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ORIGINAL ARTICLE

Technology-assisted cardiac rehabilitation for coronary heart disease patients with central obesity: a randomized controlled trial

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ABSTRACT

BACKGROUND: Limited empirical evidence is available regarding the effect of technology-assisted cardiac rehabilitation (TACR) among coronary heart disease (CHD) patients with central obesity.
AIM: To determine the effects of 12-week TACR on health outcomes of patients with CHD.
DESIGN: Two-arm randomized controlled trial.
SETTING: Cardiovascular department of a regional hospital.
POPULATION: Coronary heart disease patients with central obesity.
METHODS: The study randomized 78 hospitalized CHD patients to receive either the 12-week TACR intervention or usual care. Guided by social cognitive theory, the intervention began with an in-person assessment and orientation session to assess and identify individual risks and familiarize with the e-platform/device before discharge. After discharge, patients were encouraged to visit the interactive CR website for knowledge and skills acquisition, data uploading, use the pedometer for daily step tracking, and interact with peers and professionals *via* social media for problem-solving and mutual support. Data were collected at baseline (T0), six-week (T1), and 12-week (T2).
RESULTS: Participants in the intervention group showed significant improvement in daily steps at six weeks but not 12 weeks (T1: β=2713.48, P=0.03; T2:β=2450.70, P=0.08), weekly sitting minutes (T1: β=-665.17, P=0.002; T2: β=-722.29, P=0.02), and total (vigorous, moderate, and walking) exercise at 12-week (β=-2445.99, P=0.008). Improvement in health-promoting lifestyle profile (T1: β=24.9, P<0.001; T2: β=15.50, P<0.001), smoking cessation (T2: β=-2.28, P<0.04), self-efficacy (T2: β=0.63, P=0.02), body mass index (T1:β =-0.97, P=0.03; T2: β=-0.73, P=0.04) and waist circumferences (T1: β =-1.97, P=0.003; T2: β =-3.14, P=0.002) were identified.
CONCLUSIONS: Results indicated the effectiveness of the TACR intervention in improving healthy behaviors and anthropometric parameters for CHD patients with central obesity. Individual assessment, collaborative action planning, and ongoing obesity management support should be highlighted in TACR programs for CHD patients.
CLINICAL REHABILITATION IMPACT: Central obesity should be assessed and highlighted in TACR intervention as an independent risk factor that requires corresponding behavior change and body fat management.

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KEY WORDS: Cardiac rehabilitation; Coronary disease; Obesity, Technology; Randomized controlled trial.

Obesity is increasingly identified as an epidemic and independent risk factor for coronary heart disease (CHD).[1] It is estimated that over 80% of patients with CHD are overweight or obese.[2] A recent scientific statement from the American Heart Association highlighted that obesity contributes directly to cardiovascular risk factors, including dyslipidemia, hypertension, and type 2 diabetes, leading to cardiac event onset and mortality.[1] Empirical data showed that central obesity is a CHD risk marker that is independent of body mass index.[3, 4] Moreover, in a given BMI category, subgroups of excessive waist circumference were associated with increased cardiovascular mortality risk. Central obesity is predictive of mortality and can capture CHD patients with normal body weight but excess fat, which unmasks higher cardiovascular risk.[3, 4] Using the Asia cut-off score, a waist circumference of ≥90 cm for male and 80cm for female reflect central obesity.[5]

Cardiac rehabilitation (CR) is a multicomponent intervention that contains patient assessment, exercise training and physical activity promotion, health education, psychological support and cardiovascular risk management, tailored to the needs of CHD patients.[6] Strong evidence shows that CR can effectively improve exercise, promote healthy behavior, improve lipid profile and obesity indices, restore psychosocial wellbeing, improve quality of life, and reduce cardiac events and mortality for patients with coronary heart disease (CHD).[7, 8] Despite the effectiveness, conventional CR has low accessibility and uptake,[9] urging the development of alternative CR models.[10] Additionally, individuals with central obesity who undergo cardiac rehabilitation need to manage two comorbid chronic conditions and might require more individualized treatment to optimize recovery.[11]

Technology-assisted cardiac rehabilitation (TACR), which comprises telemonitoring and remote guidance/supervision, is a safe and cost-effective alternative to conventional CR.[12, 13] It grants readily CR access with minimal time and geographical barriers by utilizing technologies such as computers, mobile phones, and monitoring sensors.[14] The TACR not only allows healthcare professionals to provide online, individualized health information, collect real-time data and give immediate feedback, and offer ongoing professional support to the patients,[15] it can also empower self-management of patients by using a self-directed approach, particularly allowing personal settings (e.g., individualized goals) and progress visualization on the home page.[13]

