TITLE: Choice of Health Options In prevention of Cardiovascular Events (CHOICE) replication study two-year follow-up: is an extended program beneficial?

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ABSTRACT

Background: Globally, attendance at cardiac rehabilitation (CR) is between 15-30%. Alternative models of individualised care are recommended to promote participation in CR, however there has been no prospective testing of different duration of such models. We aimed to replicate the previously proven CHOICE (Choice of Health Options In prevention of Cardiovascular Events) intervention, and to determine if an extended version (CHOICE*plus*) would confer additional benefits.

Methods: Acute coronary syndrome (ACS) survivors not accessing centre-based CR (n=203) were randomised to CHOICE for three-months (n = 100) or CHOICE*plus* for 24-months (n = 103) at four urban hospitals. The program comprised telephone-based tailored risk-factor reduction.

Results: CHOICE and CHOICEplus were equivalent demographically and in risk profile at baseline. At 24-months, lipid profiles improved significantly and fewer patients had ≥3 risk factors above target compared to baseline in both groups. There were no significant differences between groups.

Conclusions: The 24-month CHOICE*plus* program did not confer additional benefit above the brief 3-month CHOICE intervention. However, participation in **either** CHOICE and CHOICE*plus* significantly improved cardiovascular risk profile in ACS survivors. Importantly, the study was feasible, and the intervention translated readily across four hospitals. Overall, this study adds to the existing evidence for brief individualised approaches to CR.

Keywords: Secondary prevention, telehealth, cardiac rehabilitation

INTRODUCTION

Attendance at a formal secondary prevention program, usually termed cardiac rehabilitation (CR), includes evidence-based strategies that have been demonstrated to lower cardiovascular risk factors, improve quality of life and decrease morbidity and mortality and is recommended in national and international guidelines for all patients after a cardiac event.[1] However, formal prevention programs are typically time-limited, facility-based and conducted in groups, in a model largely unchanged for decades.[2] Globally, attendance at CR is consistently low.[3, 4] Most recently, an Australia-wide audit identified that only 46% of patients presenting to hospital with an acute coronary syndrome (ACS) are referred to CR, with only 27% receiving optimal preventive care.[5] Concern over poor referral and attendance at facility-based CR has led to the evolution of new models to increase access to effective secondary prevention.[6]

Alternative models of individualised care include telephone-based models such as Coaching patient On Achieving Cardiovascular Health (COACH)[7] and Choice of Health Options In prevention of Cardiovascular Events (CHOICE).[8] There is considerable variation in the length and intensity of delivery of these individualised programs.[9] CHOICE was a brief three-month intervention, which focused on establishing an ongoing therapeutic alliance between patients and health professionals, where patients are active partners in managing their disease.[8] Testing of the CHOICE intervention showed sustained benefit at one year[8] and four years.[10] Although a systematic review concluded brief programs of up to 10 hours are as effective as longer programs,[9] to date, there has been no prospective testing of different durations of alternative secondary prevention program, or whether they can be sustained in the longer term

Randomised controlled trials (RCT) focus on a set of tightly controlled circumstances, which may not be closely related to clinical practice.[11] Thus, replication studies can bridge the gap between RCTs and real world practice, and provide important information on population-level scalability.[12] We aimed to determine if an extended 24-month intervention has additional

benefit on cardiovascular risk factors compared to the previously proven three-month CHOICE intervention in ACS patients; to determine if participation in either CHOICE intervention improves cardiovascular risk factor profile from baseline to 24-months; to investigate the feasibility and generalizability of the CHOICE intervention, and to investigate the benefit of an additional nutrition module, a tailored approach to management of depression, and to validate self-reported physical activity.

