Original Article

Randomized Controlled Trial of a Psychoeducation Program for the Self-Management of Chronic Cardiac Pain

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Abstract

Cardiac pain arising from chronic stable angina (CSA) is a cardinal symptom of coronary artery disease and has a major negative impact on health-related quality of life (HRQL), including pain, poor general health status, and inability to self-manage. Current secondary prevention approaches lack adequate scope to address CSA as a multidimensional ischemic and persistent pain problem. This trial evaluated the impact of a low-cost six-week angina psychoeducation program, entitled The Chronic Angina Self-Management Program (CASMP), on HRQL, self-efficacy, and resourcefulness to self-manage anginal pain. One hundred thirty participants were randomized to the CASMP or three-month wait-list usual care; 117 completed the study. Measures were taken at baseline and three months. General HRQL was measured using the Medical Outcomes Study 36-Item Short Form and the disease-specific Seattle Angina Questionnaire (SAQ). Self-efficacy and resourcefulness were measured using the Self-Efficacy Scale and the Self-Control Schedule, respectively. The mean age of participants was 68 years, 80% were male. Analysis of variance of change scores yielded significant improvements in treatment group physical functioning [$F = 11.75(1,114)$, $P < 0.001$] and general health [$F = 10.94(1,114)$, $P = 0.001$] aspects of generic HRQL. Angina frequency [$F = 5.57(1,115)$, $P = 0.02$], angina stability [$F = 7.37(1,115)$, $P = 0.001$], and self-efficacy to manage disease [$F = 8.45(1,115)$, $P = 0.004$] were also significantly improved at three months. The CASMP did not impact resourcefulness. These data indicate that the CASMP was effective for improving physical functioning, general health, anginal pain symptoms, and self-efficacy to manage pain at three months and provide a basis for long-term evaluation of the program. J Pain Symptom Manage 2008;36:126–140.

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Portions of the CASMP first appeared in or are derived from the Chronic Disease Self-Management Program Leader's Master Trainer's Guide (1999). Those portions are Copyright 1999, Stanford University.

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Chronic stable angina, self-management, randomized controlled trial, health-related quality of life

Introduction

Cardiac pain arising from chronic stable angina (CSA) pectoris is a cardinal symptom of coronary artery disease (CAD), characterized by pain or discomfort in the chest, shoulder, back, arm, or jaw.[1] CSA is a wide-spread clinical problem with a well-documented, major negative impact on health-related quality of life (HRQL), including pain, poor general health status, impaired role functioning, activity restriction, and reduced ability for self-care.[2–14] Limitations in current surveillance systems worldwide have precluded the examination of CSA prevalence in most countries. Available prevalence data estimate CSA prevalence at 6,500,000 (1999–2002) in the United States,[1] and 28/1000 men and 25/1000 women (April 2001–March 2002) in Scotland.[15] With the growing global burden of angina and CAD, nongovernmental organizations in Canada, the United States, and the United Kingdom have stressed the need for developments in secondary prevention strategies.[1,16,17] Current secondary prevention models largely target postacute cardiac event and/or coronary artery bypass patients and, depending on region, can be inaccessible to those with chronic symptoms.[18,19] Consequently, the vast majority of those with CSA and other CAD-related symptoms must manage on their own in the community. Moreover, these models focus predominantly on conventional CAD risk-factor modification to enhance myocardial conditioning and reduce ischemic threshold. However, cumulative basic science and clinical evidence point to the variability of cardiac pain perception for CSA patients, wherein pain can occur in the absence of myocardial ischemia, and conversely, ischemic episodes can be painless.[20–32] Given few alternatives, CSA patients revisit their local emergency departments when uncertain about how to manage their pain.[33,34] There is a critical need for a secondary prevention strategy with adequate scope and complexity to address CSA as a multidimensional ischemic and persistent pain problem, and to help CSA patients learn pain self-management strategies.[33]

Evidence from well-designed randomized controlled trials (RCTs) has demonstrated the effectiveness of psychoeducation for improving the self-management skills, HRQL, self-efficacy, and/or resourcefulness of persons with other chronic pains, including arthritis and chronic noncancer pain.[35–37] Psychoeducation interventions are multimodal, self-help treatment packages that use information and cognitive-behavioral strategies to achieve changes in knowledge and behavior for effective disease self-management.[38] To date, the effectiveness of psychoeducation for enhancing CSA self-management is inconclusive.[39] Although a few small trials over the last decade have demonstrated positive effects to some degree related to pain frequency, nitrate use, and stress,[40–43] numerous methodological problems, particularly inadequate power and the lack of a standard intervention approach, have precluded the generalization of findings.[39] Moreover, more recent and robust psychoeducation trial research has been limited to patients with newly diagnosed angina.[44] Therefore, the purpose of this study was to evaluate the effectiveness of a standardized psychoeducation program, entitled the Chronic Angina Self-Management Program (CASMP), for improving the HRQL, self-efficacy, and resourcefulness of CSA patients.