Emerging studies suggested the cost-effectiveness of technology-assisted cardiac rehabilitation (TACR) in improving physical activity, modifying lifestyle, alleviating stress, promoting quality of life, and reducing cardiac events/hospitalization. However, the effects of TACR in CHD patients with central obesity have not been well studied. Several randomized controlled trials provided TACR intervention to CHD patients. Results showed significant improvement in behavior modification but not in weight and/or waist circumference reduction when compared with control group receiving usual care,[16-18] waitlist control,[19] or conventional CR.[20, 21] This may be explained by mixing CHD patients with and without central obesity and/or a lack of emphasis on identifying obesity and linking its management with behavior change, such as exercise and eating, in previous TACR interventions. The favorable behavior change and ineffective body fat management urge investigation of the effects of technology-assisted cardiac rehabilitation (phase II) in CHD patients with central obesity. The aim of this study was to investigate the effect of technology-assisted cardiac rehabilitation (TACR) among coronary heart disease (CHD) patients with central obesity.

Materials and methods

Study design

The study was a two-arm randomized controlled trial (registration number: ChiCTR1800020411). The study inclines to CONSORT guidelines of reporting trials.

Setting and participants

The study was conducted in a tertiary hospital in Wuhan in 2019, China. Participants were recruited consecutively from the hospitalized patients of four cardiology units before discharge when their medical conditions became stable as confirmed by physicians.

The inclusion criteria were: 1) adults aged ≥18; 2) diagnosed with CHD; 3) have central obesity using Asian-specific cut-off point (waist circumference ≥90 cm for male, ≥80 cm for female);[5] 4) able to read Chinese with a primary or above educational level; 5) own a device with Internet connection; and 6) having no prescribed physical activity restriction.

Patients who had a life-limiting condition (*e.g.*, cancer), acute psychiatric illness, absolute and relative contradictions to exercise testing and training according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) guideline (Supplementary Digital Material 1: Supplementary Table I),[22] or have visual, auditory, and fine motor disorders were excluded.

Sample size estimation

Referring to an RCT study comparing TACR with usual care on improving physical activity, the study required a sample of 68 participants for two groups to achieve an effect size of 0.7[19] with 80% power and 0.05 significance level. To account for an expected attrition rate of 12%, a sample size of 78 was adopted, based on previous CR studies of similar duration.[23]

Technology-assisted cardiac rehabilitation intervention

The TACR followed the international guidelines and culturally appropriate national recommendations for CR,[8, 24-27] and was underpinned by the Social Cognitive Theory (SCT).[28] The SCT highlights that in order to empower behavioural change in individuals, the cognitive (*i.e.*, awareness), behavioral (*e.g*., self-efficacy) and environmental factors (*e.g*. professional support) must be optimized and addressed.[28] The intervention commenced with an in-person assessment conducted by a registered nurse with training background and practice experiences in CR prior to hospital discharge. During the session, the nurse assessed participants' exercise capacity using six-minute walk test (assisted by another cardiac nurse watching patients' Holter monitored ECG at the nurse station) and habits, diet habits, smoking status, stress management practices, and social aspects related to CHD and central obesity management. Based on the assessments, the nurse introduced guideline-based CR recommendations. The discrepancy between the patients' described behaviors and the CR guideline recommendation will be highlighted, and the impact of unhealthy behaviors and uncontrolled central obesity on CHD health outcomes will be elaborated. Ideal body weight was computed – men: 50 + [0.91 × (height in cm – 152.4)] and women: 45.5 + [0.91 × (height in cm – 152.4)][29] and normal waist circumference following Asia cut-off score were introduced to increase patients' awareness. Then, the nurse partnered with the patient to support them in setting goals and action plans in concordance with their central obesity condition, personal risks, metabolic equivalent (MET) level from the submaximal test, and preferences and upload the goals to their personal websites. The goal setting for exercise is successive, gradually increasing the frequency, duration, and intensity of exercise to achieve at least 150 min of moderate weekly exercise. The nurse taught participants the use of Borg's ratings of perceived exertion to gradually achieve moderate intensity (from "fairly light" to "somewhat hard" on a scale of 6 to 20). The MET level for different physical activities in daily life, such as slow walking, brisk walking, square dancing, and Tai Chi, were discussed in goal setting process with reference to the American College of Sports Medicine guideline.[30] The physical activity plan was reviewed and approved by patients' physician. In addition, the nurse organized a group orientation session to teach patients about using the CR website and pedometer (Mi band), telemonitoring for patients' daily steps, after which the participants were invited to join the social media chatroom for group interaction and professional consultation. A user manual of the website and pedometer was provided.

