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Fee-for-service cancer rehabilitation programs improve health-related quality of life

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ABSTRACT

Background Rigorously applied exercise interventions undertaken in a research setting result in improved health-related quality of life (HRQOL) in cancer survivors, but research to demonstrate effective translation of that research to practice is needed. The objective of the present study was to determine the effect of fee-for-service cancer rehabilitation programs in the community on HRQOL and on self-reported physical activity and its correlates.

Methods After enrolment and 17 ± 4 weeks later, new clients ($n = 48$) to two fee-for-service cancer rehabilitation programs completed the 36-Item Short Form Health Survey (RAND-36: RAND Corporation, Santa Monica, CA, U.S.A.), the Godin Leisure-Time Exercise Questionnaire, and questions about physical activity correlates. Normal fee-for-service operations were maintained, including a fitness assessment and individualized exercise programs supervised in a group or one-on-one setting, with no minimum attendance required. Fees were associated with the assessment and with each exercise session.

Results Of the 48 participants, 36 (75%) completed both questionnaires. Improvements in the physical functioning, role physical, pain, and energy/fatigue scales on the RAND-36 exceeded minimally important differences and were of a magnitude similar to improvements reported in structured, rigorously applied, and free research interventions. Self-reported levels of vigorous-intensity ($p = 0.021$), but not moderate-intensity ($p = 0.831$) physical activity increased. The number of perceived barriers to exercise ($p = 0.035$) and the prevalence of fatigue as a barrier ($p = 0.003$) decreased. Exercise self-efficacy improved only in participants who attended 11 or more sessions ($p = 0.002$). Exercise enjoyment did not change ($p = 0.629$).

Conclusions Enrolment in fee-for-service cancer rehabilitation programs results in meaningful improvements in HRQOL comparable to those reported by research interventions, among other benefits. The fee-for-service model could be an effective model for delivery of exercise to more cancer survivors.

Key Words Physical activity, quality of life, exercise therapy, fatigue

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INTRODUCTION

Cancer treatment is associated with negative physical side effects, including increased fatigue and pain, diminished cardiorespiratory fitness and strength, and negative psychological side effects, including diminished quality of life, anxiety, and depression[1–5]. Many of those side effects can be long-term and can affect health-related quality of life (HRQOL)[6], a concept that encompasses subjective perceptions of both physical and emotional symptoms and side effects of treatment[7].

Evidence from randomized controlled trials documents the ability of rigorously designed and implemented exercise interventions to ameliorate many adverse effects of cancer treatments, including reduced HRQOL[6,8]. In an initial effort to move the available research into practice, community-based cancer-specific exercise programs, offered free of charge or for a nominal fee, have been developed through partnerships with universities or not-for-profit organizations. Those programs have also reported improvements in HRQOL measured using a range of instruments[9–15]. However, a for-profit business model might be necessary to sustain and broaden access to exercise programming in the community. To our knowledge, no results about the efficacy of cancer rehabilitation programs operating with such a business model have been published. Although participants

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in a for-profit program could be expected to be different in socioeconomic status, motivation levels, and attendance from those participating in programs offered by research studies or not-for-profits, understanding the effects of the for-profit business model will help to guide future rehabilitation programming in Canada.

The 36-Item Short Form Health Survey (RAND-36: RAND Corporation, Santa Monica, CA, U.S.A.) of HRQOL is the tool most widely used to collect patient-reported outcomes in clinical trials[16]. This multipurpose health survey uses 8 multi-item scales that assess various health concepts to capture the perceptions of participants about their general health; the 8 scales then form 2 distinct higher-order clusters based on the physical and mental health variance that they have in common[17]. A number of previously published studies, including randomized controlled trials[18,19], uncontrolled research intervention studies[20–23], and evaluations of a community-based program[12,14] have used the RAND-36 to evaluate the effect of an exercise program on HRQOL for individuals after a cancer diagnosis, defined as cancer survivors. All studies reported improvements in the individual scales of the questionnaire, reaching statistical significance more often for the physical health scales (that is, physical functioning, role limitations related to physical health, energy/fatigue, pain) and the physical component summary than for the emotional health scales. Importantly, in the randomized controlled trials, the improvement was statistically larger in the exercise groups than in the usual-care control groups[18,19].

