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A Prospective, Controlled Multi-Site Study of Psychosocial and Behavioral Change following Women's Cardiac Rehabilitation Participation

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Abstract

BACKGROUND—Despite its proven benefits and need, women are significantly less likely to participate in and complete cardiac rehabilitation (CR). Thus, there are few reports of CR outcomes among women, particularly when compared to women who do not participate in CR. The purpose of this study was to prospectively assess psychosocial and behavioral changes, comparing women who participated in CR to those who did not.

METHODS—157 female cardiac inpatients from 3 hospitals consented to participate in a prospective study, and 110(79%) were retained 18 months post-discharge. A mailed survey discerned CR participation 9 months post-discharge. Quality of life (SF-12 PCS & MCS), exercise behavior (HPLPII), exercise barriers (EBBS), anxiety and depressive symptoms (HADS) were assessed in hospital and 18 months post-discharge.

RESULTS—51(45.1%) women self-reported participating in CR at 1 of 18 sites, and site-verified participation was 82.43±29.97% of prescribed sessions. For CR participants, paired t-tests assessing change from hospitalization to 18 months post-discharge revealed significant improvements in physical quality of life ($p<.001$), anxiety ($p<.05$), and exercise behavior ($p=.01$). For women not participating in CR, they experienced significant improvements in physical quality of life ($p=.02$), and depressive symptoms ($p=.03$), but not exercise behavior.

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Declaration of Interest

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CONCLUSIONS—Following a cardiac event, female patients improved their physical quality of life and affect, but only patients who participated in CR increased their exercise behavior. Given that this exercise behavior was sustained post-CR, the cardiac benefits of exercise, and that women are often sedentary, these findings are significant. Randomized controlled trials of women's CR outcomes are greatly needed.

Heart disease is the leading cause of morbidity and mortality for women.{{495 Grace, S.L. 2003;}} Cardiac rehabilitation (CR) is an outpatient secondary prevention program composed of structured exercise training and comprehensive education and counseling which addresses cardiac risk.{{30 Canadian Association of Cardiac Rehabilitation 2004; }} CR has been shown to reduce mortality by 25%,{{405 Taylor, R.S. 2004;1446 Jolliffe, J.A. 2001; }} to reduce the need for re-hospitalization and the use of interventional procedures, and to have beneficial effects on cardiac risk factors, exercise capacity, psychosocial well-being, and health behaviors including physical activity,{{305 Brown, A. 2003;45 Lavie, C.J. 1995; }} all in a cost-effective manner.{{1097 Papadakis, S. 2005;1979 Carlson, J.J. 2000; }}

Despite its proven benefits and need, women are significantly less likely to participate in and complete CR.{{1152 Bittner, V. 2003; 2506 Arthur, H.M. 2001; }} This has led to a paucity of data on women's outcomes following CR, including their psychosocial and behavioral outcomes. This dearth is notable, given that women cardiac patients are shown to have poorer psychosocial well-being than men{{336 Grace, S.L. 2005; 1152 Bittner, V. 2003; }} and to be less active,{{2507 Bock, B.C. 2003; }} and the negative prognostic effects of each.{{1243 Grace, S.L. 2005; 333 Grace, S.L. 2004; 225 van Melle, J.P. 2004; }} While there have been some descriptive studies on the effects of CR participation through comparison of women and men's psychosocial outcomes,{{3265 Cannistra, L.B. 1992;213 Ades, P.A. 1992; 532 Schuster, P.M. 1991; }} there are few gender-specific studies of CR outcomes.{{295 Oldridge, N.B. 1980; }} In particular, there are few studies on women's psychosocial and behavioural changes post-CR,{{1153 Sanderson, B.K. 2003; 1109 Moore, S.M. 2002; 1151 Sanderson, B.K. 2005; }} and none to our knowledge have examined changes post-CR in a controlled fashion. The purpose of this study was to prospectively assess changes in psychosocial health, comparing women who participated in CR to those who did not.