The TACR components were delivered through an account and password-protected CR website (accessible *via* computer/mobile phone). The design of the website was guided by Health Literacy Online[31] to optimize user-friendliness and readability. Since CR uses a multidisciplinary approach, cardiologists, cardiac nurses, physiotherapists and dietitians with experiences in providing CR services were involved in designing/commenting on the content of the eHealth CR program to ensure its accuracy and appropriateness for CHD patients.[32] The website enables two main features: self-monitoring with motivational feedback and experiential learning for knowledge and skills acquisition. Patients were encouraged to upload weekly/daily goal-attainment data (*i.e.*, physical activity, diet checklist). The website could analyze their data and generate graphical visualization and motivational messages for progress tracking. The website learning content includes the pathophysiology and manifestation of CHD, physical activity, healthy diet, smoking cessation, stress coping, cardiovascular risk factors management (central obesity, hypertension, cholesterol, and diabetes), symptom management and post-PCI management. The linkage between each behavior aspect and central obesity was explained (*e.g*., exercise and central obesity, smoking cessation and weight change).[8, 24-27] Each learning content is presented sequentially: 1) introducing the role and underlying mechanism; 2) lifestyle changes; 3) actions; 4) self-monitoring and resolutions to barriers.

The nurse moderated peer interaction in the WeChat chatroom to encourage progress and experience sharing and to moderate peer interaction/support. Patients were encouraged to raise cardiac-related questions in the chatroom using pseudonym names. During the eHealth CR program implementation, the nurse coordinated the care and consulted with the relevant CR staff if necessary to fully address participants' questions and evaluate their health status. Nurses are effective in coordinating care with other CR staff and process the professional knowledge in empowering lifestyle change in patients' home settings.

Control group

Participants in the control group received usual care, a 10-minute didactic coaching on medication usage and lifestyle modification (physical activity, diet, and smoking cessation) delivered by physicians when delivering discharge summary. They were taught how to use a pedometer for data-collection purposes.

Measurements

Sociodemographic data, including age, sex, education, marital status, employment condition, and co-residency, were collected. Clinical data were retrieved from the digital medical record, including diagnosis, treatment, diseased coronary vessels, and cardiovascular comorbidities.

Primary outcome: physical activity

Physical activity was measured objectively and subjectively using a pedometer (Mi Band, China) and International Physical Activity Questionnaire (IPAQ), respectively. Participants were asked to wear the pedometer for three days at each data collection time point to calculate average steps as an outcome.[33] The IPAQ has a good reliability with intra-class correlation coefficients of 0.74 to 0.97 for each sub-domain for Chinese adults.[34]

Other outcomes

The Health-Promoting Lifestyle Profile II (HPLP-II) was used to measure the healthy behaviors of the participants.[35] The HPLP-II has been translated and validated with Cronbach's α coefficient of 0.63 to 0.81 among Chinese adults.[36] The smoking status was assessed by asking about participants' current smoking status, including non-smoker, current smoker, and ex-smoker.[37] Cardiac self-efficacy was measured by the Cardiac Self-efficacy Scale (CSES), a 5-point Likert Scale, evaluating participants' confidence in maintaining function and controlling symptoms.[38] A higher score indicates greater self-efficacy. The CSES has an excellent internal consistency with Cronbach's alpha 0.90 (English version) and 0.926 (Chinese version)[39] Health-related quality of life was measured by the MacNew Heart Disease (MacNew HRQoL), assessing the influence of CHD on participants' physical, emotional, and social wellbeing.[40] The MacNew questionnaire was translated and validated among the Chinese CHD population, with intraclass correlation coefficients ranging from 0.88 to 0.93.[41] Psychological wellbeing was measured by the 21-item Depression Anxiety Stress Scale 21 (DASS-21).[42, 43] The translated and validated Chinese DASS-21 had Cronbach's alpha ≥0.80.[44] The cardiac physiological risk parameters were assessed using standardized approaches, containing body mass index (BMI) (Xiheng, RGZ-120-RT, China), blood pressure (Omron HEM-7124, Japan), and waist circumference.

