The effectiveness of a theory-driven behavioural change intervention on sedentary behaviour in patients with coronary heart disease: A randomised controlled trial
Participant Information Form

Research Objectives and Plans:

This randomised controlled study aims to investigate the effectiveness of a theory-driven behavioural change intervention on sedentary behaviour in patients with coronary heart disease. You will be invited to participate in this nine-month study and will be randomly assigned to either the control group or the intervention group (i.e. you will have half the chance of receiving one of the mentoring options). After random allocation, you cannot change groups.

The intervention lasted 12 weeks, with a total of four face-to-face meetings and four phone follow-ups, and the entire meeting was recorded. The intervention group will receive a total of three face-to-face personal guidance sessions conducted by the research nurse in the first three weeks, each session lasting about 45 minutes. The research nurse will start by examining your personal habits to start and teach knowledge and care about coronary heart disease. Over the next eight weeks, the study nurse will have four personal phone calls (once every two weeks) and provide ongoing support. At week 12, the research nurse will have a face-to-face meeting with you for about 30 minutes to review the process and your achievements. The control group received face-to-face personal guidance on coronary heart disease knowledge and care by the research nurse three times for about 45 minutes each during the first three weeks. For the next eight weeks, the study nurse will follow up with four personal phone calls (once every two weeks) to check on you. At the 12th week, the research nurse will have a face-to-face meeting with you for about 30 minutes to summarise the knowledge and nursing skills taught about coronary heart disease.

Before and after the intervention and six months after the intervention, you will be invited to use a wearable measurement device to record your moderate-intensity exercise and sedentary behaviour time for seven consecutive days and to complete relevant questionnaires. We will also collect your general background information to understand the impact of these factors on the effectiveness of the intervention. In addition, participants in the intervention group will have the opportunity to participate in individual interviews to learn about your experience with the programme.

Target Participants:

Conditions for participants: adult 18 years old and above, diagnosed with coronary heart disease within one year, engaged in MVPA less than 150 minutes per week and a minimum of 8 hours total sedentary time per day, both assessed using the Global Physical Activity Questionnaire, able to communicate in Cantonese, obtained medical clearance for physical activity (no medical contraindications to exercise, including walking), being able to understand and give informed consent, and having telephone access, text messaging services or WhatsApp. Participants will be excluded if they: cannot perform brisk walking exercise, are unable to perform PA independently with cognitive impairments, as indicated by an abbreviated mental test score of less than 7, are currently enrolled in another clinical trial focusing on limiting SB with/without enhancing PA, or have a doctor-diagnosed psychiatric illness.

Risk:

Participation in research does not cause harm. Whether or not to participate in this study is purely your personal decision. If you decide to participate in the program, you can keep this letter and sign a consent form. Even if you agree to participate, you still have the right to refuse to answer any questions or withdraw from the program at any time without giving any reason. Your decision will in no way affect the medical care you currently receive or lead to any negative consequences.

Benefits:

If you agree to participate in this study, results related to moderate-intensity exercise and sedentary behaviour will be shared as recorded in the wearable measurement device. At the same time, your participation in this research will help develop future support services for patients with coronary heart disease.

Allowances:

Each study participant will receive a cash voucher worth HK$50 (HK$150 in total) after completing each survey to compensate for the time spent.

Data Protection:

Your data will be kept strictly confidential and will be used for research purposes only. All research data (including audio recordings and measurement records during the intervention) will be properly stored and managed in accordance with the Confidentiality and Privacy Policy of the Chinese University of Hong Kong and handled in accordance with the Personal Data (Privacy) Ordinance (Cap. 486 of the Laws of Hong Kong) to protect your privacy. Sensitive information about individuals will only be identified by code numbers. If we use an online video conferencing platform, we will set a password to join the online meeting, and only researchers and invited participants can participate. In addition, all collected paper data is kept in a locked cabinet, while electronic data is stored in a password-protected computer. Only the researchers in question have access to this data. The Joint Committee on Clinical Research Ethics of the New Territories East Cluster also has access to the study data for ethical review. The information obtained from this study may be published in international medical journals or presented at conferences, but the personal identities of the participants will not be disclosed. All personal data will be stored for six years and then destroyed.

Voluntary participation:

Your participation in this study is entirely voluntary. You can withdraw from the study at any time without facing negative consequences. After you opt out, researchers retain information about you until it is destroyed and will not continue to use or disclose it.

Funding sources:

No external funding was received for this study.

Contact:

If you have any questions about this study, please contact the lead researchers listed below:

Ms. Elaine Yi Ning Miu, PhD student, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong. Telephone: 3943 0516.

Associate Professor Cheng Ho Yu, the Academic Supervisor, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong. Email address: hycheng@cuhk.edu.hk.

If you have any questions about your rights, you may also consider contacting:

Joint Committee on Clinical Research Ethics of the New Territories East Cluster, Telephone: 3505 3935.

Office of the Privacy Commissioner for Personal Data, Hong Kong, Telephone: 28272627.

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Informed consent form for participants

I hereby agree to participate in the above study.

I have read the above information and have received answers to all my questions. I understand this study and agree to provide relevant information for this study. I will be subject to intervention and telephone follow-up, questionnaires, interviews and general background information and health information.

I can terminate my participation in this study at any time without affecting the quality of my services and treatment, and all information provided will be recorded anonymously and kept confidential, but the overall research results will be published in international medical journals or conferences.

I voluntarily sign this informed consent form and agree that the information and audio recordings collected will be kept by the researchers for six years after the conclusion of the study in accordance with the Personal Data (Privacy) Ordinance (Cap. 486 of the Laws of Hong Kong) and the Confidentiality and Privacy Policy of the Chinese University of Hong Kong, and then destroyed.

By signing below, I agree to participate in the study.

Participant Signatures:	_____ (Name:).	Date:	_____
Signature of the person who obtained the consent form :	_____ (Name:).	Date:	_____

After signing the consent form, I will be provided with a copy of the information page of this study and a copy of the signed consent form for safekeeping.