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Methodological Issues in Exercise Intervention Research in Oncology

Bernardine M. Pinto, Ph.D. [Associate Professor] and
Centers for Behavioral and Preventive Medicine, Miriam Hospital and Brown Medical School, Providence, RI

Andrea Floyd, M.A.
Brown Medical School, Providence, RI

Abstract

Objectives—To review randomized controlled trials (RCTs) that offered exercise interventions for adults diagnosed and treated for cancer related to design, sample, type of intervention and outcomes.

Data sources—Several electronic data-bases were searched and recent review papers were scanned to identify relevant publications.

Conclusion—Exercise adoption seems clearly feasible for early-stage cancer patients, particularly breast cancer patients. Data support positive effects for physical functioning, quality of life (QOL), and psychological well-being. Effects for patients with later-stage disease and other cancers are less clear. The impact of exercise adoption on biomarkers of disease status, immune functioning and hormone levels should also be examined.

Implications for nursing practice—There are many opportunities for nurses to promote exercise in clinical care and in a research context.

Since the early 1990s, there has been an exponential interest in the potential benefits that exercise participation can offer to individuals diagnosed with cancer. Consistent with these developments, there have been several recent reviews of the literature [1-5]. Interest in this research focus has also been strengthened by data on women diagnosed with breast cancer who participated in the Nurses Health Study [6], and from clinical trials among colorectal cancer patients [7, 8] that suggested that exercise participation may contribute to improved survival. Our review takes a broad overview of RCTs of exercise interventions for adults at any point of the cancer trajectory from diagnosis onwards with attention to the implications for oncology nurses.

Method

To identify studies to be included in the present review, the following electronic databases were searched up to January 2007: Medline, PsychInfo, CINAHL, CancerLit and Cochrane Controlled Trials Register. Search terms included: cancer patients, cancer survivors, oncology patients, exercise, physical activity, rehabilitation, interventions, clinical trials, controlled clinical trials, randomized trials, accrual, recruitment, retention, adherence and measures of

Mailing address: Bernardine M. Pinto, Ph.D., Centers for Behavioral and Preventive Medicine, Coro Bldg., Suite 500, One Hoppin Street, Providence RI 02903, Ph:401-793-8230, Email: Bpinto@lifespan.org.

physical activity. Also, the reference lists from identified studies as well as recent reviews [3-5, 9] on this topic were scanned to identify additional studies to be included. Only RCTs published in the English language were included. Participants were adults of either sex, diagnosed with any type or stage of cancer, in current treatment or in post-treatment. Both physical activity and exercise interventions[1] were included. Studies of relaxation exercises, such as yoga or tai chi were excluded. Also excluded were studies of physical therapy or rehabilitation as well as dissertations and conference abstracts. Thirty-three RCTs were identified for inclusion in the present review [10-44] (note: 12 was the follow-up to the RCT [11] and [24] presented different outcomes from the RCT[20]).

Review

Theoretical Bases

A majority of the exercise interventions have been atheoretical with a few exceptions. Demark-Wahnefried and colleagues, [45] and Pinto and her team, [37] used concepts from the Transtheoretical Model (TTM) [46] and Social Cognitive Theory (SCT) [47] as the basis for their interventions (primarily, telephone-based counseling). Basen-Engquist and her colleagues [13]; and Carmack Taylor and her team, [16] used the lifestyle approach to exercise [48, 49] that was also based on concepts from TTM and SCT. Similarly, Matthews and his team [28] based their exercise program on the Stanford Active Choices Program that incorporated SCT concepts. According to the TTM, individuals adopting a new behavior, such as exercise, progress along a continuum of five stages of change: 1) precontemplation (i.e., not considering exercise adoption in the next 6 months), 2) contemplation (considering exercise adoption in the next 6 months), 3) preparation (exercising but not regularly), 4) action (regularly exercising for fewer than 6 months), and 5) maintenance (regularly exercising for 6 months or more)[50]. TTM-based interventions attempt to tailor exercise recommendations to a participant's motivational readiness to become physically active; hence, participants who are ready for action (e.g., those in contemplation or preparation) receive appropriate guidance on setting exercise goals (e.g., choosing specific types of exercise, deciding where to exercise, setting up reminders to exercise and the like). Conversely, the TTM would suggest that such action-oriented recommendations would be ineffective for those who have no intention to adopt exercise (e.g., those in precontemplation). Exercise interventions based in SCT often focus on the construct of “self-efficacy” or self-confidence that one can achieve a particular goal. These interventions attempt to enhance self-efficacy by techniques such as setting realistic, easily attainable goals, focusing on participants' progress, and reinforcing successes; using social modeling, and training participants in self-regulation strategies and developing social support[37]. Mock and colleagues [30, 31] used the Roy Adaptation model [51] and also the Levine Conservation model of adaptation [32, 52] to guide their exercise interventions. In the Roy model, adaptation is viewed as an active process initiated by the individual of adjusting to environmental changes through physiological or psychological modes and in turn, affecting the environment. The rehabilitation model used by these researchers focused on physiological and psychosocial interventions to promote positive, adaptive responses to a cancer diagnosis and treatment. The Levine model is based on conserving individual integrity for maintenance of life and as applied by the Mock and colleagues [32] focused on exercise as an intervention that may support conservation of energy and structural integrity among women living with breast cancer.