The primary objective of the present study was to evaluate the effect on HRQOL of enrolment in a fee-for-service cancer rehabilitative exercise program offered in the community by for-profit businesses. The secondary objectives were to evaluate the effect of this program type on physical activity, exercise self-efficacy and enjoyment, and perceived barriers to exercise. An exploratory objective was to determine whether changes in those outcomes were related to program attendance.

METHODS

Participants and Setting

This observational study evaluated individuals who enrolled in two established community-based fee-for-service exercise programs for cancer survivors in Vancouver or White Rock, British Columbia. New English-speaking adult clients between 1 May 2011 and 31 January 2014 were invited to participate by program staff at their initial program visit. Exclusion criteria initially included stage IV cancer, orthopedic or neurologic injury affecting balance or gait, uncontrolled hypertension, pregnancy, cardiac illness, or psychiatric conditions. The eligibility criteria were amended on 16 January 2013 to accept any new English-speaking adult clients with a cancer diagnosis who were approved by the programs to participate in exercise. Reasons for ineligibility or for not approaching clients about the study were not collected by program staff. The University of British Columbia research ethics board approved the study.

The standard operating procedure for the programs is that new clients receive a baseline fitness assessment (at a cost of $85–$100, although that cost is included in the cost of an integrative cancer care membership for some) performed by staff exercise trainers with a cancer-specific exercise certification[a]. The trainers then develop an individualized exercise program generally consisting of 20–30 minutes of aerobic (50%–80% heart rate reserve), 15–20 minutes of resistance, and 5–10 minutes of flexibility and core strength exercises. The client can then perform their individualized program in one-on-one sessions (cost: $70–$75) or in small groups with other survivors (cost: $15–$25) supervised by an exercise trainer. Clients are encouraged to aim to attend 2 sessions per week, but attendance depends on their willingness to pay for each individual session. Using an observational approach, the research staff did not intervene in the program's standard operating procedure. No minimum attendance of supervised sessions was required for inclusion in the study because the goal was to capture changes that occur with real-life program use.

Outcome Measures

A study package with a self-addressed and stamped envelope was provided at the first program visit. Interested participants returned the completed study package—which included a signed informed consent form; a questionnaire package with questions about demographics, cancer diagnosis and treatments; and the questionnaires discussed in the subsections that follow—by mail. The consent form did not discuss attendance requirements for study participants, and the goal of the study was presented as a general review of the exercise program.

Primary Outcome: HRQOL

The RAND-36, a multipurpose health survey that captures the perceptions of participants about their general health across 8 multi-item scales[17] was used to measure HRQOL.

Secondary Outcomes: Physical Activity and Correlates

The American and Canadian physical activity guidelines for healthy adults, and the joint guidelines from the American College of Sports Medicine and the American Cancer Society for cancer survivors recommend 150 minutes of moderate-to-vigorous aerobic physical activity (MVPA) per week to achieve health benefits[8,24,25]. We used the Godin Leisure Time Exercise Questionnaire[26] to measure self-reported frequency and duration of moderate and vigorous physical activity in the preceding 7 days.

Known correlates of physical activity, including exercise self-efficacy and enjoyment, and perceived barriers to exercise, were also measured. Exercise self-efficacy is described as an individual's perceived confidence in their ability to persist with exercise in various situations; it is a variable that is closely tied to the future performance of

[a] See, for example, the American College of Sports Medicine's ACSM/ACS Certified Cancer Exercise Trainer, http://certification.acsm.org/acsm-cancer-exercise-trainer, and the University of Northern Colorado's Clinical Cancer Exercise Specialist Workshop, http://www.unco.edu/nhs/cancer-rehabilitation-institute/education/workshop/index.aspx.

exercise[27]. The exercise self-efficacy questionnaire contained 5 items (answered on an 11-point Likert scale) about the responder's confidence in his or her ability to persist with exercise in various situations[27]. Exercise enjoyment was measured by a single question that asked participants to rate (on a 5-point Likert scale) their enjoyment of engaging in regular exercise[28]. The exercise barriers questionnaire asked participants to rank (on a 5-point Likert scale) how often 21 different barriers interfered with exercise in the preceding month[28].