Methods

Procedure and Design

This study utilized a prospective, controlled quasi-experimental design, and represents secondary analysis of data collected within the context of a larger study on access to CR. {{2953 Grace, S.L. 2007; }} Ethics approval was obtained from participating sites. Participants were followed from admission for an acute coronary syndrome (ACS) or revascularization for 18 months. Consecutive patients were recruited on relevant cardiovascular units by a research assistant when medically stable. ACS diagnosis was confirmed based on indication in patient chart of detailed history, focused physical examination, diagnostic ECG changes (i.e., Q waves, and/or ST-T segment changes), and/or troponin levels above the 99th percentile of normal. Patients admitted for percutaneous

coronary interventions (PCIs), or acute coronary bypass (ACB) were also eligible. Exclusion criteria from the larger study included being medically unstable, too confused to participate, previous participation in CR, being ineligible for CR based on Canadian Association of Cardiac Rehabilitation { 30 Canadian Association of Cardiac Rehabilitation 2004; } guidelines due to musculoskeletal, vision, non-dysphoric psychiatric, or other comorbidities, or being unable to read or speak English. Those who met study criteria and agreed to participate signed a consent form and were provided with a self-report questionnaire. Consent was also obtained to extract cardiac clinical data from their medical charts.

Nine and 18 months later, participants were mailed a survey. The 9 month post-discharge assessment generally corresponds to the end of the average CR programs in the region (i.e., 6 month programs plus recovery and wait list time), while the 18 month post-discharge assessment would reflect any changes sustained post-CR.

Participants

Four hundred and twenty-one consecutive female patients at Trillium Health Centre or University Health Network Toronto General or Toronto Western Hospitals in Ontario, Canada were approached to solicit informed consent. Of these patients, 157 consented to participate and 186 were ineligible for the study (response rate = 157/235=67%). Reasons for ineligibility were as follows: lack of English language proficiency ($n=52$; 28.0%), too ill to participate ($n=41$, 22.0%), previous attendance at CR ($n=36$; 19.4%), comorbid condition not indicated for referral to CR ($n=34$; 18.3%), patient too confused or experiencing cognitive impairment ($n=11$; 5.9%), comorbid musculoskeletal condition which precludes ambulation ($n=5$; 2.7%), patient being unable to complete the questionnaire ($n=5$, 2.7%), or patient already participating in two studies ($n=2$, 1%).

Characteristics of participants and non-participants are shown in Table 1. There were no significant differences in participation based on marital status. Of the patients approached, participants were significantly younger than those who were ineligible to participate. Participants' ages ranged from 36-85. The majority of participants self-reported their ethnocultural background as white ($n=95$, 94.1%).

Measures

Sociodemographic data assessed in the self-report survey administered in hospital included age, ethnocultural background, marital status, work status, level of education, and gross annual family income. Body Mass Index (BMI) was computed based on self-reported height and weight (kg/m^2). Participants were asked if they were current, past or non-smokers. They were also asked to check comorbidities from a list of 13 conditions including musculoskeletal, gastrointestinal and respiratory conditions. The number of conditions was counted and a total score was generated. Data were extracted from clinical charts including confirmation of reason for index hospitalization, and disease severity. (NYHA Class { 199 The Criteria Committee of the New York Heart Association 1994; })

The Duke Activity Status Index (DASI; { 371 Hlatky, M.A. 1989; }) is a brief 12-item, self-administered survey to determine functional capacity. Participants were asked about their ability to perform common activities of daily living, such as personal care, ambulation,

household tasks, sexual function, and recreational activities, which are each associated with specific metabolic equivalents (METs). This valid and common tool correlates highly with peak oxygen uptake.{{392 Nelson, C.L. 1991; }}

Cardiac rehabilitation participation

In the survey administered by mail 9 months post-discharge, participants self-reported whether or not they participated in CR and at which site. Eighteen CR centers were contacted to verify referral date, participant enrollment and to provide the percentage of the prescribed program the participant attended. CR is publicly funded in the province for 6 months of intervention. CR programs in Ontario offer a median of 2 on-site exercise sessions per week (i.e., average of 48 prescribed sessions).