Methods

Study Design

This study was a randomized controlled trial. On completion of demographic and baseline measures, participants were randomly allocated to either 1) the six-week CASMP group or 2) the three-month wait-list control group; post-test study outcomes were evaluated at three months from baseline. A short-term

follow-up period was chosen for this study as it was the inaugural test of the effectiveness of the CASMP and the basis for a future larger-scale trial, with long-term follow-up. Ethical approval for the study was received from a university in central Canada and three university-affiliated teaching hospitals.

Study Population and Procedure

This study was conducted in central Canada over an 18-month period. The target population was CSA patients living in the community. Participants had a confirmed medical diagnosis of CAD, CSA for at least six months and were able to speak, read, and understand English. Individuals were excluded if they had suffered a myocardial infarction and/or undergone a coronary artery bypass graft in the last six months, had Canadian Cardiovascular Society (CCS) Class IV angina[45] and/or a major cognitive disorder. Participants were recruited from three university-affiliated teaching hospitals with large cardiac outpatient programs, allowing for timely subject referral. Three recruitment strategies found to be effective in prior psychoeducation trials with community-based samples were used.[36,37,46,47] First, clinicians at designated hospital recruitment sites identified eligible patients in the clinic setting. Second, study information was made available in participating clinicians' offices and hospital recruitment site newsletters. Third, the study was advertised in community newspapers.

Participant eligibility was initially assessed by a research assistant (RA) via telephone. Willing participants were then interviewed by the RA on-site to confirm eligibility and obtain informed consent. Demographic and baseline measures were completed on-site and participants were randomly allocated to either the six-week CASMP group, or the three-month wait-list control group. Randomization was centrally controlled using a university-based, tamper-proof, computerized randomization service. Those randomized to the six-week intervention group were invited to participate in the next available program, whereas those randomized to usual care were told that they were in the three-month wait-list control group. Usual care consisted of all nursing, medical, and emergency care services as needed; those allocated to the control group did not receive the CASMP during the study period.

Participants were contacted by the RA to schedule post-test data collection at three months from baseline. Assiduous follow-up procedures were used to minimize attrition; participants received up to three telephone calls and a follow-up letter regarding collection of their three-month follow-up data. Participants' completion of all study questionnaires was invigilated by the RA blinded to group allocation. Blinding was preserved by informing participants that their questions would be answered after they completed the questionnaire booklet and that a letter explaining their part in the next phase of the project was forthcoming. Those in the wait-list control group were offered entry into the next available CASMP once post-test measures were completed.

Intervention

The CASMP is a standardized psychoeducation program given in two-hour sessions weekly, over a six-week period. The goal of the CASMP is to improve HRQL by increasing patients' day-to-day angina self-management skills. The CASMP is an adaptation of Lorig et al.'s Chronic Disease Self-Management Program (CDSMP, © 1999 Stanford University).[47–50] In 2004, McGillion et al. conducted a preliminary study to identify CSA patients' specific pain-related concerns and self-management learning needs.[33] With permission, the results of this study were used to adapt the CDSMP to make it directly applicable to CSA. The principal investigator (PI) was certified as a CDSMP "Master Trainer" at the Stanford Patient Education Research Center to ensure that all tenets of the adapted program were in accordance with the standardized CDSMP psychoeducation format.

The program was delivered by a registered nurse using a group format (e.g., 8–15 patients) in a comfortable classroom setting. Program sessions were offered both day and evening and participants were encouraged to bring a family member or friend if they wished. A facilitator manual specified the intervention protocol in detail to ensure consistent delivery of the CASMP across sessions. In addition, all sessions were audio taped and a random sample of these tapes (10%) was

externally audited to ensure standard intervention delivery.

The CASMP integrates strategies known to enhance self-efficacy, including skills mastery, modeling, and self-talk. Designed to maximize discussion and group problem solving, it encourages individual experimentation with various cognitive-behavioral self-management techniques and facilitates mutual support, optimism, and the self-attribution of success. Key pain-related content includes relaxation and stress management, energy conservation, symptom monitoring and management techniques, medication review, seeking emergency assistance, diet, and managing emotional responses to cardiac pain. Fig. 1 provides an overview of all content covered over the six-week course of the program.

Both the content and process components of the CASMP are grounded in Bandura's Self-Efficacy Theory, which states that self-efficacy is critical to improve health-related behaviors and emotional well-being and that one's self-efficacy can be enhanced through performance mastery, modeling, reinterpretation of symptoms, and social persuasion.[51,52] Throughout the program, participants worked in pairs between sessions to help one another to stay motivated, problem solve, and meet their respective self-management goals. A CASMP workbook was also provided for reinforcement of key material from each session.

CASMP Program Overview

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Overview of Self-management and Chronic Angina	✓					
Making an Action Plan	✓	✓	✓	✓	✓	✓
Relaxation/Cognitive Symptom Management	✓		✓	✓	✓	✓
Feedback/Problem-solving		✓	✓	✓	✓	✓
Common Emotional Responses to Cardiac Pain: Anger/Fear/Frustration		✓				
Staying Active/Fitness		✓	✓			
Better Breathing			✓			
Fatigue/Sleep Management			✓			
Energy Conservation				✓		
Eating for a Healthy Heart				✓		
Monitoring Angina Symptoms and Deciding when to Seek Emergency Help				✓		
Communication				✓		
Angina and Other Common Heart Medications					✓	
Evaluating New/Alternative Treatments					✓	
Cardiac Pain and Depression					✓	
Monitoring Angina Pain Symptoms and Informing the Health Care Team						✓
Communicating with Health Care Professionals About Your Cardiac Pain						✓
Future Self-Management Plans						✓

Fig. 1. CASMP overview.