Exploratory Outcome: Program Attendance

The total number of supervised sessions attended by each participant was collected from the program staff.

Follow-Up

At 12–16 weeks after enrolment, participants were mailed another questionnaire package and stamped envelope. That timeframe coincided with a planned physical fitness reassessment conducted by the exercise trainers[29]. A study investigator not affiliated with the exercise programs also contacted participants by telephone to encourage completion.

Scoring and Analyses

The RAND-36 questionnaires were scored as specified by the RAND Corporation to calculate the 8 scales; the physical and mental component summaries were calculated using factor score coefficients multiplied by each scale[30–32]. Scales were not calculated if 50% or more of the individual response items had not been answered. The number of barriers was calculated as a count of barriers occurring "often" or "very often" for each participant. The prevalence of each individual barrier occurring "often" or "very often" at both time points was calculated as a percentage of all participants answering that question. Exercise self-efficacy was calculated as the sum of the answers to the 5 questions. Weekly minutes of vigorous or moderate exercise were calculated for each individual as their reported vigorous-to-moderate exercise frequency multiplied by their reported vigorous-to-moderate exercise time. Those two variables were added together to calculate total weekly minutes of MVPA. The individual MVPA was then used to categorize individuals as meeting or exceeding current public health exercise guidelines (MVPA $\geq$ 150 minutes), sedentary (MVPA = 0), or achieving insufficient exercise (MVPA = 1–149 minutes)[33].

Descriptive statistics and frequencies (using the total available responses as the denominator) were used to describe the demographic, cancer diagnosis and treatment, and exercise characteristics of all participants at baseline. Paired t-tests were used to assess the change between baseline and follow-up for all continuous variables, except for physical activity, for which Wilcoxon signed rank tests were used, because those data were skewed by a high number of zeros. The McNemar test was used to assess change in frequency distribution between baseline and follow-up. Yates correction was applied for categorical variables having n $\leq$ 5 data points per cell. To assess the effect of attendance on the size of the change, the median number of total sessions attended was used to split the group into "low attenders" and "high attenders." Mann–Whitney U-tests were used to test whether there were differences in the size of the change between those groups. The Python statistics software application (version 2.7.9: Python Software Foundation, Wilmington, DE, U.S.A.) was used for statistical analyses, with statistical significance set at an alpha of 0.05 without adjustment for multiple comparisons. The G*Power software application (version 3.0.10: Heinrich-Heine-Universität, Düsseldorf, Germany) was used for sample size calculation.

RESULTS

During the time of open enrolment, new clients with a cancer diagnosis totalled 281. Of those 281 clients, 82 (29%) both were eligible for the study and were provided with the study package by program staff; 50 (18%) agreed to participate. Later, 2 participants requested to withdraw, and their data are not included. A sample size of 50 with a 25% dropout rate provided a power of 0.90 to detect a mean difference of 4 in RAND-36 physical functioning (minimal important difference estimated to be 3–5[34]) and a standard deviation of 8.

Table I describes the baseline demographic, cancer, and exercise characteristics of the 48 remaining participants. Median age in the group was 58 years (range: 20–78 years), and median time since diagnosis was 10.5 months (range: 1–174 months). Most participants were female, white, college-educated; annual income was $60,000 or more. Most had an early breast cancer diagnosis and had completed chemotherapy and radiation therapy. Approximately one quarter of the participants enrolled in the program during active treatment. Equal proportions of participants were categorized as sedentary, performing insufficient exercise, and meeting or exceeding exercise guidelines in the week before they completed the baseline questionnaires. Fatigue and pain or discomfort were both common barriers to exercise in the preceding month (44% and 31% respectively). Overall, nausea was a barrier for only 7% of participants; however, of those who were currently receiving chemotherapy (and answered the question), nausea was a barrier for 44% (data not shown). Overall, the demographics of the study population were fairly narrow.