Dependent variables assessed in hospital and at 9 and 18 months post-discharge

The Short-Form Health Survey (SF-12) is a 12-item measure of health-related quality of life, which provides a Physical and Mental Component Summary score. {{1185 Ware, J.E. 1996; }} The SF-12 has been found to be a reliable and valid scale in variety of patient populations,{{983 Ware JE, Kosinski M, Keller SD. 1998;1185 Ware, J.E. 1996; }} including cardiac patients. Higher scores indicate greater quality of life.

The exercise behavior subscale of the Health-Promoting Lifestyle Profile II (HPLPII){{3338 Walker, S.N. 1987; }} was used to assess the amount of recreational and physical activity in which participants engaged. The subscale consists of 7 items rated on a 4-point Likert scale from 'never' to 'routinely'. A mean score was computed, with higher scores indicating greater exercise participation. During its development, the HPLPII showed high internal consistency, with a Cronbach's alpha coefficient of 0.92.{{3338 Walker, S.N. 1987; }}

Dependent variables assessed in hospital and at 18 months post-discharge

The Exercise Benefits and Barriers Scale (EBBS){{2401 Sechrist, K.R. 1987; }} was administered to assess perceived physical activity barriers. Items were rated on a four-point Likert scale. The Barriers subscale consists of 14 items and assesses a person's belief about negative aspects of exercise. Higher scores indicate greater perceived barriers. The standardized Cronbach's alpha coefficients was 0.89. {{2401 Sechrist, K.R. 1987; }}

The Hospital Anxiety and Depression Scale (HADS){{204 Zigmond, A.S. 1983; }}, a reliable and well-validated scale {{2860 Bjelland, I. 2002; }} was used to assess anxiety and depressive symptoms, or affect. The HADS is a 14-item self-report questionnaire: anxiety and depressive symptomatology were each measured through 7 items rated on a 4-point Likert-type scale. Total scores range from 0 to 21, where a score below 8 indicates the 'normal' range of subthreshold symptoms, a score of 9 to 10 represents moderate affective symptomatology, and a score of 11 or greater represents severe affective symptomatology. {{204 Zigmond, A.S. 1983; }}

Statistical Analyses

SPSS 15.0 was used for the following analyses. Following data cleaning and screening, differences between participating, ineligible and declining patients were tested by Pearson's

chi-square and analyses of variance as appropriate. Differences between participants retained 18-months post-discharge and those lost to follow-up were then tested, followed by differences in patients who participated in CR versus those who did not. Data were split by CR participation, and a descriptive examination of dependent variables at the in-hospital, 9 and 18 month post-discharge assessments was performed. Paired *t*-tests were performed to test for significant differences in dependent variables over time among the participants who participated and did not participate in CR.

Results

Respondent Characteristics

Of the 157 consenting female participants, 12 were ineligible and 116 were retained at the nine-month post-discharge assessment (retention rate = $116/145 = 80.0\%$). Reasons for ineligibility were as follows: too ill to participate ($n=4$; 33.3%), deceased ($n=4$; 33.3%), unable to reach/incorrect contact information ($n=3$; 25.0%), and not an ischemic/cardiac related diagnosis ($n=1$; 8.3%).

At 18 months post-discharge, 110 participants were retained in the study (87.3% retention rate). Reasons for ineligibility were as follows: cannot reach/incorrect contact information ($n=7$; 36.8%), too ill to take part ($n=5$; 26.3%), deceased ($n=4$; 21.1%), and other reasons ($n=3$; 15.8%). Characteristics of participants and those who declined or were ineligible 18 months from hospitalization were compared. Retained (65.5 ± 10.3) and ineligible (66.8 ± 13.9) patients were significantly older than declining (59.8 ± 12.9) patients ($p<.05$), but there were no other sociodemographic differences.

