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Comparison of telecardiac rehabilitation with centre-based cardiac rehabilitation and usual care: a protocol for systematic review including a meta-analysis

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ABSTRACT

Introduction Cardiac diseases are the leading causes of morbidity and mortality. Cardiac rehabilitation is proven to be beneficial in reducing morbidity, mortality and rehospitalisation rates. Recently, more emphasis is given to home-based telemonitored cardiac rehabilitation due to the recent pandemic of SARS-CoV-2. We plan to perform this systematic review and meta-analysis to compare the differences in functional capacity (FC) (measured in peak oxygen uptake (PVO_2)) and health-related quality of life (hr-QoL) between telecardiac rehabilitation and both centre-based cardiac rehabilitation (CBCR) and usual care (UC) separately. It will showcase the feasibility of using telemonitored cardiac rehabilitation as an alternative to CBCR considering the ease of performance, safety and limiting unnecessary contact.

Methods and analysis This systematic review and meta-analysis protocol was structured according to the published Preferred Reporting Items for Systematic Review and Meta-analysis–Protocol guidelines. We will devise a search strategy to use online databases to search for the randomised controlled trials (RCTs). Inclusion criteria will include adult population (18 years or older) suffering from at least one cardiac disease referred for cardiac rehabilitation comparing telecardiac rehabilitation with both CBCR and UC. Exclusion criteria will be RCTs in non-English language, hybrid studies, cross-over trials, observational studies and case series. The outcome of interest will be FC measured in PVO_2 and hr-QoL. The articles will be reviewed by two independent reviewers and a third reviewer will be available to adjudicate any conflicts. The bias in the selected studies will be assessed using Cochrane risk-of-bias tool for randomised trials. The overall bias of the studies will be assessed. The selected articles will be reviewed and the data will be collected on Microsoft Excel spreadsheet for analysis. These data will include number of subjects in the intervention arm and the comparator arm (which will either be CBCR or UC), measures of FC and hr-QoL and SD. Subgroup analysis and sensitivity analysis will be considered based on heterogeneity among the study effect estimates and the number of available studies for each outcome. Results of the pooled estimates will be reported as standardised mean difference (and 95% CI) with fixed-effect model, if heterogeneity is not significant ($I^2 < 50\%$). Otherwise, random-effects model will be used for $I^2 > 50\%$. The data of the subjects who completed the rehabilitation

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Hybrid cardiac rehabilitation has been studied and specific cardiac aetiology requiring rehabilitation has been compared between hybrid, telecardiac and centre-based cardiac rehabilitation (CBCR).

WHAT THIS STUDY ADDS

⇒ We plan to compare phase 2 cardiac rehabilitation programme between pure telecardiac rehabilitation and both CBCR and usual care separately. We will consider all cardiac aetiologies requiring cardiac rehabilitation for this review which include but are not limited to ischaemic heart disease, non-ischaemic cardiomyopathies and valvular heart disease. This will enable us to determine the feasibility of pure telecardiac rehabilitation, across cardiac pathologies requiring rehabilitation, as an alternative option to CBCR especially during infectious disease pandemic such as SARS-CoV-2. It will add to the growing body of evidence on considering telecardiac rehabilitation as an effective alternative to CBCR. Our study will provide more robust data as it includes purely telecardiac rehabilitation with less than 2 weeks of rehabilitation training under direct supervision prior to commencement of home-based telecardiac rehabilitation programme. We have also included latest studies which have used novel telemonitoring techniques based on latest technological advancements for communication, surveillance and providing periodical feedback.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ It will enable future cost comparison between telecardiac rehabilitation and CBCR. It will also act as a stepping stone for future research on comparison between rehospitalisation rates in short term and morbidity in long term between telecardiac rehabilitation and CBCR. It will also pave way for future consideration of incorporating telecardiac rehabilitation as a guideline alternative to CBCR.