Measures

Sociodemographic information and angina and related clinical characteristics were obtained via a baseline questionnaire developed for the trial. Braden's evidence-based Self-Help Model of Learned Response to Chronic Illness Experience guided our selection of trial outcomes.[53,54] Braden's model emphasizes human resilience and suggests that people can develop enabling skills to enhance their life quality when faced with the adversities of chronic illness.[53,54] Therefore, the primary outcome was life quality, conceptualized as CSA patients' HRQL. The secondary outcome was enabling skill, reflected by CSA patients' self-efficacy and resourcefulness to self-manage their pain.

Primary Outcome: HRQL. HRQL was measured using the Medical Outcomes Study 36-Item Short Form (SF-36).[55–57] The SF-36 is a comprehensive, well-established, and psychometrically strong instrument designed to capture multiple operational indicators of functional status, including behavioral function and dysfunction, distress and well-being, and self-evaluations of general health status.[58,59] Eight subscales are used to represent widely measured concepts of overall quality of life: physical functioning (PF), role limitations due to physical problems (RP), social functioning (SF), bodily pain (BP), mental health (MH), role limitations due to emotional problems (RE), vitality (VT), and general health perception (GH).[57] Raw SF-36 data were submitted to QualityMetric Incorporated's 100% accurate online scoring service. Scoring was according to the method of summated ratings where items for each subscale are summed and divided by the range of scores. Raw scores were transformed to a 0–100 scale where higher scores reflect better functioning.[57] We also used norm-based scoring (NBS) where linear T-score transformations were performed to transform all scores to a mean of 50 and standard deviation (SD) of 10.[57,60] We chose the NBS method to allow our SF-36 scores to be readily comparable to current published SF-36 CSA population norms.[57] (Raw SF-36 scores available on request from the first author.) NBS also guards against subscale ceiling and floor effects; scores below 50 can be understood as below average.[57]

Reliability estimates for all eight SF-36 subscales have exceeded 0.70 across divergent patient populations including CSA[58–61] and exceeded 0.8 in this study: PF (0.87); RP (0.86); BP (0.81); RE (0.87); SF (0.83); VT (0.83); MH (0.85); and GH (0.83). SF-36 construct, convergent, and discriminant validities also have been well documented.[57–59,62]

Although the SF-36 has discriminated among patient samples with divergent medical, psychiatric, and psychiatric and other serious medical conditions, some evidence suggests that it may inadequately discriminate among those with differing CCS angina functional class.[61] The potential for the SF-36 to be insensitive to changes in angina class necessitated the use of a second disease-specific instrument, the Seattle Angina Questionnaire (SAQ),[61,63] to evaluate HRQL.

The SAQ is a disease-specific measure of HRQL for patients with CAD, consisting of 19 items that quantify five clinically relevant domains of CAD: physical limitation, angina pain stability and frequency, treatment satisfaction, and disease perception.[63] The SAQ is scored by assigning each response an ordinal value and summing across items within each of the five subscales. Subscale scores are transformed (0–100) by subtracting the lowest score, dividing by the range of the scale, and multiplying by 100.[63] Higher scores for each subscale indicate better functioning; no summary score for the five subscales is derived. SAQ reliability, construct validity, and responsiveness to intervention have been demonstrated in a number of studies.[13,14,61,63–65] Internal consistency reliabilities for the SAQ in this study were PL (0.85), AF (0.71), TS (0.73), and DP (0.68).

Secondary Outcomes: Self-Efficacy and Resourcefulness. Self-efficacy to manage angina pain and other symptoms was measured with a modified version of the 11-item "Pain and Other Symptom" scale of Lorig et al.'s Self-Efficacy Scale (SES), originally developed for arthritis intervention studies.[66] This scale assesses people's perceived ability to cope with the consequences of chronic arthritis, including pain and related symptoms and functioning,[66] via a 10-point graphic rating scale ranging from 10 (very certain) to 100 (very uncertain) for each of its 11 items. A total score for perceived

self-efficacy is obtained by summing all items and dividing by the number of items completed; a higher score indicates greater perceived self-efficacy.

SES test-retest stability and construct validity have been reported in large samples.[35,36,67] The SES also has performed consistently with theoretical predictions in a prior psychoeducation trial for chronic pain, having negative correlation with pain (−0.35) and disability (−0.61), and strong positive correlation with role functioning (0.62) and life satisfaction (0.48); internal consistency was 0.90.[37] Permission was received from the SES developer to adapt the SES by replacing the word "arthritis" with "angina." The internal consistency of our adapted version of the SES in this study was 0.94.