Referrals were verified with CR sites, and received a median of 31.5 days from acute care admission (range 0–208 days). Fifty-one (45.1%) women self-reported participating in CR at one of 18 sites, and site-verified participation was $82.4 \pm 30.0\%$ of prescribed sessions. Table 2 presents the characteristics of patients who participated in CR versus those who did not. The only significant differences were that CR participants were less likely to have a PCI as the reason for their index admission, and were likely to be more educated than non-participants.

Changes in Psychosocial Health and Behavior by CR Participation

Table 3 displays the mean dependent variable scores by CR participation across all 3 time points. With regard to differences between CR participants and non-participants, the only difference in hospital was that non-participants perceived greater exercise barriers. This significant difference persisted at 18 months post-discharge. With regard to exercise behavior, while there were no significant differences in hospital, CR participants engaged in significantly more exercise at 9 and 18 months post-discharge. There were no significant differences in quality of life or affective symptoms between CR participants and non-participants at any time point.

Paired *t*-tests assessing change from hospitalization to 9 months post-discharge revealed significant improvements in physical quality of life ($p=.001$ for CR participants, $p<.001$ for non-participants), and mental quality of life ($p=.05$ for CR participants, $p=.03$ for non-

participants). Only CR participants reported significant increases in exercise behavior ($p < .001$). Paired t-tests assessing change from 9 to 18 months post-discharge revealed significant attrition in exercise behavior among CR participants ($p < .001$), and a trend toward attrition among CR non-participants ($p = .07$).

For CR participants, paired t-tests assessing change from hospitalization to 18 months post-discharge revealed significant improvements in physical quality of life ($p < .001$), and anxiety symptoms ($p < .05$). Among women who did not participate in CR, by 18 months they experienced significant improvements in physical quality of life ($p = .02$) and depressive symptoms ($p = .03$). However, only the CR participants reported an overall sustained increase in exercise behavior ($p = .01$) from hospitalization to 18 months post-discharge.

Discussion

There are few studies assessing women's psychosocial and behavioral outcomes following CR participation.{{1153 Sanderson, B.K. 2003; 1109 Moore, S.M. 2002; }} and even fewer of these are controlled studies, or studies which assess change post-CR. Our results suggest that the simple passage of time may result in significant improvements in quality of life and affect for women following a cardiac event or procedure, where these benefits are generally experienced within 9 months or earlier and sustained thereafter. However, only CR participation results in significantly greater exercise behavior following a cardiac event and when compared to non-CR participants.

Psychosocial Outcomes

Previous uncontrolled studies of women's outcomes following CR participation have shown improvements in quality of life following CR participation.{{1151 Sanderson, B.K. 2005; 213 Ades, P.A. 1992; 2508 Oldridge, N. 1991; }} However, non-CR studies of quality of life among women in the months following a myocardial infarction also reveal improvements in quality of life.{{2013 Worcester, M.U. 2003; }} Results reveal that women's quality of life appears to improve following an acute cardiac event or procedure regardless of CR participation. These findings warrant replication with a randomized design and larger sample however.

Depressive and anxiety symptoms are highly prevalent in cardiac patients. For example, a recent review reported major depression in 19.8% of cardiac patients, with 31.1% experiencing elevated depressive symptoms.{{1534 Thombs, B.D. 2006; }} Anxiety is even more common than depression following a cardiac event.{{333 Grace, S.L. 2004; }} Women cardiac patients suffer a greater burden of negative affect than men,{{336 Grace, S.L. 2005; 1152 Bittner, V. 2003; }} and this affective distress can negatively affect prognosis.{{1243 Grace, S.L. 2005; 225 van Melle, J.P. 2004; }} The current results suggest that women who participate in CR experience significant decreases in anxiety over 18 months from hospitalization, whereas non-participating women experience significant decreases in depressive symptoms over this time interval. Given there is some overlap in depressive and anxiety symptoms,{{2514 Kendall, P.C. 1990; }} and both are so common in women heart patients,{{927 Abbey, S.E. 2000; }} it is likely that these results generally reflect improvements in overall affect following an acute cardiac event or procedure. These

results do corroborate reports in the literature on the effects of CR in reducing anxiety among women participants,{ {44 Lavie, C.J. 2004; } } and mixed effects of CR in reducing depressive symptoms.{ {1122 Lavie, C.J. 1999; 1151 Sanderson, B.K. 2005;2512 Uniken Venema-van Uden, M.M. 1989; 45 Lavie, C.J. 1995; } } Overall, replication is warranted given the negative effects of some psychosocial interventions on women's outcomes.{ {229 Frasure-Smith, N. 1997;187 Berkman, L.F. 2003; } }