Data collection and ethics considerations

The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee granted ethical approval for this study (No.2018.469). Eligibility was assessed by the nurse by reviewing medical records, interviewing patients, and seeking advice from a senior CR nurse wherever there was uncertainty. The nurse introduced the study to potential participants with an information sheet and verbal explanation. They were ensured of their right to withdraw at any time without adverse effects. The nurse obtained final confirmation on eligibility from on-site physicians for eligible patients who agreed to participate. Two trained research assistants collected baseline data after obtaining written informed consent in the hospital. Block randomization, with a random block size of four, six and eight generated by 'Random Allocation Software', was used to allocate the participants. The group assignments were written and enclosed in an opaque and sealed envelope in the sequence accordingly. Another research assistant opened the envelope to the participants after the baseline data collection. Post-test data were collected 6-week and 12-week post-intervention by the two research assistants who had no information about group assignment.

Statistical analysis

Data analysis was conducted using SPSS 28. Descriptive statistics were calculated to summarize participants' characteristics. Normality assessment of continuous variables was assessed by estimating skewness that a skewness value within -2 to 2 was considered as normally distributed. The *t*-test, Chi-square, and Mann-Whitney Test were selected to determine between-group comparability in demographic, clinical, and outcome variables at baseline. The generalized estimating equation (GEE) model was used to calculate changes in the outcome variables between the two groups across the study endpoints. The GEE model follows the intention to treat principle, can handle the missing data mathematically, and accommodate group*time interaction effect for better estimation of intervention effect. Any sociodemographic and clinical variables with between-group differences P<0.20 at baseline were regarded as a covariate and adjusted in the GEE

model. Effect sizes were calculated for all mean differences at T_2 (12 weeks) using Hedges' g. All tests are two-sided with a significance level of 0.05.

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Recruitment, attrition, intervention engagement

A total of 78 participants were recruited, with 39 per study group. The CONSORT flow diagram is presented in Figure 1.

Participants had an average age of 55.73±7.17, and the majority were male (80.8%, N.=63), married (97.4%, N.=76) and co-reside with their family (97.4%, N.=76).

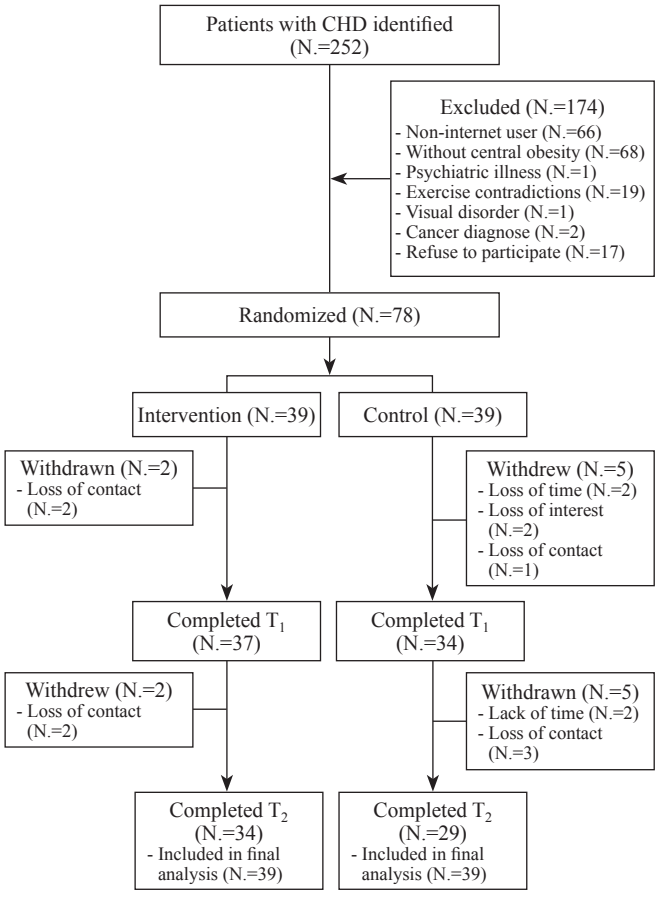

Figure 1.—CONSORT patient flow diagram.

The baseline characteristics and outcome variables of participants are presented in Supplementary Digital Material 2 (Supplementary Table II). No significant between-group differences were detected at baseline. Two sociodemographic and clinical variables with baseline difference P<0.2 were adjusted in the GEE model, including PCI treatment (or medication only) and dyslipidemia.