Resourcefulness was measured by Rosenbaum's Self-Control Schedule (SCS),[68] designed to assess individual tendencies to use a repertoire of complex cognitive and behavioral skills when negotiating stressful circumstances. Thirty-six items are scored using a six-point Likert scale (−3 to +3) to assess individual tendencies to engage in aspects of self-control behaviors, including 1) the use of cognitions and positive self-statements to cope with negative situations, 2) application of problem solving strategies, 3) delay of immediate gratification, and 4) maintenance of a general belief in self when dealing with challenging circumstances.[68] Eleven items are reverse scored, and all items are summed to generate a total score for resourcefulness ranging from −108 to 108; higher scores indicate greater resourcefulness.[68] SCS test-retest stability, internal consistency, and validity are well documented.[37,68–73] The internal consistency for the SCS in this study was 0.80.

All instruments were pilot tested prior to the trial on a sample of six CSA patients (aged 46–68 years) to assess their comprehension of items and response burden; no changes were required.

Sample Size

Sample size estimation was based on achievement of a moderate effect size in our primary outcome of HRQL. Cardiac patients have reported minimum 10-point improvements in SF-36 scales up to four years postinvasive intervention.[7,11] Prior trials suggested that psychoeducation can achieve comparable minimal levels of short-term change in a number of SF-36 scales for patients with chronic pain via the acquisition of disease self-management skills and the self-attribution of success.[35,37] We specified a 10-point difference in SF-36 scores as being clinically important and the sample size was set to test for this difference. Based on Chronic Pain Self-Management Program (CPSMP) trial data,[37] we used an estimated SD of 18; comparable SDs for five SF-36 scales, including physical functioning, bodily pain, general health, social functioning, and mental health, have been reported among cardiac patients aged 44–84 years.[7] Larger SDs, however, were reported for two role functioning scales of the SF-36 including role emotional and role physical functioning, thus requiring estimated sample sizes beyond the allowable time frame for this study.[7,57] Therefore, we expected potentially inadequate power to detect meaningful change in these two SF-36 scales. Allowing for an alpha of 0.05 and 80% power, the required sample for each group was 52. Telephone reminders and flexibility in CASMP program offerings were expected to help minimize attrition. However, to allow for losses to follow-up, the final sample estimate for each group was 65, or 130 in total. The statistics program nQuery Advisor 4.0 was used to compute this sample size estimate.

Data Analysis

Analyses were based on intention-to-treat principles.[74] Equivalence of groups on baseline demographic characteristics and pretest scores was examined using Chi-squared analysis for discrete level data and the Student *t*-test for continuous level data. Change score analyses were conducted to determine the impact of the CASMP on HRQL, self-efficacy, and resourcefulness to manage symptoms. Significant differences in change scores between treatment and control groups were examined via analysis of variance (ANOVA).[75] To guard against Type I error, multivariate analysis of variance (MANOVA) was conducted prior to ANOVA testing on SF-36- and SAQ-related data, due to the multiple subscales involved.[75] We chose a change score approach as opposed to analysis of covariance (ANCOVA) so that observed differences in change scores between treatment and control groups would be

accessible to the reader and, therefore, the magnitude of any intervention effects would be readily apparent.[75,76] For verification, we reanalyzed our data via ANCOVA; the findings supported our change score approach. All data were cleaned and assessed for outliers and departure from normality; assumptions of all parametric analyses were met.

Results

Derivation of the Sample and Attrition

In total, 277 potential participants were assessed for inclusion via telephone during an 18-month period. Of these potential participants, 130 were included and 147 were excluded. Of those excluded, 44% did not meet the inclusion criteria, 30% refused, and 26% missed their initial appointment for consent and completion of baseline questionnaires, despite assiduous follow-up (i.e., three telephone calls and a follow-up letter). Reasons for refusal included: not interested ($n=18$), too busy to participate ($n=15$), transportation problems ($n=6$), and physical limitations precluding travel ($n=5$). Those who did not arrive for enrollment procedures were also counted as refusals when determining acceptance rate. The acceptance rate for enrollment among those eligible was 61%. Of the 130 consenting participants, 66 were randomized to the CASMP, and 64 were randomized to the wait-list control group.

Thirteen participants (treatment group, $n=9$; usual care group, $n=4$) did not complete post-test measures, yielding a 10% lost to follow-up (LTF) rate. Of these, nine participants dropped out of the study without explanation and could not be contacted, and four became ineligible to continue due to hospitalization. One hundred seventeen participants (treatment group, $n=57$; usual care group, $n=60$) completed pre- and posttest measures that were used for data analyses (see Fig. 2).