Exercise and Exercise Barriers

A key component of CR is on-site exercise, with most programs prescribing home-based exercise nearly all other days of the week. Thus, it may be expected to find that women who participate in CR engage in significantly greater exercise behavior than women who do not. However, the literature suggests that 50% of CR participants drop out, and that a greater percentage of women than men drop out.{ {386 Moore, S.M. 1998;2056 Moore, S.M. 2003; } } Therefore, the significantly greater exercise among female CR participants compared to non-participants evidenced in this study is noteworthy. The benefits of exercise for cardiac patients including women are well established and include reduced mortality, morbidity, risk factor burden including hypertension and hyperlipidemia, risk of diabetes, psychosocial distress, and improved weight and body composition, as well as endothelial function.{ {1749 Hambrecht, R. 2000;1985 Hambrecht, R. 1993; 966 Franco OH, de Laet C, Peeters A, Jonker J, Mackenbach J, Nusselder W 2005 Nov 14; } }

It is remarkable that this exercise increase among CR participants was sustained 18 months post-discharge, well after the termination of a CR program. Given their greater exercise behavior 9 months post-discharge than 18 months however, clearly full increases are not sustained. Similar results among women who participated in CR were presented by Gupta et al. { {2503 Gupta, R. 2007; } } in an uncontrolled prospective study. A trend toward the same pattern of increased exercise post-discharge with subsequent decay was seen among CR non-participants nevertheless, suggesting that motivation to change behavior might be greatest following a cardiac event, but then decrease over time. A similar pattern has been shown in other prospective studies of exercise in cardiac patients who did not participate in CR.{ {2055 Reid, R.D. 2006;1977 Blanchard, C.M. 2002; } } Future research should investigate interventions which exploit this increased motivation post-event in an effort to prolong and sustain it over time, so patients can realize a lifestyle change.

Finally, results revealed greater exercise barriers in women who did not participate in CR at both the in-hospital and 18 month post-discharge assessment. There were no significant changes in perceived exercise barriers over time. This suggests that women who perceive fewer exercise barriers are more likely to enroll in CR, and that perhaps the identification of women with greater perceived exercise barriers and applying means to target these women for CR enrollment may be warranted. Perhaps the development of interventions to aid women cardiac patients in identifying and addressing their exercise barriers is warranted.

Limitations

Caution is warranted when interpreting these results, most notably in relation to design, generalizability, sample size, and measurement issues. First, given the non-random study

design, causal conclusions regarding the changes realized for female heart patients cannot be drawn. Second, generalizability is limited by the selection biases and differences between CR participants and non-participants. In particular, and as shown in other studies, { { 110 Pell, J. 1996; 2055 Reid, R.D. 2006; 511 Cooper, A.F. 2002; } } CR participants were more likely to have had ACS or an ACB than a PCI, and were more educated than non-participants. Third, due to the small number of females in the sample, lack of power may be masking changes. A sufficiently-powered randomized controlled trial (wait list control for ethical reasons) of women's outcomes following CR participation is greatly needed. Finally, the use of self-report measures is open to social desirability bias and other errors in reporting. In particular, self-report of exercise behavior may be biased. Moreover, we did not assess whether participants met exercise recommendations with regard to intensity, duration and frequency, and therefore these results only speak to change and differences in exercise behavior.

Overall, female patients improved their physical quality of life and affect following a cardiac event, but only patients who participated in CR increased their exercise behavior. Given that this exercise behavior is sustained post-CR, the cardiac benefits of exercise, and that women are often sedentary, these findings are significant. Randomized controlled trials of women's CR outcomes are greatly needed.

