to you. At the same time, feedback from your participation in this study can inform future management of metabolic syndrome complicated by chronic kidney disease. We want to thank you for participating in scientific research and contributing to the development of medicine!

7. Voluntary Participation

You can withdraw at any time without any impact on your interests. After your withdrawal, the researcher will keep your relevant information (including the blood sample) until the destruction and will not continue to use or disclose this information.

8. Research Cost

There will be no additional cost to participate in this study.

9. Research Harm

There is unanticipated harm associated with this study.

10. Personal Information Protection

Your participation in the study will be strictly confidential. Your evaluation questionnaire is digitally coded, and the staff and reviewers of this survey can only see the number without your name. All hard copies of the personal data will be stored in a locked cabinet, and electronic data will be stored in a password-protected computer. Only the principal investigator will have access to the data. The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee have access to the study data for ethics review purposes. Your personal identity will not be disclosed in future publishing articles. All data would be stored for six years and would be destroyed thereafter.

11. Contact details

If you have any questions related to the study, please feel free to contact YAN Linjia (Tel: +86 157 7592 8530 / Email address: 1155185244@link.cuhk.edu.hk); Or the academic supervisor Professor CHENG Ho Yu (Email address: hycheng@cuhk.edu.hk).

If you have any questions related to your rights, contact the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Tel: +852 3505 3935 / Email address: crec@cuhk.edu.hk).

Statement of Consent

I have read the above information and understand the purpose of this study and the potential risks and benefits of participating in this study. All my questions about the research procedure and content have been answered. I agree to provide health information for this study. I signed this informed consent form voluntarily and participated in this study voluntarily.

_____	_____	_____
Patient's name	Patient's signature	Date
_____	_____	_____
Researcher's name	Researcher's signature	Date