Participant Characteristics and Comparability of Groups

Baseline sociodemographic- and angina-related characteristics of the treatment and control groups are presented in Tables 1 and 2, respectively. The mean age of the sample was 68 (SD 11), living with CSA for 7 (SD 7) years on average. The majority of the sample was male, married or cohabitating, and Caucasian. Individuals of East Indian and Pakistani origin constituted the second largest racial group

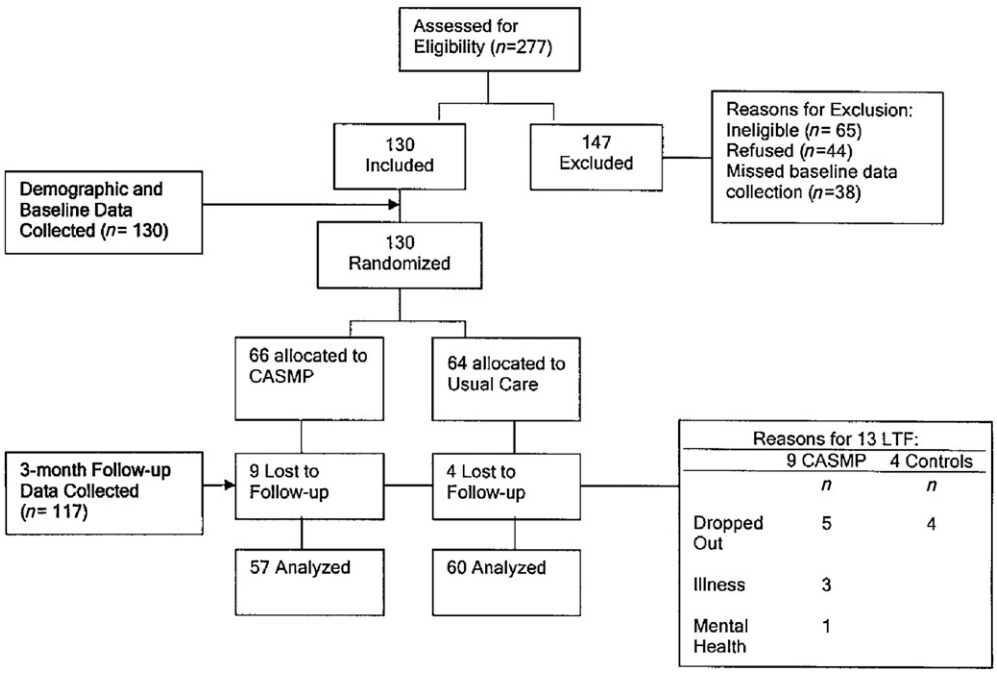

Fig. 2. Trial flow: sample derivation, randomization, data collection, and losses to follow-up.

Table 1
Sociodemographic Characteristics by Group

Characteristic	Treatment ($n=66$)	Control ($n=64$)
Demographics	*n* (%)	*n* (%)
Mean age (years [SD])	67 (11)	70 (11)
Married/cohabitating	44 (67)	44 (69)
Male	53 (80)	50 (78)
Working full time	16 (24)	15 (23)
Retired	46 (70)	42 (66)
High school	59 (89)	55 (86)
Postsecondary education	42 (64)	44 (69)
Caucasian	48 (73)	54 (84)
Black	3 (5)	0 (0)
Latin American	0 (0)	1 (2)
Asian	2 (3)	1 (2)
East Indian/Pakistani	11 (17)	6 (9)
Middle Eastern	3 (5)	1 (2)
Aboriginal	0 (0)	1 (2)

SD = standard deviation.

enrolled. Most were either retired or working full time. The majority had completed high school and/or had postsecondary education. Approximately half had two prior cardiac revascularization procedures, typically either coronary artery bypass grafting or angioplasty. The majority reported having a comorbid condition, typically a minor medical problem or diabetes. The treatment and control groups were not significantly different on any sociodemographic characteristic, comorbid condition, CCS functional class, number of prior revascularizations, or pretest measure. Comparisons were also made on all sociodemographic characteristics and pretest scores between those LTF ($n=13$) and those who completed ($n=117$) the study; no significant differences were found. (All baseline scores available on request from the first author.)

Table 2
Angina and Related Clinical Characteristics by Group

Characteristic	Treatment ($n=66$)	Control ($n=64$)
Angina-related history		
Mean (SD) years living with angina	6 (6)	8 (8)
Mean (SD) revascularizations (including CABG, PCI)	2 (1)	2 (1)
Comorbid conditions	*n* (%)	*n* (%)
Heart failure	2 (3)	5 (8)
Asthma	4 (6)	2 (3)
Diabetes	18 (27)	9 (14)
Emphysema	1 (2)	1 (2)
Renal failure	2 (3)	1 (2)
Peptic ulcer	1 (2)	3 (5)
Thyroid problems	3 (5)	7 (11)
Other minor medical problem	34 (52)	27 (42)
Canadian Cardiovascular Society Functional Class		
Class I	23 (35)	19 (30)
Class II	26 (39)	29 (45)
Class III	17 (26)	16 (25)
Medications		
Ace inhibitors	33 (50)	29 (46)
Anti-arrhythmics	3 (5)	2 (3)
Anticoagulants	57 (86)	48 (73)
Beta-blockers	40 (61)	38 (59)
Calcium channel blockers	22 (34)	20 (32)
Cholesterol lowering agents	49(74)	38(59)
Diuretics	11(16)	13(20)
Insulins	18 (27)	9 (14)

SD = standard deviation; CABC = coronary artery bypass graft; PCI = percutaneous coronary intervention.