Effects on physical activity

The changes from baseline to each post-test endpoint across outcome variables of both groups are presented in Supplementary Digital Material 3 (Supplementary Table III). Based on the GEE analysis, participants in the intervention group showed a significant group*time interaction effect in physical activity as measured by daily steps (β=2713.48, P=0.03), weekly sitting minutes (β=-665.17, P=0.002), compared to the control group at 6-week post-intervention. Participants in the intervention group maintained their improvement over the control group in physical activity as measured by weekly sitting minutes (β=-722.29, P=0.02), total (vigorous, moderate, and walking) exercise (β=-2445.99, P=0.008). A favorable improvement in daily steps in the intervention group was observed, although not statistically significant (β=2450.70, P=0.08). The effect size falls in the range of small to medium (Hedge's g 0.30-0.78).

Effects on other outcomes

Participants in the TACR group also showed a significant group × time interaction effect in health-promoting lifestyle profile from baseline to 6 weeks (β=24.9, P<0.001) and to 12 weeks (β=15.50, P<0.001) compared with the control group. The improvement in smoking cessation (β=-2.28, P<0.04) and self-efficacy (β=0.63, P=0.02) were observed from baseline to 12 wks when compared with the control group. The effect size falls in the range of small to large (Hedge's g 0.21-1.44).

For HRQoL, no significant intervention effect was observed on global quality of life across study endpoints (T_1: β =-0.03, P=0.89; T_2: β=0.38, P=0.20) between the two groups. There were no significant effect on physical domain (T_1: β=-0.11, P=0.61; T_2: β=-0.39, P=0.22), emotional domain (T_1: β=0.03, P=0.90; T_2: β = 0.32, *p*=0.27), and social domain (T_1: β=-0.15, P=0.50; T_2: β=0.51, P=0.12) of HRQoL.

Pertaining psychological wellbeing, compared to the control group, the intervention group showed no significant improvement in DASS total score (T_1: β=0.13,

P=0.94; T_2: β=-0.53, P =0.80) and depression (T_1: β=-0.04, P=0.92; T_2: β=-0.59, P=0.43), anxiety (T_1: β=-0.1, P=0.83; T_2: β=0.03, P=0.83), stress (T_1: β=0.26, P=0.77; T_2: β=0.08, P=0.94) subscale.

Participants in the intervention group showed significant improvement in body mass index (T_1: β =-0.97, P=0.03; T_2: β=-0.73, P=0.04) and waist circumferences (T_1: β=-1.97, P=0.003; T_2: β=-3.14, P=0.002). The effect size falls in the range of medium to large (Hedge's g 0.64-2.42).

For blood pressure, participants in the intervention group showed no significant differences in systolic blood pressure (T_1: β=1.24, P=0.81; T_2: β=-3.3, P=0.53) and diastolic blood pressure (T_1: β=-0.94, P=0.80; T_2: β=-1.90, P=0.64) when compared to the control group.

Adverse events

There was no report of adverse events related to study participation. Four participants in the intervention group and two in the control group reported receiving planned PCI treatment during the study period. Two participants in the intervention group and two in the control group reported cardiovascular-related re-hospitalization.

Intervention usage

During the 12-week, the study has a website visit rate of 66.7% (26 participants logged in to the website). The average number of website visits among participants who visited the website was 8.7±10.14. The study observed active interaction in an online chatroom by 30 participants with an average of 3.33±4.55 peer interaction and 2.2±2.38 professional consultation (messages on the same topic were counted once). Only 17 participants uploaded data on their personal website regarding goal attainment, among which all achieved predetermined behavior change goals. Seven participants never visited the website nor engaged in the online chatroom dialogue, among which four participated in the post-test data collection.

Discussion

Limited empirical evidence is available regarding the effect of TACR in CHD patients with central obesity. Given the adverse effects of central obesity on CHD progression, this study provided technology-assisted CR, including a website, a pedometer, and an online chatroom, for CHD patients with central obesity condition after hospital discharge. Guided by social cognitive theory, a cardiovascular nurse engaged patients in identifying central obesity problem and personal risk factors, engaging goal setting, together with telemonitoring data and a motivational website to reflect/encourage goal attainment. Patient-professional interaction was facilitated in a peer-supported chatroom to optimize real-time professional advice, promote health conversation, and mobilize peer influence/support for problem-solving. The positive effects on physical activity, health-promoting lifestyle profile, smoking cessation, body mass index, and waist circumference of patients with CHD were encouraging. Managing these risk factors is crucial in slowing disease progression and preventing subsequent cardiac events. The improvement in self-efficacy further supported the use of social cognitive theory in TACR.