programme of the study period will be used to calculate the effect estimates (per-protocol effect). Publication bias in the meta-analysis will be assessed using Egger's test and funnel plot. The strength of body of evidence

of the outcomes will be assessed using Grading of Recommendations Assessment, Development and Evaluation (GRADE) method. Data analysis will be performed using Stata SE V.15.0 (College Station, Texas, USA).
Ethics and dissemination There will be no direct involvement of the patient or the public in the conception, design, data collection, and analysis of this systematic review and meta-analysis. Results of this systematic review and meta-analysis will be disseminated via journal articles.
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INTRODUCTION
Cardiovascular diseases contribute significantly to the disease burden and are among the leading causes of morbidity and mortality in the USA and the world over.[1] Cardiac rehabilitation has proven benefit in patients suffering from cardiac diseases and is a class 1A recommendation of the American Heart Association and American College of Cardiology for secondary prevention after a coronary event.[2,3] It has shown to improve quality of life, functional capacity (FC) and rehospitalisation rates.[4,5] Centre-based cardiac rehabilitation (CBCR) is underused due to the inability of cardiac patients to participate at the centre for various reasons.[6,7] However, the recent SARS-CoV-2 pandemic has further affected participation at the cardiac rehabilitation centres.[8] In addition, the infectious disease pandemic has caused the closure of many centre-based rehabilitation centres due to recommendations of social distancing, limiting congregations, and shortening of staff as a result of redeployment of resources, staff, and infrastructure to more critical areas of the healthcare system.[9] In this meta-analysis, we will compare telecardiac rehabilitation with both CBCR and usual care (UC) separately for the effectiveness and comparability of changes in FC and health-related quality of life (hr-QoL). Recent meta-analyses are published comparing the hybrid, home-based CBCR and/or UC.[10,11] There are a few reviews published that account for a specific cardiac disease, either heart failure or ischaemic heart disease, for cardiac rehabilitation.[12–14] A few articles on cardiac rehabilitation are published in the context of recent SARS-CoV-2.[14,15] We intend to compare pure telecardiac rehabilitation for phase 2 cardiac rehabilitation programme with both CBCR and UC separately without discriminating between cardiac aetiologies warranting cardiac rehabilitation. Hence, this review will capture additional data published from inception until the end of search period, accounting for advancements in telemonitoring strategies, to allow for a deeper understanding of the impact of telecardiac rehabilitation on FC and hr-QoL in comparison with CBCR and also the feasibility of telecardiac rehabilitation as an equally effective, if not superior, alternative option.

Review question
How does telecardiac rehabilitation impact FC and hr-QoL when compared with both CBCR and UC separately in patients diagnosed with at least one cardiac disease referred for rehabilitation? Can telecardiac rehabilitation be used as an alternative to CBCR, especially in the context of pandemics like SARS-CoV-2?

METHODS AND ANALYSIS
The systematic review and meta-analysis will include randomised controlled trials (RCTs). This protocol is reported according to the published Preferred Reporting Items for Systematic Review and Meta-analysis–Protocol guidelines.[16]

Search strategy and participants
Literature search strategy will be developed using medical subject heading and text words related to cardiac diseases and rehabilitation including but not limited to 'tele-cardiac rehabilitation', 'center-based cardiac rehabilitation', 'usual care', 'heart failure', 'ischemic heart disease', 'valvular heart disease', 'functional capacity' and 'health related quality of life' will be used (online supplemental figure 1). The search will be conducted on CINAHL, PubMed and EMBASE. A database search will be conducted from inception until the time of final analysis to ensure all the articles, which meet our inclusion criteria, are included. All RCTs published in the English language which involve the adult population (age ≥18 years) will be included.

Inclusion and exclusion criteria
Inclusion criteria will be based on Population, Intervention, Comparison and Outcome (PICO) framework and will include the adult population, ≥18 years of age, diagnosed with at least one cardiac disease and referred for cardiac rehabilitation. Exclusion criteria will include hybrid studies that consist of proper cardiac rehabilitation at the centre or hospital for more than 2 weeks before continuing telecardiac rehabilitation at home, cross-over studies, case series and observational studies (online supplemental table 1).

Description of groups
Telecardiac rehabilitation
Patients are prescribed home-based exercise regimen which is monitored remotely using technology-based interface (telephone, mobile/smartphone, mobile application (app), instant messaging services, web-based apps, portable computer, video conferencing, internet and biosensors). This monitoring includes communication with the patients and providing them with periodical feedback.

Centre-based cardiac rehabilitation
Patients participate in exercise training sessions with direct supervision by a cardiac rehabilitation professional at a hospital or a CBCR centre.

Usual care

No active cardiac rehabilitation intervention (exercise regimen) is prescribed and patients follow suitable diet, lifestyle changes and pharmacological therapy only.