Intervention Effects: Between-Group Differences in Change Scores

Primary Outcome: HRQL. Mean change scores by group, group differences in change scores, and results of MANOVA and ANOVA testing for significant differences in change scores between groups for the SF-36 and SAQ are presented in Tables 3 and 4, respectively. Two omnibus MANOVA tests were performed on the SF-36 data as four subscales reflect mental health aspects of HRQL, and four subscales reflect physical health aspects. MANOVA yielded significantly greater positive change for the treatment group on the overall physical health component of the SF-36 ($F=4.39$, $P=0.003$), compared to the usual care group; no significant differences in change were found for the overall mental health component. MANOVA also yielded significantly greater positive change for the treatment group on the SAQ ($F=3.23$, $P=0.009$), compared to the usual care group.

Individual-level ANOVA testing on SF-36 subscales indicated significant improvements for the treatment group on physical functioning (PF) [$F=11.75$ (1,114), $P<0.001$] and general health (GH) [$F=10.94$ (1,114), $P=0.001$]. The Mann-Whitney U test was used to test for significant differences in change between groups for the role physical and role emotional functioning (RP, RE) and bodily pain (BP) subscales, due to their discrete distributions[75]; no significant differences between groups were found. ANOVA also yielded significant improvements for the treatment group on two subscales of the SAQ

Table 3
MANOVA and ANOVA Tests for Significant Differences in SF-36 Change Scores Between Groups

SF-36 NBS	Change Treatment	Change Control	Difference in Change between Groups	MANOVA		ANOVA	
Range (0−100)	$\Delta(T_2 - T_1)$ M (SD)	$\Delta(T_2 - T_1)$ M (SD)	$(T_\Delta - C_\Delta)$ M (SD)	*F* (df)	*P*	*F* (df)	*P*
Physical health-related items							
PF	5.3 (9.4)	−0.68 (9.3)	5.95 (9.3)	4.39 (4, 110)	0.003[b]	11.75 (1, 114)	<0.001[c]
RP	4.8 (12.7)	3.2 (9.6)	1.66 (11.2)			1.47[a]	ns
BP	4.4 (8.7)	2.1 (9.2)	2.31 (8.95)			1.68[a]	ns
GH	2.27 (7.7)	−1.6 (6.4)	4.33 (7.0)			10.94 (1, 114)	0.001[c]
Mental health-related items							
RE	4.9 (12.2)	3.6 (12.2)	1.31 (12.2)	0.47 (4,108)	ns	1.49[a]	ns
SF	2.1 (10.9)	0.1 (9.5)	2.04 (10.2)			0.28 (1, 114)	ns
VT	2.3 (8.6)	0.3 (7.3)	1.97 (8.0)			1.77 (1, 114)	ns
MH	1.5 (8.8)	0.9 (7.9)	0.58 (8.3)			0.14 (1, 114)	ns

NBS = Norm-based scores; T_1 = Time 1; T_2 = Time 2; T = treatment; C = controls; Δ = mean change; T_Δ = mean change, treatment; C_Δ = mean change, controls; PF = physical functioning; RP = role physical functioning; BP = bodily pain; GH = general health; RE = role emotional functioning; SF = social functioning; VT = vitality; MH = mental health.
Note: SD of mean change scores expected to be large, as range of scores not bound by zero.
[a]Mann-Whitney *U* test.
[b]$P < 0.05$.
[c]$P \leq 0.01$.
ns = Nonsignificant ($P > 0.05$).

including angina pain frequency (AF) [$F = 5.57$ (1,115), $P = 0.02$] and stability (AS) [$F = 7.37$ (1,115), $P = 0.001$]. At three months, the CASMP resulted in significantly greater improvements in physical functioning and general health, as measured by the SF-36, and significantly greater improvements in angina pain frequency and stability, as measured by the SAQ, compared to usual care.

Secondary Outcomes: Self-Efficacy and Resourcefulness. Mean change scores by group, group differences in change scores, and results of ANOVA testing for significant differences in change in SES and SCS scores between groups are presented in Table 5. ANOVA yielded significant improvement for the treatment group on the SES [$F = 8.45$ (1,115), $P = 0.004$] compared to controls. No significant group differences in SCS change scores were found. Overall, the CASMP resulted in significantly improved self-efficacy scores at three months, compared to usual care. The CASMP did not impact resourcefulness.