MATERIAL AND METHODS

Study design

This replication study with 24-month follow up was conducted at four tertiary referral hospitals in Sydney, Australia and is registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12608000182392). The study was approved by the Sydney South West Area Health Service Human Research Ethics Committee - Concord Repatriation General Hospital zone (CH62/6/2007-142). At three of the four sites, ACS patients who had declined an offer from the CR team to participate in standard CR, or did not attend the initial CR appointment, were randomly allocated to either a group participating in the previously tested three-month CHOICE program or a 24-month CHOICE program (CHOICE*plus*) (Figure 1). At the remaining site, ACS patients not accessing CR were randomised to one of three groups: CHOICE, CHOICE*plus,* or a comparator group participating in conventional care, which allowed investigation of the effect of the addition of nutrition module and depression management.

The study protocol has been described in detail previously.[13] Briefly, to identify eligible participants, CR coordinators reviewed the Cardiology Department admission summaries daily. Participants were eligible if they had an ACS diagnosis up to eight-weeks prior to recruitment, and excluded if they had a clinical diagnosis of a severe coexisting medical condition that would prevent participation, or insufficient English to provide written informed consent. The intervention for both groups comprised tailored risk factor reduction with an initial clinic visit and follow-up phone support (Figure 2). Individuals could choose up to three tailored

modules to address risk factors. The modules were cholesterol management, blood pressure management, physical activity, diet, and smoking cessation. Within each module, participants could choose how they wanted to manage the risk factor from four options: medical; hospital-based; home-based; or self-directed. For CHOICE, this was delivered over three months; for CHOICE*plus*, the intervention was intended to be delivered over 36-months, but was shortened to 24-months due to local site resourcing issues. The intended number of telephone calls was four for CHOICE participants and eight for CHOICE*plus* participants. Frequency of calls was determined by a mutual agreement. The intervention was underpinned by social cognitive theory[14] and encouraged formation of a therapeutic alliance between participants and health care providers.[15] Compared to the previously tested CHOICE study,[8] a single-centre study with a single clinician (physiotherapist) delivering the intervention, this study was conducted at four hospitals in culturally diverse areas of Sydney, delivered by six staff of differing professions (nurses, physiotherapist and dietitians).

Outcome measures

The primary outcome measures were total cholesterol (TC), measured by fasting blood sample; systolic blood pressure (SBP) using standardised procedures;[16] smoking status (self-report and carbon monoxide measure);[17] and physical activity (Active Australia Survey (AAS), validated with accelerometer).[18] Secondary outcomes included readmission rates, all-cause mortality, cardiac mortality, proportion with three or more cardiac risk factors (smoking, SBP >140mmHg, LDL >2.5mmol/l, BMI ≥30 kg/m^2, physical inactivity) above the targets set by the National Heart Foundation of Australia,[19] waist circumference, quality of life and dietary intake, determined by a nutritional screening tool.[20] For quality of life, the physical component score (PCS) and mental component score (MCS) were derived from the SF-12 instrument. The sub-components were scored based on normative data from the US general population[21] which has been demonstrated appropriate for use in studies of the Australian population.[22]

To evaluate the generalisability of the previously supported CHOICE study,[8] process evaluation

measures of the intervention included: record of participant recruitment, withdrawal from the program, the context of the interventions and the resources used and assessment of barriers to implementation and fidelity to the intervention components.

Validation of the Active Australia Survey

Self-reported physical activity using the AAS[23] was validated in a subset of participants (n=54) at 12-months. Each participant wore an ActigraphGT1M accelerometer for 7 days then completed the AAS.

Valid data were obtained for four or more days from 46/54 participants. We analysed the data with the complete set of questions and also with question four removed. Question four asks participants to estimate the total time spent doing "vigorous gardening or heavy work around the yard" over the past week. Previous studies have shown that question four does increase over-reporting of moderate to vigorous physical activity.[24] There was modest correlation for the complete AAS and the accelerometry data (0.266) (mean AAS 491 (SD 239); mean accelerometry 239±165), and moderate correlation for the AAS with question four removed (0.526) (mean AAS 344 (SD 246); mean accelerometry 239 (SD 165)) . Therefore, final results were analysed with question four removed. Further, accelerometry data showed moderate to vigorous physical activity was slightly correlated with AAS reported moderate to vigorous physical activity (R^2=0.168). This corresponds well with the literature for self-reported physical activity data,[24] and was considered acceptable for reporting of physical activity data for participants this study.