[1]Physical activity refers to movement that results in energy expenditure; exercise is defined as regular, repetitive planned activity done to improve fitness. We used the term “exercise” to include physical activity.

Exercise Training

Many of the programs offered exercise training on-site with supervision [11, 12, 14, 15, 20, 22, 23, 25-27, 34, 36, 44] a growing number have been home-based [17, 19,18, 21, 28, 32, 35, 37, 41, 42] and one training program offered both on-site and home-based components [10]. A few programs provided on-site classes to teach behavioral skills relevant to exercise [13, 15, 16, 28]. One study compared on-site supervised exercise to home-based exercise and to a control condition [39]. In a few studies, exercise was offered along with an educational component, [13] group psychotherapy/support group [19,30], stress management [26], a dietary intervention [21] or as part of a multi-component intervention [11].

The training modality has been for the most part, aerobic exercise [13-15, 18-20, 22, 23, 26, 27, 31, 32, 35-37, 39, 41, 43, 44]. More recently a few investigators have offered resistance exercise training [10, 38, 40]; and in four studies, cancer patients received both aerobic and resistance training [17, 25, 29, 34]. The intensity of the aerobic exercise training has shown some variability; however, most programs required participants to exercise from at least 50% maximum heart rate (max. HR) [23, 39, 44] to an upper limit of 75% max. HR [15, 19]. In two on-site supervised programs and one home-based program, the maximum exercise intensity was set at 85% max. HR [41, 43, 44]. Several programs promoted exercise goals similar to the U.S. Surgeon General's recommendations for U.S. adults [53] of exercising at least at moderate-intensity on most days (at least 5 days) of the week for at least 30 minutes each day [13, 16, 19, 45,18,32, 35, 37]. The length of the programs showed considerable variability ranging from 2 weeks [33] to 6 months,[10, 13, 21, 32, 39] with one program lasting a year [38]. The trainers or interventionists (not always specified in the publications) have included research staff [22, 37], fitness professionals [10, 11, 26, 36, 38-40, 42], and oncology or research nurses [11, 30, 35].

Attendance rates for on-site supervised programs have been good to excellent ranging from 70% [15] to 98% [20] and have been used as indices of program adherence. For home-based programs, less is known about adherence; although a few investigators have reported adherence rates that ranged from 75% [18] to 94% [28]. A few studies reported contamination effects (as high as 52% [18]) with control groups also exercising [18, 32, 35]. Such contamination effects are likely to become prevalent since ethics boards are inclined to disallow restrictions on control participants not to exercise. Hence, it will be a challenge for researchers to identify appropriate and comparable “control” groups.

At this time, there is scant data to address the minimum exercise dose needed to yield a specific benefit vis a vis symptom reduction (e.g., reduction of fatigue, improvement in sleep), overall improvement in QOL, mood or physical functioning. Burnham and Wilcox [14] compared two exercise intensities with a control condition: the two exercise groups did not differ from each other on physiological outcomes (aerobic capacity, percent body fat and flexibility). Hence, the results of the two exercise groups were combined. As the field develops from pilot studies to quasi-experimental designs, and more recently, to RCTs, one can expect further examination of this important question.

Participants

The majority of studies to date have utilized small sample sizes that are rarely based on power calculations, thus resulting in many underpowered studies. Of the 33 RCTs in the present review, only eight studies had greater than 100 participants [11, 12, 16, 19, 21, 39, 40, 42]. Participants in most of these studies have been composed of breast cancer patients and survivors, thus participants have been mainly female. Twenty-one of the studies were composed solely of breast cancer patients [10, 13, 15, 20, 24-30, 32, 34-39, 41, 43, 44]. Two were composed solely of prostate cancer patients [16, 40]. In seven of the studies reviewed, the samples were composed of mixed cancer diagnoses with the majority of the participants being

breast cancer patients [11, 12, 14, 19, 21, 22, 42]. One study was conducted among 13 multiple myeloma patients receiving high-dose chemotherapy and autologous peripheral blood stem cell transplantation [17]. Another was conducted among 93 colorectal cancer patients [18]. Additionally, one study was conducted among stomach cancer patients [33].