Of the 48 participants, 36 (75%) completed the follow-up questionnaire package at a mean of 17 ± 4 weeks after the baseline questionnaire package. There was no difference in demographics between those who did and did not complete the follow-up package. Significant improvements were observed in the RAND-36 scales of role limitations related to physical health (p = 0.006) and energy/fatigue (p = 0.042), and in the physical component summary (p = 0.020); the physical functioning and pain scales approached significance (p = 0.098, p = 0.055 respectively; Table II). As demonstrated in Figure 1, the mean changes observed in the current study exceeded the minimal important difference in all of the physical health scales, the physical component summary, and the role limitations related to emotional health scale[34]. Overall, enrolment in the exercise program was associated with meaningful improvements in the physical health scales of the RAND-36 measure of HRQOL, but not in the emotional health scales.

Mean weekly minutes of MVPA increased to 138 ± 155 from 101 ± 125 ($p = 0.186$), explained predominantly by a significant increase in vigorous minutes (to 39 ± 73 from 13 ± 30, $p = 0.021$). Moderate weekly minutes and the proportion of exercise meeting public health guidelines (≥150 MVPA minutes weekly) did not change ($p = 0.831$ and $p = 1.000$ respectively).

TABLE I Baseline demographics, cancer diagnosis and treatment, and exercise characteristics of the study cohort

Variable	Value
Patients (*n*)	48
Age (years)	
Median	58
Range	20–78
Female sex [*n* (%)]	39 (81)
White race [*n* (%)]	42 (88)
Marital status[a] [*n* (%)]	
Married or living with partner	31 (66)
Divorced, separated, or widowed	10 (21)
Never married	6 (13)
College or higher education [*n* (%)]	30 (63)
Income ≥$60,000[a] [*n* (%)]	37 (79)
Time since diagnosis (months)	
Median	10.5
Range	1–174
Cancer type [*n* (%)]	
Breast	28 (58)
Gynecologic	5 (10)
Head and neck	3 (6)
Hematologic	3 (6)
Other	9 (19)
Stage [*n* (%)]	
0	1 (2)
I	7 (15)
II	13 (27)
III	12 (25)
IV	3 (6)
Undetermined or don't know	12 (25)
Underwent surgery [*n* (%)]	41 (85)
Chemotherapy [*n* (%)]	
None	15 (31)
Planned or current	12 (25)
Completed	21 (44)
Radiation [*n* (%)]	
None	19 (40)
Planned or current	10 (21)
Completed	19 (40)
MVPA (minutes/week)	
Median	58
Range	0–450
Exercise characteristics [*n* (%)]	
Sedentary	17 (35)
Insufficient exercise	15 (31)
Meeting exercise guidelines	16 (33)

[a] One missing response.
MVPA = moderate-to-vigorous physical activity.

The total number of perceived exercise barriers declined to 2.6 ± 3.7 from 4.1 ± 3.6 ($p = 0.035$). The prevalence of fatigue and nausea as barriers to exercise declined to 27% from 55% and to 0% from 9% ($p = 0.003$ and $p < 0.001$ respectively). The only other barriers to exercise that declined were "not in routine" (to 9% from 32%, $p = 0.027$) and "lack of exercise professional" (to 0% from 16%, $p < 0.001$). Responses to the barriers questionnaire from 3 participants were missing.

Self-efficacy and exercise enjoyment did not change ($p = 0.549$ and $p = 0.629$ respectively), and 1 participant's response was missing for each question. So, despite a lack of improved confidence in their ability to exercise or increased enjoyment in exercise, participants who enrolled in the supervised exercise program experienced a reduction in the total number of barriers to performing exercise, including some specific cancer-related and non-cancer-related barriers.

The number of supervised program visits attended was available for 29 participants. Data from the other 7 participants were excluded because of incomplete attendance records. On average, the participants for whom records were available attended 14.7 ± 13.5 supervised sessions (range: 0–50 sessions) or 0.9 ± 0.7 sessions per week (range: 0–2.4 sessions). Compared with low attenders, high attenders (that is, those who attended the median of 11 or more sessions) experienced significantly greater changes in general health (3.1 vs. –4.1, $p = 0.007$) and self-efficacy (7.0 vs. –3.6, $p = 0.002$), and a trend toward a significant change in total barriers (–3.4 vs. –0.6, $p = 0.058$). No differences between the attendance groups were observed in the other RAND-36 scales, in self-reported physical activity, or in exercise enjoyment (data not shown).

