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A theory-driven behavioural change intervention to reduce sedentary time in individuals with coronary heart disease

Submission date 23/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 23/10/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/04/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Coronary heart disease (CHD) is a worldwide health problem and a major contributor to disability, with a high prevalence of 315 million cases globally in 2022. Promoting movement behaviours, which are characterised by having an adequate amount of physical activity (PA) and replacing sedentary behaviour (SB) with PA of all intensities, is beneficial for cardiometabolic health and thus secondary prevention. However, reviews of interventional studies indicate that currently available non-pharmacological interventions (NPIs) are effective in increasing the amount of PA, yet limited attention is given to the reduction of SB in current cardiac rehabilitation. Therefore, it is imperative to develop an NPI targeting SB for adults with CHD based on the synthesised scientific evidence. The design of the theory-driven behavioural change intervention is based on the findings of our systematic review and the implications of the qualitative study.

This study comprises both a pilot and a main randomised controlled trial (RCT) to evaluate a theory-driven behavioural change intervention for individuals with CHD. The objective of the pilot RCT is to assess the feasibility and acceptability of the intervention and to explore its preliminary effects on total sedentary time, moderate-to-vigorous PA time, intention to change behaviour, future time perception (consideration of future consequences), behavioural prepotency, and self-regulation capacity. The main RCT aims to examine the effectiveness of the intervention in reducing total sedentary time (primary outcome) and improving MVPA, behavioural intentions, future time perception, behavioural prepotency, and self-regulation capacity in a larger sample.

Who can participate?

Individuals aged 18 years or above who have been diagnosed with coronary heart disease (CHD) within the past year will be invited to participate. Eligibility will be assessed using a standardised screening protocol before recruitment.

What are the possible benefits and risks of participating?

The study does not pose a potential harm to participants. Participants will be encouraged to communicate with the principal investigator (PI) whenever they need information about CHD

and to report any adverse events. Participants will be asked to start the brisk walking at a low intensity and gradually increase in frequency, duration, and intensity. The intervention booklet provided to the participants also included the signs and symptoms that they may encounter during the exercise, such as angina, breathlessness, tiredness, nausea, and vomiting, as well as information on how to manage these symptoms. If they experience any discomfort and need to seek medical help, they will be advised to stop exercising immediately. An emergency card containing the name of the PI, contact information, and a statement confirming that the participants have joined this study will be given to all participants for communication purposes in case they experience any discomfort during the exercise. They will be recommended to go to the Accident and Emergency unit if necessary.

Where is the study run from?
This clinical trial is run from the Chinese University of Hong Kong, with participating sites in Hong Kong.

When is the study starting and how long is it expected to run for?
September 2023 to April 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Principal investigator: Elaine Yi Ning Miu, elainemiu@link.cuhk.edu.hk
Corresponding person: Prof. Ho Yu Cheng, hycheng@cuhk.edu.hk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
CREC_2025.458

Study information

Scientific Title
The effectiveness of a theory-driven behavioural change intervention on sedentary behaviour in individuals with coronary heart disease: A pilot randomised controlled trial

Study objectives
Current study objectives as of 07/04/2026:

Objective of the pilot RCT:
To examine the feasibility and acceptability of the theory-driven behavioural change intervention and to evaluate preliminary effects on total sedentary time (primary outcomes), moderate-to-vigorous physical activity (MVPA) time, intention of behavioural change, future time perception (consideration of future consequences), behavioural prepotency, and self-regulation capacity in individuals with coronary heart disease using a RCT study.

Hypotheses:
Compared to the participants in the control group, participants in the intervention group will demonstrate:
1. Significantly less total sedentary time
2. Significantly improved MVPA time,
3. Significantly better intention of behavioural change,
4. Significantly higher level of behavioural prepotency,
5. Significantly enhanced self-regulation capacity, and
6. Significantly greater future time perception
at the immediate post-intervention (T1), the 1-month post-intervention (T2), and the 6-month post-intervention (T3).

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Previous study objectives:

This study involves a pilot randomised controlled trial (RCT) and the main RCT.

Objective of the pilot RCT:
To examine the feasibility and acceptability of the theory-driven behavioural change intervention and to evaluate preliminary effects on total sedentary time (primary outcomes), moderate-to-vigorous physical activity (MVPA) time, intention of behavioural change, future time perception (consideration of future consequences), behavioural prepotency, and self-regulation capacity in individuals with coronary heart disease using a RCT study.

Objective of the main RCT:
To examine the effectiveness of a theory-driven behavioural change intervention for total sedentary time (primary outcomes), moderate-to-vigorous physical activity time, intention of behavioural change, future time perception, behavioural prepotency, and self-regulation capacity in individuals with coronary heart disease.

Hypotheses:
Compared to the participants in the control group, participants in the intervention group will demonstrate:
1. Significantly less total sedentary time
2. Significantly improved MVPA time,
3. Significantly better intention of behavioural change,
4. Significantly higher level of behavioural prepotency,
5. Significantly enhanced self-regulation capacity, and
6. Significantly greater future time perception
at the immediate post-intervention (T1), the 1-month post-intervention (T2), and the 6-month post-intervention (T3).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/09/2025, The Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital Shatin, Hong Kong, 00000, Hong Kong; +852 (0)3505 3935; crec@cuhk.edu.hk), ref: CREC_2025.458

Study design
Two-arm pretest-post-test and assessor-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention

Health condition(s) or problem(s) studied
Prevention of recurrent myocardial infarction or coronary revascularisation in patients with coronary heart disease

Interventions
Participants will be recruited from the Prince of Wales Hospital in Hong Kong. Potential participants will be assessed and invited to participate in this study by the principal investigator. After the participants provide informed consent and baseline data, they will be randomly

allocated to the intervention group or the control group in a 1:1 ratio using a randomised block design. The random sequence will be generated via a computerised randomisation program and will be concealed using sealed, opaque envelopes prepared by a research assistant, who will not be involved in participant recruitment or data collection. The sealed envelope will be given to the study participant after the baseline assessment. Due to the nature of the interventions, it is not feasible to blind the intervention provider and participants to the group allocation. However, the data collector will be blinded to the group allocation.