Validation of the dietary assessment

Validation of our dietary assessment was conducted by comparing the nutritional screening tool used here against a multiple pass dietary assessment (conducted by a qualified dietitian) which has been published previously.[20] These results show high correlation for alcohol, fish, and fruit and vegetables with a multiple pass dietary assessment. There is lower correlation for soluble fibre and monounsaturated fats, perhaps due to these items being harder to

quantify in the diet. Therefore, only intake results of alcohol, fish and fruit and vegetables are presented here.

Statistical analysis

Our sample size was based on the previous CHOICE study and was calculated on reduction in TC of 0.35mmol/l from baseline to study end. Our aim was to recruit 276 participants (138 per group) with an alpha error rate of 0.05 and power of 0.8. We imputed missing data by imputing the mean value of the variable (estimated by the Expectation-Maximisation algorithm in the MI procedure) at each time point for each arm. For binary variables this was rounded to between 0 and 1 (i.e. no negative numbers or numbers greater than 1), the outcome set to '1' and the imputed value used as a weight in the analysis. Non-missing values were given a weight of 1. Summary data were produced for each group (CHOICE, CHOICE*plus*) at each time-point (baseline, 24 months). First, we tested whether there was difference in outcome variables between CHOICE and CHOICE*plus* groups at 2 years using Welch's t-test (a precaution for unequal variances between groups) for continuous variables, and Pearson's chi-squared test for binary outcomes. Secondly, we compared changes over time when these two groups were combined using paired t-tests for continuous outcomes and McNemar's test for binary outcomes. As a sensitivity analysis to check that the results of an analysis of change are comparable to a single final measurement, we have used generalised estimating equation (with exchangeable correlation structure) to avoid the assumption of sphericity in RM-ANOVA and to allow the analysis of outcomes other than continuous measurements. We estimated the differential effects of group on time, and included adjustments for age, sex, country of birth, working status and tertiary education. All tests were undertaken in SAS 9.4.

RESULTS

Participants

We identified 1,764 patients across the four hospital sites who were admitted with an ACS, of whom 888 were eligible for secondary prevention (Figure 1). Following blinded baseline

assessment, 203 patients who were not accessing CR were randomly allocated to CHOICE (n=100) or CHOICE*plus* (n=103). Data were complete at two-years for 168 participants: 79 in CHOICE; and 89 in CHOICE*plus.* A further 67 participants were randomly allocated to a comparator group at one site to validate the nutrition module and the tailored approach to depression. Data were complete at two years for 61 in the comparator group. There was no difference in drop-out rate between the groups.

Baseline characteristics are shown in Table 1. There were no significant differences between the groups at baseline. Most participants were aged in their early sixties, and the majority were male. Around half were currently working and just over a third had a previous history of CVD. The majority were admitted with unstable angina and around two thirds had a revascularisation procedure during their ACS presentation. The mean baseline TC was 4.2mmol/l in both groups.

Primary outcomes

No significant differences were found between CHOICE and CHOICE*plus* in any variable at 24 months (Table 2). In a sensitivity analysis using multiple imputation for patients with a missing final outcome, there was no evidence of an important difference between groups (p=0.147). When we combined the groups, and analysed differences from baseline, total cholesterol improved significantly, while blood pressure increased significantly (Table 3). In the combined groups, the percentage smoking reduced, however this did not achieve significance. There was a significant decrease in the proportion of participants with three or more risk factors above the national targets. The further sensitivity analysis showed the only outcome for which we had a different effect from just one measurement was for HDL level, where with the extra adjustments we found a change over time but no difference in change over time between groups.