DISCUSSION

The objective of the present study was to evaluate the effect of enrolment in a fee-for-service cancer-specific rehabilitative exercise program offered by for-profit businesses in the community on HRQOL, physical activity habits, and their correlates. We also explored whether the number of sessions attended influenced the changes. In the 75% of participants who returned a follow-up questionnaire package, statistically significant and meaningful mean improvements in several scales of the RAND-36 questionnaire, in self-reported weekly vigorous-intensity exercise, and in the total number of perceived barriers to exercise were noted approximately 17 weeks after enrolment in the program, regardless of attendance. Participants with low attendance experienced a decrease in general health and self-efficacy, and no reduction in barriers to exercise. Therefore, it seems that the act of enrolling in the fee-for-service program, including attending and paying for the initial fitness assessment, was associated with numerous benefits regardless of attendance level, and yet participants with higher attendance experienced more benefits,

TABLE II Changes in health-related quality of life[a] for 36 participants who completed the follow-up questionnaire

Scale or summary	Scoring			*p* Value[b]	Responses (*n*)
	Baseline	Follow-up	Difference		
Physical functioning	43.9±9.1	47.2±10.8	3.2	0.098	36
Role physical	26.1±14.5	33.2±16.2	7.1	**0.006**	33
Bodily pain	46.3±10.2	50.5±10.5	4.2	0.055	34
General health	47.7±8.4	46.4±9.5	–1.4	0.283	36
Energy/fatigue	41.2±11.8	45.4±11.6	4.2	**0.042**	36
Social functioning	43.4±10.5	45.9±10.2	2.6	0.164	34
Role emotional	30.9±21.3	35.6±20.0	4.7	0.216	33
Emotional well-being	46.4±9.6	47.4±10.4	1.0	0.616	36
Physical summary	41.3±9.5	45.7±9.8	4.4	**0.020**	34
Mental summary	40.4±15.1	42.7±14.6	2.2	0.409	34

[a] Mean ± standard deviation.
[b] Significant values shown in boldface type.

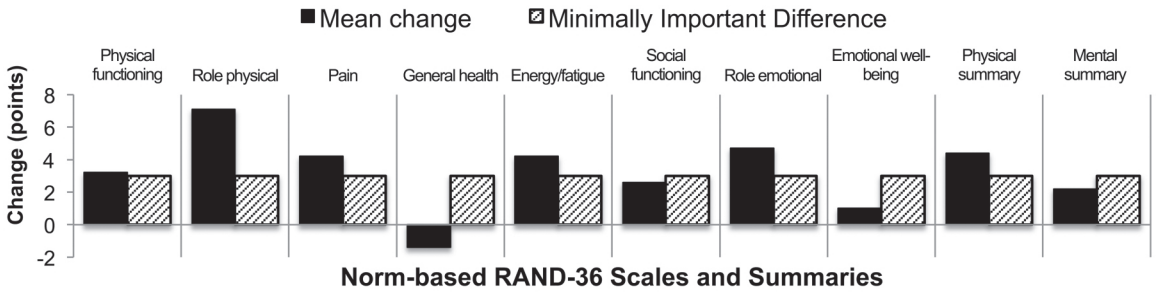

FIGURE 1 Change in health-related quality of life compared with the minimal important difference for individuals who enrolled in a fee-for-service cancer-specific community-based rehabilitation program[34].

including improvement in general health and self-efficacy, and a reduction in barriers to exercise.

Eight other studies were identified that measured the effect of exercise on HRQOL via the RAND-36 in cancer populations and that reported mean baseline and either follow-up or unadjusted mean change for 0–100 scores for the scales. The percentage change at follow-up in each scale of the RAND-36 was calculated for the present study and for those eight studies (Figure 2). In the research-based experimental studies after cancer treatment completion, Korstjens *et al.*[19] reported, for several scales, a noticeably larger improvement relative to those observed in the present study and the others. The intervention in the Korstjens study consisted of 12 weeks of twice-weekly 2-hour sessions involving aerobic, resistance, and sports training of unknown intensity, plus an education component related to exercise training, use of training logs, and goal setting. Van Weert *et al.*[22] implemented a similar 15-week intervention, except that only 1 weekly hour-long session of sports and 1 weekly 1.5-hour session of moderate-to-vigorous intensity aerobic and resistance exercise were used. Together, those two studies showed the greatest improvement in most HRQOL scales, perhaps because of the addition of sports training (for example, badminton, soccer) and education components. Notably, a shorter 6-week intervention, with a higher weekly volume of exercise, resulted in less than half the improvement on the physical scales, despite including components similar to those in the Korstjens and van Weert studies[23].

