Cover page

Official title: Effect of mindfulness-based eHealth cardiac rehabilitation on psychological wellbeing and risk factor management for patients with coronary heart disease: A randomized controlled trial

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1. Purpose of the study

The purpose of this study is to test the effect of eHealth cardiac rehabilitation incorporating mindfulness as a stress management component for people with coronary heart disease (CHD). CHD is a leading cause of death globally, including in Hong Kong, and its prevalence is expected to increase due to the aging population and stressful modern lifestyles. With the widespread use of information and community technology, eHealth cardiac rehabilitation (CR) is recognized as an effective, safe, and cost-saving alternative to improve traditional CR accessibility and improve patient outcomes. However, the stress management component is under-addressed; there is a lack of integrating evidence-based psychological therapy and insufficient involvement of mental health professionals in eHealth CR. This is a pressing concern as more than half of People with CHD reported a significant level of psychological stress which can trigger acute cardiac events or increase the chance of cardiac events. To resolve this critical gap, the proposed study aims to test the effect of a comprehensive eHealth CR program that incorporates mindfulness as a stress management component for people with CHD.

5. Methods:

a. Research Design

The proposed project is a single-blinded, two-arm randomized controlled trial (RCT), embedded with qualitative process evaluation (this is to be completed after the polit RCT and will not be included in this current grant application), investigating the effects of mindfulness-based eHealth CR on stress and related health outcomes of people with CHD.

b. Subjects and Setting

Inclusion criteria. People will be eligible for this study if they were diagnosed with CHD (within the past 3 months), undergone conservative treatment, such as percutaneous coronary intervention (PCI) and/ or medication, currently under stable medication regimen and discharged to home. Additional requirements are adults aged 18 years or older; reported scores ranging from 3 (to some degree) to 5 (very much) scores on a single-item stress symptoms scale (Elo et al., 2003), using a computer and/or smartphone to access the Internet at home; and, read and speak Chinese. Exclusion criteria are a diagnosis of acute psychotic disease; presence of a life-limiting condition; prescribed contradictions to physical activity; and, presence of hearing, visual, or ambulatory disorders.

c. Instruments

Outcome evaluation will take place in the PI's research center at the baseline. At the 6-week intervention point (T1), and upon completion of the 12-week intervention (T2), data collection will be conducted online using Qualtrics Survey Software. A link and QR code will be generated to be disseminated to participants by trained research assistants who are blinded as to the participant's group allocation.

Socio-demographic and clinical data will be collected at baseline. Socio-demographic data will be collected from the participants, including age, sex, education, marital status, employment, co-residency, and internet usage. Clinical data will include diagnosis, documented hypertension, dyslipidemia and diabetes, current blood pressure and body weight, treatment, and the number of medications.

Primary outcome

The Perceived Stress Scale (PSS-10) will be used to assess stress levels over the past month (Leung et al., 2010) with total scores ranging from 0 to 40 and higher scores indicating higher psychological stress. The Chinese version of PSS-10 has demonstrated good reliability with Cronbach's α coefficient of 0.83 and 0.76 for positive and negative subscale, respectively. It also exhibits factorial validity with adequate fit (Leung et al., 2010).

Secondary outcomes

The presence of psychological symptoms regarding anxiety and depression will be measured using the Chinese version of Generalized Anxiety Disorder 7-item and Patient Health Questionnaire (PHQ-9). The Chinese version of the GAD-7 scale has demonstrated good reliability with a Cronbach's alpha coefficient of 0.928 (Shih et al., 2022). It has also shown validity by exhibiting a significant correlation with the Beck Anxiety Inventory (Shih et al., 2022). The reliability of the is good, with a Cronbach's alpha coefficient of 0.86. Additionally, it has good concurrent validity with the SF-36, a widely used health-related quality of life measure (Wang et al., 2014).

Physical activity levels will be measured using records of one-week step counts by accelerometer (Mi band), with good concurrent validity when compared to a WIMU PRO^{TM} inertial device at the scapular level (considered as a gold standard), with average bias less than 2.6 steps) (Pino-Ortega et al., 2021). The accelerometer records of sleep time (total, rapid eye movement stage, and non-rapid eye movement stage) will be used to reflect the quality of sleep, which displayed 78% accuracy, 89% sensitivity, and 35% specificity compared to the polysomnography (Concheiro-Moscoso et al., 2023). The tele-monitored data will be synchronized by enabling sharing to researcher functionality. To protect data security the data sharing function will be authorized only to the research team with prior written consent obtained.

The Short-Form Six Dimensions (SF-6D) (highly correlated with SF-36 with Pearson correlation coefficient ranging from 0.861 to 0.954 (Wong et al., 2018) will be used to assess quality of life. The SF-6D focuses on six dimensions of health, capturing both physical and mental aspects, including physical functioning, role limitations, social functioning, pain, mental health, vitality.

Adverse events. Adverse events related to study participation, if reported by participants, will be documented by the research assistants (RAs) during follow-up calls or outcome assessments. It is important to emphasize that this study is a **minimal-risk**, and the utilization of the eHealth CR intervention is not expected to cause any discomfort or inconvenience to the participants. Each device is for use by a single patient. The intervention implementation will be determined by the research team following the study proposal, following established clinical standards.

e. Plan for Data Management and Analysis

The data collected from outcome assessment, accelerometers, and the website system will be stored following General Data Protection Regulation (GDPR) guidelines. These data will be stored on encrypted servers within the data infrastructure of the PI's University, ensuring compliance with GDPR standards. If any data are recorded on paper documents, they will be stored securely in locked cabinets to maintain confidentiality. Access to these paper documents will be restricted to personnel involved in data recording and interpretation. Other recorded data will be stored in a secured file on the University computer, which will be protected with password authentication to ensure limited access.

SPSS version 23.0 will be used for data analysis, following an intention-to-treat principle. Descriptive statistics will be generated for demographic data. Normality assumptions for the variables will be examined using the Kolmogorov-Smirnov (KS) test. Independent sample t-test or Chi-square test will be conducted to examine baseline comparability between the two study groups. Generalized estimating equations (GEE) model will be employed to compare the changes in the outcomes across the different time points between the groups. The GEE model allows for estimation of missing data using the maximum likelihood estimation method. The potential confounding variables will be selected based on clinical judgment and statistical incomparability. As there were no clinically known covariates in the outcomes, baseline variables with statistical incomparability ($p<0.2$) will be adjusted to obtain a more precise estimation of the intervention effect. All data analyses will be conducted with a 5% significance level (two-tailed).