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Table 1

Characteristics of Participating, Declining, and Ineligible Patients at Baseline Recruitment, N=421

Characteristic	Participants (<i>n</i> =157)	Declined (<i>n</i> =78)	Ineligible (<i>n</i> =186)
Condition/Procedure ¹ (%PCI)	90 (57.3%)	41 (53.2%)	69 (37.5%)*
Marital Status (% married)	95 (60.5%)	44 (60.3%)	101 (55.2%)
Age (mean $\pm$ <i>SD</i>)	64.5 $\pm$ 11.4	67.7 $\pm$ 12.0	69.1 $\pm$ 11.6*

*
p .001

PCI, percutaneous coronary intervention

Table 2

Baseline Characteristics of CR Participants and Non-Participants

Characteristic	CR Participants (n=51)	Non-Participants (n=65)	Total (n=116)
Condition/Procedure ^I (%PCI)	26 (51.0%)	43 (69.4%)	69 (61.1%) [*]
Marital Status (% married or common law)	35 (68.6%)	38 (61.3%)	73 (64.6%)
Age (mean ± SD)	63.9 ± 9.5	65.9 ± 12.2	65.5 ± 10.3
Body Mass Index (mean ± SD)	28.6 ± 5.9	27.4 ± 5.7	28.0 ± 5.7
Activity Status (mean ± SD)	31.2 ± 18.4	26.6 ± 16.6	28.8 ± 17.4
NYHA Class ^I (% Class 1)	42 (89.4%)	46 (83.6%)	88 (86.3%)
Diabetes (% yes)	10 (20.4%)	18 (29.0%)	28 (25.2%)
Arthritis (% yes)	22 (43.1%)	22 (35.5%)	44 (38.9%)
Smoker (% current)	6 (12.2%)	9 (14.8%)	15 (13.6%)
Ethnocultural Background (% white)	44 (91.4%)	52 (91.2%)	96 (91.4%)
Education (% some post-graduate or greater)	31 (60.8%)	18 (30.5%)	49 (44.5%) ^{**}
Family income (% \$50 000CAD)	20 (50.0%)	14 (30.4%)	34 (39.5%)

*
 $p < 0.05$,**
 $p < 0.001$ ^I
Extracted from medical charts.

PCI, percutaneous coronary intervention; NYHA, New York Heart Association.

Table 3
Mean and Standard Deviation of Psychosocial Health Variables by CR Participation Across Eighteen Months Post-Discharge

	In Hospital N=157		9 Months Post-Discharge N=116		18 Months Post-Discharge N=110	
	CR Participants(n=51)	CR Non- participants (n=106)	CR Participants (n=51)	CR Non- participants (n=65)	CR Participants (n=45)	CR Non- participants (n=65)
Quality of Life- Physical	35.5±10.2	36.0±9.9	43.8±9.8 [‡]	43.3±11.3 [‡]	44.3±10.0 [§]	41.8±11.6 [§]
Quality of Life - Mental	45.4±11.5	45.4±11.0	48.9±10.0 [‡]	49.0±10.5 [‡]	48.0±11.3	49.1±11.4
Exercise Behavior	1.9±0.7	1.8±0.7	2.6±0.7 ^{***‡}	1.9±0.6	2.2±0.7 ^{***‡§}	1.8±0.7
Exercise Barriers	2.0±0.5	2.3±0.5 [*]	-	-	2.0±0.5	2.2±0.4 [*]
Anxiety	7.9±4.6	7.7±4.5	-	-	6.4±4.6 [§]	6.6±4.0
Depressive Symptoms	4.6±3.5	5.0±2.8	-	-	4.3±3.7	4.1±3.3 [§]

* $p < 0.05$,
** $p < 0.01$,
*** $p < 0.001$ for differences between CR participants and CR non-participants
[‡] $p = 0.05$ for difference between in hospital to 9 months
^{‡*} $p < 0.05$ for difference between 9 months to 18 months
[§] $p < 0.05$ for difference between in-hospital to 18 months