Adamsen *et al.*[18,20,21] implemented a 6-week intervention during chemotherapy treatment with higher frequency (thrice weekly) and intensity (moderate- to high-intensity), and different additional program components including relaxation, massage, and body awareness training. The magnitude of the change in HRQOL was similar to that in the present study, despite a much higher frequency and intensity of supervised exercise sessions than were attended by our study participants. However, only about one quarter of the participants in the present study were actively receiving treatment, and follow-up was much longer. Those factors are likely to affect the magnitude of the changes in HRQOL observed.

Noble *et al.*[14] reported changes after a community-based exercise program offered in partnership with a Canadian university. However, that program differed significantly from the programs in the present study: it was a structured 12-week program with 2 scheduled sessions weekly, and it appeared to be offered free of

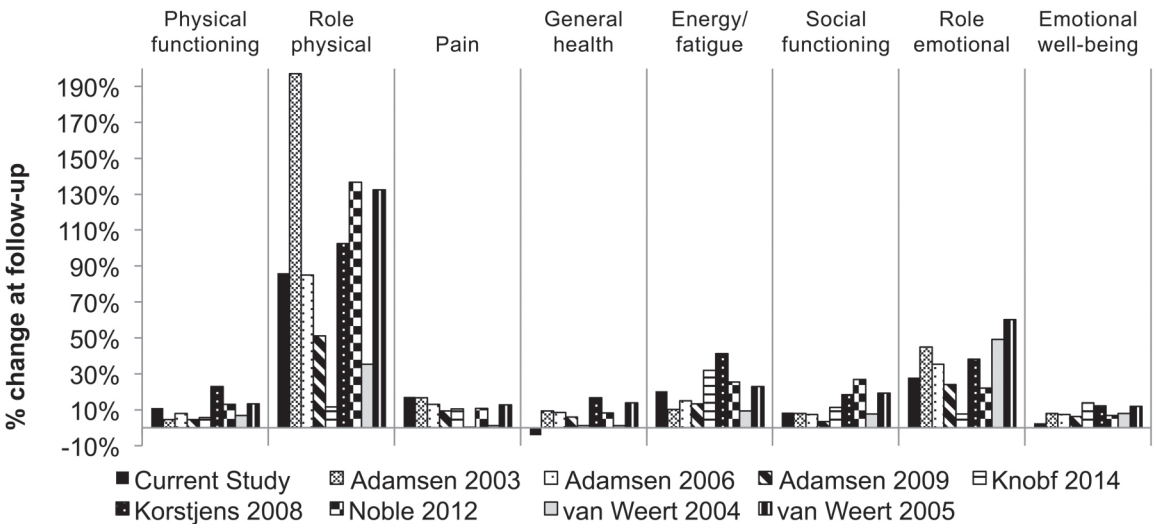

FIGURE 2 Comparison of percentage change from baseline to follow-up in health-related quality of life (0–100 on the 36-Item Short Form Health Survey scales) in the current study and in research-based supervised exercise intervention studies[18–23], a community-based exercise program[14], and a research-based study in a community setting[12].

charge. Despite differences in cost, structure, and (likely) attendance because of removal of the cost barrier, similar improvements in physical functioning, pain, and energy/fatigue were noted relative to the present study. Another similar 12-week twice-weekly community-based program offered in partnership with a not-for-profit organization to cancer survivors after treatment resulted in improvements similar to those observed in the present study[15] (data omitted from Figure 2 because of the norm-based reporting used in that study). That program involved 1 hour of predominantly resistance exercise, followed by 30 minutes of education. Interestingly, type of exercise could be a key consideration, because a 16-week research-based study implemented in a community gym, consisting of thrice-weekly aerobic exercise[12] resulted in much smaller improvements in physical functioning or role limitations related to physical health than did studies also involving resistance exercise (Figure 2).