Secondary outcomes

There were two deaths in the CHOICE group, both due to non-cardiac causes, and no deaths in the other groups. In the CHOICE group there was one readmission for a cardiovascular cause unrelated to coronary artery disease (aortic valvuloplasty) and one for non-cardiovascular cause (shoulder surgery). In the CHOICE*plus* group there were two readmissions for cardiovascular causes (septum resection for hypertrophic cardiomyopathy; coronary angiogram) and one for a non-cardiovascular cause (bladder cancer). In the comparator group there was one readmission for a cardiovascular cause (cardioversion for atrial fibrillation) and one for a non-cardiovascular cause (shoulder surgery).

Process implementation evaluation

Recruitment to the CHOICE intervention was slower than anticipated. Five hundred people declined enrolment in the study: the principal reason was unwillingness to participate in a research study (n=223) (Figure 1). Follow-up was completed at 24-months, rather than the planned 36-months, due to local site issues, including room availability and recruitment of staff.

Telephone calls

Telephone calls were delivered as per protocol: The CHOICE group received a mean of 4±2 successful calls; five participants in CHOICE were not able to be contacted subsequent to enrolment in the trial. The CHOICE*plus* group received a mean of 8±3 successful calls; two participants in CHOICE*plus* were not able to be contacted subsequent to enrolment in the trial. The mean duration of telephone calls was 9±5 minutes (range 1-40 minutes). For each successful telephone call, a mean of 2±1 attempted calls (range 1-17) per participant, i.e., approximately 50% of calls were successful.

Selection of modules

In terms of module selection, 8/203 (4%) participants chose only one module; 80/203 (39%) chose two modules; 109/203 (54%) chose three modules; and 6/203 (3%) chose four modules.

All participants in the interventions were required to undertake the cholesterol module (203/203), with the majority selecting the medical option. The majority of participants chose either the nutrition module (130/203, 64%), and/or the physical activity module (142/203, 70%), with the home based intervention as the preferred mode of delivery for both. Of the participants who were not sufficiently active at baseline as classified by the AAS (61/203), over half (38/61, 63%) elected to take up the physical activity module. Of those with hypertension, 26/50 (52%) chose the BP module, with just over half selecting the medical option. Of the 39 participants who reported smoking at the baseline assessment, 21/39 (54%) chose the smoking module, with the majority choosing the self-directed option. There were no between-group differences in module selection.

The nutrition module enabled people in the intervention groups to make significant changes in their diet, which were not observed in the comparator group, as reported previously.[20] However, our tailored approach to depression did not significantly reduce the mean depression score of people in the intervention groups (Table 2) when compared to baseline, nor did the results change in the comparator group (14.3 vs 13.2 respectively, p=0.06). Therefore, it is suggested that the nutrition module had additional benefit over the original four modules in the original CHOICE study, but the tailored approach to depression did not.

DISCUSSION

This study was a replication of the methods of a previously proven RCT of a brief three-month intervention, compared to an extended 24-month intervention for ACS survivors not attending CR, but with assessment at 24-months for both groups. Our findings suggest that there was no additional benefit for the extended intervention in this sample. Participation in either CHOICE intervention improves cardiovascular risk factor profile from baseline to 24-months, however, changes in cardiovascular risk factors were less pronounced than in the original CHOICE study.[8] Of note, baseline cardiovascular risk factors and medication prescription were much better than anticipated from the results of the original CHOICE study suggesting

more intensive therapy and better adherence to guidelines.[8] In particular baseline total cholesterol was 4.7mmol/l in the original CHOICE study but only 4.2mmol/l in the current study, while the target for cholesterol reduction remained at 4.0mmol/l. These improvements in lipid levels and prescription of lipid lowering therapy for secondary prevention have been noted in Australia during the time period covering the two CHOICE studies.[25] It is likely that TC goals need to be individualised and made even lower after ACS, when the global risk is not high and especially when the TC is close to or below the current target. Policy and/or guidelines should consider decline in baseline TC.