Intervention group:
In addition to the usual care, which is the same as the control group, participants allocated to the intervention group will receive a 12-week theory-driven behavioural change intervention. The intervention will be delivered by the PI to ensure consistency and is structured into eight individual sessions, including four face-to-face sessions (45 minutes each) and four telephone sessions (20 minutes). The intervention is underpinned by the Temporal Self-Regulation Theory (TST). Intervention sessions focus on strengthening intention to change (connected beliefs and temporal valuations), behavioural prepotency and enhancing the self-regulatory capacity, as guided by the TST.

Control group:
Participants in the control group will continue to have the usual care, which includes regular follow-up at the cardiac clinic. In Hong Kong, cardiac patients' conditions are reviewed regularly to adjust drug regimens and to remind participants to stay physically active. Education sessions, consisting of information about healthy lifestyles, except PA and SB, with the same schedule as the intervention group, will be provided to account for potential attention effects from contacts.

Intervention Type
Behavioural

Primary outcome(s)
Total sedentary time (per day) will be measured using the ActiGraph accelerometer (ActiGraph, Pensacola, FL), wGT3X-BT (during participants' waking time over 7 consecutive days, including both weekdays and weekends), at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (one month after intervention), and T3 (6 months after intervention).

Key secondary outcome(s))
1. Moderate-to-vigorous physical activity time (per week) will be measured using the ActiGraph accelerometer (ActiGraph, Pensacola, FL), wGT3X-BT (during participants' waking time over seven consecutive days, including both weekdays and weekends), at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (one month after intervention), and T3 (6 months after intervention).
2. Self-regulation capacity will be measured using the Chinese version of the Brief Self-Control Scale (BSCS) at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (one month after intervention), and T3 (6 months after intervention).
3. Behavioural prepotency (on both MVPA and SB) will be measured using the Chinese version of the Self-Reported Behavioural Automaticity Index (SRBAI) at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (1 month after intervention), and T3 (six months after intervention).
4. Future time perception will be measured using the Chinese version of the Consideration of Future Consequences Scale (CFCS-14) at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (1 month after intervention), and T3 (6 months after intervention).
5. Intention of behavioural change will be measured using three questions, including (1) I intend

to ...; (2) I plan to ...; and (3) It is likely that I will ... Specifically, questions such as "I intend to do at least 150 minutes of MVPA in the coming week" and "I intend to engage in less than 8 hours of total sedentary time per day in the coming week" will be asked, and participants will respond on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree." The sum average will be calculated. Higher scores represent higher intention. This outcome will be measured at T0 (on enrollment), T1 (immediately after a 3-month intervention), T2 (1 month after intervention), and T3 (6 months after intervention).

For the pilot RCT, in addition to the outcomes above, the following will also be measured:
1. Feasibility of the intervention will be measured through participants' attrition rates and attendance rates at T1 (immediately after a 3-month intervention). Reasons for exclusion, refusal to participate, and any record of incompletion or dropout will be documented.
2. Acceptability of the intervention will be assessed using a semi-structured interview guide based on the Theoretical Framework of Acceptability (TFA) at T1 (immediately after a 3-month intervention). Interviews will be conducted in Cantonese by the principal investigator at T1. Participants from the intervention group will be recruited for these interviews. The questions will explore key components of the TFA, including affective attitude, burden, ethicality, intervention coherence, opportunity costs, self-efficacy, perceived effectiveness, and suggestion. All the interviews will be recorded and transcribed verbatim, and content analysis, following the steps of Hsieh and Shannon, will be used for data analysis. The approach comprises five stages: data identification and collection, coding categories determination, content coding, validity and reliability checking, as well as analysis and presentation of results. Two researchers will first familiarise themselves with the data, and the transcribed text will then be divided into meaningful units. Finally, the meaningful units are sorted into code, subcategories, and main categories. The analysis will continue until the data saturation point.

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Adult 18 years old and above
2. Diagnosed with coronary heart disease within one year
3. 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
4. Able to communicate in Cantonese
5. Obtained medical clearance for physical activity (no medical contraindications to exercise, including walking)
6. Being able to understand and give informed consent
7. Having telephone access, text messaging services or WhatsApp

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Cannot perform brisk walking exercise
2. Unable to perform PA independently
3. Cognitive impairments, as indicated by an abbreviated mental test score of less than 7
4. Currently enrolled in another clinical trial focusing on limiting SB with/without enhancing PA
5. Doctor-diagnosed psychiatric illness

Date of first enrolment
10/11/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince of Wales Hospital
30-32 Ngan Shing Street
Shatin
New Territories
Hong Kong
Hong Kong
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Study participating centre
The Chinese University of Hong Kong
The Nethersole School of Nursing, 6-8/F
Esther Lee Building
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Sponsor information

Organisation
Chinese University of Hong Kong

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available from the corresponding author upon reasonable request. Please contact Professor Ho Yu Cheng at hycheng@cuhk.edu.hk for further information.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/10/2025	No	Yes