The programs evaluated in the present study involved only an exercise component, and potentially for that reason, changes on the emotional and social scales were smaller than those observed in studies with interventions that also implemented a weekly psychosocial or education component[19,22]. The small mean decrease (–5%) in general health in the present study differs from results observed in the other studies identified in the literature, which all reported a small improvement. However, high attenders in the present study experienced a mean improvement of 3.1 points, while the low attenders group experienced a mean decrease of 4.1 points. Whether the decrease in general health resulted in lower attendance, or whether low attendance resulted in decreased general health is unknown.

Higher exercise self-efficacy and lower exercise barriers at the end of an intervention study have been reported to predict maintenance of physical activity in the subsequent 6 months[35]. In the present study, a mean decrease in exercise barriers was observed, and the high attenders experienced a significant mean improvement in self-efficacy. Those results suggest that the high attenders are likely to maintain their improved physical activity habits over time.

The prevalence of fatigue as a perceived barrier to exercise significantly declined at follow-up. Fatigue can persist for years after treatment[36], but can be improved by exercise training[3]. Our finding could either indicate reduced levels of fatigue at follow-up or the possibility that some participants learned to overcome the perception of fatigue as a barrier to exercise.

The demographics of individuals who enrolled in the current study were fairly narrow and not representative of the general population. Not surprisingly, most (79%) reported a household income at or above the median[37]. Study participants were disproportionately female (81%) and white (88%) in a geographic area in which 50% of the population is of Asian descent[38]. Furthermore, 58% had a breast cancer diagnosis—a diagnosis that represents only 26% of new cancer cases in Canadian women[39]. Finally, 13% were 70 years of age or older, an age group that represents 43% of all new cancer cases[39]. The ratios of women, white race, breast cancer diagnosis, and age in the present study were not unlike those for previously published free-of-charge community-based cancer rehabilitation programs in Canada and the United States[14,15]. Those findings indicate the need for community-based programs to broaden their reach to attract participants who are male, non-white in ethnicity, diagnosed with cancer types other than breast, and coming from older age groups. Further research is required to determine whether similar changes occur in those underrepresented demographics.

The present study provides a unique real-world perspective on the effects on HRQOL and physical activity level of a fee-for-service community-based cancer rehabilitation program. However, it has some limitations. First, with an 18% recruitment rate, the representativeness of the study

sample relative to the entire population attending the programs is unknown. Second, it is possible that participants who had a less-positive experience with the program or who did not participate as much were less likely to return their follow-up questionnaire, which would bias the results in a positive direction. Third, our measure of physical activity was self-reported, which tends to be an overestimate relative to objectively measured physical activity[40]. Last, because of our small sample size for attendance data, we were limited in the statistical power to detect the moderating effect of attendance on the outcome measures.

CONCLUSIONS

Enrolment in a fee-for-service cancer-specific program is associated with clinically significant improvements in HRQOL, increased self-reported exercise, and decreased perceived barriers to exercise, including fatigue. Specifically, improvements in the physical functioning, role limitations related to physical health, pain, and energy/fatigue scales of the RAND-36 questionnaire exceeded minimally important differences and were similar in magnitude to improvements reported in research-based experimental studies of structured and rigorously applied exercise interventions. Exercise self-efficacy improved only in participants who attended more than 11 sessions. Although an increase in vigorous-intensity exercise was observed, weekly self-reported MVPA did not significantly increase, nor did the proportion of exercise meeting the public health guidelines of 150 minutes or more per week. Those observational results are promising initial findings of the potential of fee-for-service cancer exercise rehabilitative programs in a real-world setting to positively affect HRQOL in cancer survivors.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare the following interests: JM and SH are the owners of the two centres in this study. They were involved in study design and data collection and reviewed the manuscript, but were not involved in data analysis, interpretation, or reporting of results. SW and TM are employees of the two centres and were involved in the same aspects of the project. The other authors have no conflicts to declare.

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