Examination of Intervention Cohort Effects

Because the CASMP was delivered to the treatment group in six small group cohorts of eight to fifteen participants, we examined for significant associations between intervention

Table 4
MANOVA and ANOVA Tests for Significant Differences in SAQ Change Scores Between Groups

SAQ	Change Treatment	Change Control	Difference in Change between Groups	MANOVA		ANOVA	
Range (0−100)	$\Delta(T_2 - T_1)$ M (SD)	$\Delta(T_2 - T_1)$ M (SD)	$(T_\Delta - C_\Delta)$ M (SD)	*F* (df)	*P*	*F* (df)	*P*
AF	11.4 (23.7)	2.2 (18.4)	9.23 (21.2)	3.23 (5,109)	0.009[a]	5.57 (1,115)	0.02[a]
AS	18.0 (35.0)	2.9 (24.4)	15.07 (30.0)			7.37 (1,115)	0.001[b]
DP	9.9 (23.5)	3.3 (19.1)	6.61 (21.4)			2.80 (1,115)	ns
PL	7.1 (16.5)	1.6 (15.1)	5.55 (15.8)			3.54 (1,113)	ns
TS	9.7 (24.6)	4.8 (18.7)	4.82 (21.8)			1.43 (1,115)	ns

SAQ = Seattle Angina Questionnaire; T_1 = Time 1; T_2 = Time 2; T = treatment; C = controls; Δ = mean change; T_Δ = mean change, treatment; C_Δ = mean change, controls; AF = angina frequency; AS = angina stability; DP = disease perception; PL = physical limitation; TS = treatment satisfaction; SD = standard deviation.
Note: SD of change scores expected to be large, as range of scores not bound by zero.
[a]$P < 0.05$.
[b]$P \leq 0.01$.
ns = nonsignificant ($P > 0.05$).

Table 5
ANOVA Tests for Significant Differences in SES and SCS Change Scores Between Groups

	Change Treatment	Change Control	Difference in Change between Groups	ANOVA	
Variable (Range)	$\Delta(T_2 - T_1)$ M (SD)	$\Delta(T_2 - T_1)$ M (SD)	$(T_\Delta - UC_\Delta)$ M (SD)	F (df)	P
SES (10−100)	8.4 (17.6)	−0.2 (14.4)	8.62 (16.1)	8.45 (1,115)	0.004[a]
SCS (0−100)	4.2 (26.5)	−1.6 (19.2)	5.80 (23.0)	1.60 (1,115)	ns

T_1 = Time 1; T_2 = Time 2; T = treatment; C = Controls; Δ = mean change; T_Δ = mean change; treatment; C_Δ = mean change; controls; SES = Self-Efficacy Scale; SCS = Self-Control Schedule; SD = standard deviation.
Note: SD of change scores expected to be large as range of scores not bound by zero.
[a] $P < 0.01$.
ns = Nonsignificant ($P > 0.05$).

cohort and differences found in change scores between treatment and control groups. No significant associations between intervention cohort and group differences in change scores were found.

CASMP Attendance

As a form of process evaluation, an attendance record was kept to track the number of CASMP sessions attended by the treatment group participants. Ninety-three percent of those in the treatment group attended all six program sessions; the remaining 7% attended three or more sessions. The average number of sessions attended overall was 5.8.

Discussion

Statistically reliable short-term improvements in HRQL and self-efficacy were found for those who participated in the CASMP as compared to the control group; specific components of HRQL significantly improved included overall physical functioning and general health (SF-36) and frequency and stability of angina pain symptoms (SAQ). As no prior psychoeducation-based trials for CSA have used the SF-36 or the SAQ, direct comparisons of our HRQL-related results were not possible. However, our findings generally compare favorably with those of trials that have used other means to evaluate HRQL. We found four psychoeducation trials that reported significant improvements in symptoms, including duration, frequency, and severity of cardiac pain.[40−43] Two of these trials also found significant improvements in physical functioning with respect to exercise tolerance and general disability.[40,42] Although our findings are consistent with these positive trends, comparisons must be viewed with caution due to heterogeneity of methods including design, interventions, timing of outcome measurement, and instrumentation.[39] Nevertheless, sample characteristics across trials are similar to our sample, suggesting that physical functioning and angina symptoms can improve after participation in psychoeducational interventions that target angina pain symptoms, self-management techniques, and physical activity enhancement. Future angina psychoeducation randomized controlled trials (RCT) using robust methods, and standard reliable and valid measures to evaluate HRQL would allow for more direct comparisons to this trial.

Although focused on a different population, LeFort et al.'s CPSMP trial is the only other known study to have used the SF-36 to evaluate the impact of psychoeducation on a persistent pain problem.[37] Comparable to our study with respect to intervention format, design, and sample size, LeFort et al. found that their CPSMP program significantly improved SF-36 role physical functioning, bodily pain, vitality, and mental health for persons with chronic noncancer pain ($P < 0.003$).[37]

LeFort et al.'s significant improvement in a broader array of SF-36 dimensions than those achieved by our program may be attributable to the nature of respective pain problems addressed and participants' corresponding foci for self-management. Participants in LeFort et al.'s study had a number of chronic pain problems, averaging 6.7 somatic locations for pain per participant. Individuals, therefore may have focused on a broader range of goals for pain self-management than our sample, leading to improvements across SF-36 physical and mental health components. Participants in our study, however, were most concerned with reducing their fear of cardiac pain to

enhance their physical capacity. Based on pilot data, our program targeted a common misbelief among CSA patients that sedentary behavior will minimize cardiac pain and risks to personal safety.[33] Accordingly, the vast majority of our treatment group identified their fear of physical activity and subsequent pain as a major contributor to deconditioning, poor overall health, fatigue, and obesity. Enhancement of physical activity was, therefore, their immediate self-management priority. This concentrated self-management focus may account for our treatment group's narrower, although significant, improvements in SF-36 physical functioning and general health. There is also some evidence to suggest that the SF-36 may inadequately discriminate among those with differing CCS angina functional class.[61] Because our sample included those with CCS Classes I–III angina, some SF-36 subscales may not have been sensitive to improvements in angina-induced disability as a result of our program. Finally, baseline scores on all SF-36 dimensions in this study are below Canadian- and U.S. population-adjusted norms.[57,77] Given the deleterious impact of CSA on HRQL, improvement in multiple SF-36 dimensions may be difficult to achieve for CSA patients in the short term.