Participants in the CHOICE intervention groups increased their physical activity levels, but this was not significant. It is possible that introduction of a nutrition module, not present in the original CHOICE intervention, lessened the impact of the physical activity module. It was also noted that at one year, participants who used the accelerometer over-reported the amount of physical activity that was of moderate to vigorous level by around 30%. Indeed, the literature suggests that people over-estimate the time spent in physical activity[26], which may be due to perceived social desirability of appearing physically active on the part of the participants.[27]

For sedentary behaviour, we observed a significant increase from baseline in the number of hours participants reported sitting per week. Inactivity physiology suggests that separate to lack of physical activity, sitting may have independent detrimental effects on cardio-metabolic health.[28] Encouraging people to adopt less sedentary patterns of behaviour is not traditionally included in CR programs. Given the high level of sedentary behaviour among the CHOICE participants, and the observed increase over one year, this requires this requires further research to determine the impact of including interventions to reduce sedentary behaviour in CR.

Importantly, the brief CHOICE intervention was easily adapted to multiple hospital sites. The study engaged 203 additional people who had previously declined to take part in a facility-based CR program, and this number would likely have been higher had it not been offered

only as part of a research study. It is likely that the CHOICE intervention (brief and extended) was successful because it engaged local service providers, was tailored to the individual needs of the patient and was delivered in a timely fashion soon after the acute event. Furthermore, CHOICE was based on behaviour change theories that have shown that patient engagement is central to making successful behaviour changes, particularly where long-term change is necessary to deliver lasting health benefits.[29] It is therefore recommended that behaviour change theories should be embedded in clinical practice and specific consideration is given to the training needs of staff.

An interesting finding of this study was the large number of people who refused to take part "because it was a research project". It has been shown that people who refuse to participate in research are usually older, of lower socioeconomic status, have more cardiovascular risk factors and higher subsequent mortality.[30] However, in this study, the participants had already refused to take part in CR. Previous work has demonstrated that people who do not attend CR are at higher baseline risk than those who do not attend.[31] It is possible that those at the very highest risk did not attend and this needs to be addressed in future studies, with some examination of the role of the consent process in the inability to enrol these high risk participants.

This study has several limitations. We recruited fewer participants than anticipated, and the study only went for 24-months rather than planned 36 months. Although it is possible that this resulted in no observed differences between groups, we believe this is unlikely. However, we undertook sensitivity analyses to ensure that the results were not an effect of insufficient data points on study participants. We also found that improved background treatments meant that people were at significantly lower baseline risk than in previous studies. This particularly affected blood cholesterol, one of the primary endpoints, which was 0.5mmol lower than the baseline value in our previous study, so absolute changes at 24-months were smaller. The difference in the number of telephone calls was only 4 over a 24-month basis, however this was determined by mutually agreed need on a case-by-case basis. In common with most

trials of a lifestyle intervention, the majority of the participants were male, aged in the early sixties, and a number of people refused to participate because the intervention was research.

CONCLUSIONS

The 24-month CHOICE*plus* program did not confer additional benefit above the brief 3-month CHOICE intervention. However, participation in **either** CHOICE and CHOICE*plus* significantly improved cardiovascular risk profile in ACS survivors. Importantly, the study was feasible, and the intervention translated readily across four hospitals particularly where resourcing was sustained. The greatest value was seen in the initial three-month period of the original intervention, suggesting that program structure and efficiency are important in designing interventions of this nature. Overall, this study adds to the existing evidence for brief individualised approaches.

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Figure Legend

Figure 1- Trial recruitment

Figure 2- CHOICE intervention

Table 1- Baseline characteristics of participants

Table 2- Outcomes of CHOICE vs CHOICE*Plus* at 2 years

Table 3- Outcomes of combined groups: baseline vs 2 years

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