Study selection and data extraction

The titles and abstract will be screened based on the inclusion and exclusion criteria. This will be followed by screening of selected full-text articles based on the eligibility, study design, participant characteristics, treatment characteristics, outcome variables, results, risk of bias and sources of funding by two independent reviewers (ZB and AS). Differences in eligibility assessment or outcome data will be resolved by discussion between the two mentioned reviewers. In case of disagreement, the conflict will be resolved by involving the third reviewer (HI) who will have the final say on the fate of the study. The outcome measures assessed will be the FC measured in peak oxygen uptake (PVO$_2$) and the hr-QoL determined by standardised questionnaires. The studies which meet the search strategy will be imported on EndNote V.X9.

The data from the included studies will be extracted on Microsoft Excel spreadsheet in a tabulated form under specific headings for the duration of study of telecardiac rehabilitation, CBCR and UC, where applicable (online supplemental tables 2 and 3). These data will include numbers of intervention population, comparator population, duration of study period, type of comparator group and difference in FC and hr-QoL for the intervention group and the comparator group. The difference in FC and hr-QoL will be calculated using simple arithmetic prior to filling in the tables. In addition, higher SD of the outcome measures (FC and hr-QoL) reported in the studies will be recorded in the spreadsheet to maintain uniformity in collected data.

Outcome measures

The primary outcome will be the difference in FC between the beginning of the study and the end of the study period. The end of the study period will be considered end of the intervention period for telecardiac rehabilitation and end of rehabilitation period for CBCR as the comparator group. The study period of UC will be based on the study period of the intervention arm, which in this case will always be telecardiac rehabilitation. FC measured in PVO$_2$ will be taken as the standard of measure. Any article which mentions FC measured differently will be included in the meta-analysis after converting the measured FC into PVO$_2$ using standardised formula if applicable. Otherwise, that study will be mentioned in narrative description only. The secondary outcome will be the hr-QoL reported using the time points mentioned above. The hr-QoL will be assessed using validated standardised questionnaires like Short Form Health Survey-36, Minnesota Living with Heart Failure Questionnaire and EuroQoL-5D.[17–19] The non-quantitative data or articles not reporting the standard measurements and

which cannot be converted into the standard measures will not be included in statistical meta-analysis but will be mentioned in the narrative description.

Quality and risk of bias in studies

Quality assessment and risk of bias in the included studies will be independently reviewed by two authors (ZB and AS), using the revised Cochrane risk-of-bias tool for randomised trials blinded to each other's selection.[20] The assessment of the quality of studies will be based on five components of above-mentioned tool which include: (1) bias arising from the randomisation process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome and (5) bias in selection of the reported result. Each of these domains contains several signalling questions that enable these to be assessed as one of the three: low risk of bias, some concerns and high risk of bias. The assessment of these domains will also enable the assessors to determine the overall risk of bias in each study.

Data synthesis

We will use aggregate participant data for quantitative synthesis. We will use narrative synthesis where applicable. For continuous variables, means and SDs will be extracted. Results will be pooled as standardised mean difference (SMD) with 95% CI for FC and hr-QoL scores. We will pool results from included studies by using a fixed-effect model. The DerSimonian and Laird random-effects model will be used when heterogeneity is significant (I^2 >50%) to give an overall estimate of the treatment effect. We will present results as pooled SMDs and 95% CIs. We will quantitatively explore heterogeneity in included studies by using Q statistics. Funnel plots and the Egger's test will be used to assess publication bias. A p value of <0.05 will be considered significant. Subgroup analysis and sensitivity analysis will be considered based on the level of heterogeneity of the effect estimates and the number of final studies included in the meta-analysis. The strength of body of evidence of the effect estimates will be graded as very low, low, moderate and high using the five domains of Grading of Recommendations Assessment, Development and Evaluation (GRADE) method. These domains are used to assess the certainty in evidence and are (1) risk of bias, (2) imprecision, (3) inconsistency, (4) indirectness and (5) publication bias. Data analysis will be conducted using Stata SE V.15.0 (College Station, Texas, USA).

CONCLUSION

This meta-analysis will provide a comparison of pure telecardiac rehabilitation with both CBCR and UC separately for FC and hr-QoL. It will enable us to assess the viability of telecardiac rehabilitation in pandemics like SARS-CoV-2. It will serve as a stepping stone to determine whether it can be used as an alternative to the CBCR especially in the context of pandemics of infectious diseases. Thus far, to our knowledge, hybrid cardiac rehabilitation or certain

cardiac disease-specific cardiac rehabilitation is studied. This study will give a more comprehensive comparison of the two entities. Hence, our study will contribute to the evidence base of considering the telecardiac rehabilitation programme as an equally effective, safe and convenient alternative to the CBCR.

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