Prior work has established that a minimum change of 10 points in SAQ subscales reflects clinically meaningful change for angina patients.[13,63,65] In our study, AS and AF scores changed in a positive direction for the treatment group by a mean 18 (35.0) and 11.4 (23.7) points, respectively, and, therefore, meet this criterion for clinically meaningful change. This finding is consistent with the positive results of recent studies that have tested multifaceted CSA secondary prevention strategies, with some educational components.[65,78] Spertus et al.[65] and Moore et al.[78] reported similar findings resulting from their intervention strategies, featuring combinations of antianginal drug therapy, regional anesthesia, exercise rehabilitation, education sessions, and/or individual counseling. Greater short-term improvement in frequency and stability of angina pain symptoms in our trial as compared to these studies may be due to the self-efficacy enhancing nature of our standardized intervention format. Our significant improvement in treatment group self-efficacy is consistent with LeFort et al.'s CPSMP trial.[37] and Lorig and Holman's psychoeducation trials for arthritis self-management.[35] Consistent with Bandura' self-efficacy theory, health behavior change by instruction—without addressing self-efficacy—has not been shown to be as effective as those interventions that target self-efficacy directly.[79]

Other scores not significantly improved at post-test included SAQ-treatment satisfaction, disease perception and physical limitation, and resourcefulness, as measured by the SCS. As with some SF-36 subscales, a longer-term evaluation period may be required to see significant improvement in these scores for CSA patients. In addition, psychometric properties of the SAQ-physical limitation (PL) scale may account for our lack of a significant finding in this disease-specific HRQL dimension. The SAQ-PL scale was adapted by Spertus et al.[63] from Goldman et al.'s Specific Activity Scale,[80] designed to assess CAD patients' capacity for physical stress. Six of nine total SAQ-PL items examine activities known to increase myocardial oxygen demand, including climbing a hill or flight of stairs without stopping, gardening, vacuuming or carrying groceries, walking more than a block at a brisk pace, lifting or moving heavy objects, and participating in strenuous sports.[63] However, as our pilot study suggests, most CSA patients will learn to avoid moderate levels of physical activity due to their fear of pain.[33] Therefore, more strenuous activities captured by the SAQ-PL scale may not be relevant to CSA patients. Notably, Spetrus et al.[65] and Moore et al.[78] also found no significant improvements in SAQ-PL for their chronic angina samples. These data suggest that the responsiveness of the SAQ-PL scale to improvements in mild physical activity for CSA patients, such as walking and household activity, warrants further investigation.

The strengths of our study are the robust methods used to minimize biases and random error, including a priori power analysis, centrally controlled randomization, valid and reliable measures, blinding of data collectors, intention-to-treat analyses, and examination for possible intervention cohort effects. In addition, assiduous follow-up procedures and the use of a wait-list control condition guarded against attrition bias, ensuring minimal loss to follow up. Treatment integrity was also maximized using a theoretically sound and

standardized intervention protocol, verified by an external auditor via audio recording.

Performance bias cannot be ruled out, as it is not possible to blind participants or interveners in a socially-based intervention study. Social desirability may also be a possibility due to our use of self-report measures.[81] However, randomization should have equally distributed those prone to socially desirable responses.[74] The risk of sample size bias may be further reduced in a future study by obtaining a larger sample to ensure adequate power for the two SF-36 role functioning scales. Also, our follow-up period was limited to three months after baseline. Therefore, the long-term sustainability of the observed intervention effects is not known. In addition, all CASMP sessions were delivered by a single facilitator. Future studies of this intervention should use multiple facilitators to enhance external validity and include longer-term follow-up. Finally, this study was conducted at a university site in central Canada; the clinical utility and knowledge translation potential of future investigations may be enhanced by examining the effectiveness of the CASMP as an adjunctive component to facets of health care with preexisting infrastructure, such as standard cardiac rehabilitation programs (where applicable), or community health-care programs and facilities.

In conclusion, cumulative evidence supports the deleterious impact of CSA on HRQL. The CASMP was found effective for improving physical functioning, perceived general health, angina pain frequency and stability, and self-efficacy to manage angina at three months post-test. Further research is warranted to determine the capacity of the program to improve other dimensions of generic and disease-specific HRQL, and resourcefulness in the longer term. A subsequent long-term evaluation would also allow for examination of the sustainability of the short-term improvements observed in HRQL and self-efficacy for CSA patients.

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