The study's findings are consistent with a meta-analysis that demonstrated positive effects of TACR programs in improving the physical activity of patients with CHD.[13, 45] More time spent in moderate-to-vigorous physical activity has been associated with a lower incidence of cardiovascular disease.[46] The finding of increased levels of daily steps and moderate-vigorous physical exercise from the study results in patients with central obesity is encouraging, given that at least 20 minutes of moderate-vigorous physical exercise per week is associated with the lowest risks of all-cause and cardiovascular mortality.[47]

Furthermore, this study observed comprehensive heart-healthy behavior modifications, whereas previous studies more frequently reported the effects of program on physical activity and put less emphasis on dietary or smoking cessation. Smoking cessation and a healthy diet are strongly recommended in the context of secondary prevention and rehabilitation by cardiology specialists in at-risk populations who have experienced a cardiac event.[29] Progress in a broader range of behavioral changes may be reflective of the comprehensiveness of the CR program with an extensive embodiment of behavior change techniques.[48]

More importantly, the TACR intervention showed significant improvement in anthropometric parameters (*i.e.*, body weightand waist circumference). Such results added evidence regarding the effectiveness of TACR in optimizing behaviour risk factors and anthropometric outcomes for patients with central obesity conditions. Previous studies that suggested no significant improvement in body weight reduction and/or waist circumference when compared with the control group[16-21] may be attributed to the recruitment of general CHD patients with/without obesity condition and a focus on exercise. Assessing and elaborating on central obesity condition and linking obesity reduction regarding exercise and other healthy lifestyle behaviors should be highlighted in TACR intervention for CHD patients with central obesity.

Patients' engagement was captured by tracking website visits, data uploading activities, and chatroom interactions. Considering the combined number of website visits, pedometer, and online chatrooms by the patients, this study reached a high intervention usage rate based on the definition of a previous review.[49] Engagement in each platform may not appear high, which implies that participants have different preferences and compatibility conditions in using their smartphones/laptops to access the CR. To improve intervention usage, some models/frameworks that focus on reducing the barriers to technology-based self-learning at home should considered, such as the effort-optimize Intervention Model.[50] Using artificial intelligence or gamification that includes rewards or the opportunity to compare goal attainment with peers may attract the participants to improve engagement for the future TACR.[51] Future studies may also evaluate their perceived website usability and qualitative experiences to improve eHealth design.

Limitations of the study

Several limitations should be mentioned. First, the generalizability is limited by recruiting participants from one regional hospital with a good literacy level with smartphone/computer usage background. The low representation of women is also worth noticing. The TACR interventions for women should be further investigated, as they tend to be older and have more medical and psychological comorbidities.[52] Second, the non-use attrition may challenge the cause-effect relationship as four participants had no/minimal intervention use. Lastly, the study only evaluated the effects of TACR for 12 weeks to mimic the duration of conventional CR. Future studies should incorporate a longer-term evaluation to determine the sustained intervention effects.

Conclusions

This study identified the significant effects of a 12-week TACR program in improving physical activity, health-promoting lifestyle profile, smoking cessation, body mass index, and waist circumference of patients with CHD with central obesity following a cardiac event. The effectiveness of this intervention provided insights into the development of a comprehensive CR program with an intensive embodiment of theory-guided initiatives/techniques to promote health outcomes of CHD patients with central obesity. Long-term follow-up is needed to determine long-term effectiveness.

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The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Jing-Jing Su, Arkers-Kwan-Ching Wong, and Li-Ping Zhang have given substantial contributions to the conception and design of the study. Jing-Jing Su and Rose S. Lin contributed to the data curation and analysis. Jonanthan Bayui, Rose S. Lin, and Hammoda Abu-Odah contributed to the study supervision.

Jing-Jing Su and Ladislav Batalik gave contributions to the data interpretation. Jing-Jing Su, Jonanthan Bayui, and Rose S. Lin contributed to the manuscript draft. Hammoda Abu-Odah and Ladislav Batalik have given contributions to manuscript revision and editing. All authors read and approved the final version of the manuscript.

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Supplementary data
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