Most of the studies were conducted with patients in early-stage disease with very few studies including patients with Stage IV disease. These studies were conducted at various points in the cancer trajectory, including newly diagnosed patients, patients undergoing various forms of treatment, as well as survivors who had completed treatment. Participants in the studies were generally middle-aged ranging in age from 39 to 60 years. There were two exceptions: one study of prostate cancer patients had a mean age of 69 years [16]. The other focused specifically on breast and prostate cancer patients aged 65 years and above [21], the mean age for participants in this study was approximately 72 years. The majority of study participants were White and educated (at least high school or greater). Furthermore, recruitment methods and inclusion/exclusion criteria for research studies often necessarily result in carefully selected samples in which many potential participants have been screened out [54]. For example, participants in later stages of cancer and those with other concurrent chronic illnesses are often excluded.

Outcomes

Taken together, an Agency for Healthcare Research and Quality report [1], recent reviews [3-5, 9] as well as the studies included in the present review all suggest that exercise interventions in cancer patients and survivors are associated with favorable outcomes. Benefits have been conferred with respect to reduction of fatigue, enhancement of QOL, psychological well-being, body image, and improvements in physical functioning (oxygen capacity, cardiorespiratory fitness, other fitness or strength measures, flexibility and global health), anthropomorphic measures (body weight, body fat and waist/hip circumference) and health-related biomarkers (blood pressure, heart rate, hemoglobin concentration, circulating hormone levels and immune parameters) [55]. The most common categories of measures utilized in exercise intervention studies in oncology patients, as mentioned above, have been measures of physical fitness, physical functioning, QOL, psychological well-being, morphological measures and health-related biomarkers. However, studies often use only certain categories of these measures and the assessment measures vary widely across studies. The diversity of outcome measures used in exercise intervention research with cancer patients and survivors makes comparisons across studies difficult.

Only a handful of studies have looked at health-related biomarkers after exercise intervention in oncology patients. Fairey and colleagues [24] as well as Na and colleagues [33] have found increases in natural killer cell activity, an important immunological response to tumors, among oncology patients who participated in exercise programs. Nieman and co-authors [34], on the other hand, found no significant differences in natural killer cell activity in breast cancer patients after an exercise intervention. Insulin-like growth factor increased after a weight training intervention in breast cancer patients [38]. Segal and colleagues [40] found no change in testosterone or prostate specific antigen (PSA) levels after their supervised resistance exercise intervention in men with prostate cancer.

Little attention has been given to examining the mechanisms of change in exercise intervention research. This is related to the fact that much of the research has not been guided by or based on theory. Pinto and colleagues [37] whose home-based physical activity intervention for breast cancer patients was based on the TTM of behavior change and SCT found that participants in the intervention group were more likely to progress in motivational readiness for physical activity with corresponding improvement in physical activity behaviors than participants in the control group. Carmack Taylor and colleagues [16] whose lifestyle activity intervention for prostate cancer patients was also guided by TTM and SCT found that participants in the

intervention group reported using more cognitive and behavioral processes of change for physical activity and reported advances in motivational readiness for physical activity at post-intervention as well as at the 6 month follow-up; however, there were no significant increases in their physical activity. In Demark-Wahnefried and colleagues' [21] home-based exercise and diet intervention among breast and prostate cancer patients, participants in the intervention group reported significant improvements in self-efficacy for exercise as well as exercise frequency post-intervention, but no changes were observed in the readiness to exercise.

Additionally, few studies include adverse reactions or tolerability as outcome measures in exercise intervention research in oncology patients. Courneya in his RCT among breast cancer patients found a higher incidence of lymphedema in the exercise group [20]. Thorsen [42] found increased fatigue among exercise participants (note that this was not reported as a side-effect but as an outcome). In their study of resistance training, Schmitz and colleagues[38] reported a total of 22.5% injury rate among those who trained for a year.

Attrition rates reported in RCTs to date have typically been low, further supporting the feasibility of exercise interventions among oncology patients who were carefully screened for study participation. Segal and colleagues [39] in their study of a supervised vs. a self-directed walking program with breast cancer survivors reported an 80% retention rate. In their subsequent study of a supervised resistance exercise intervention among prostate cancer patients receiving androgen deprivation therapy, [40] they reported an 87% retention rate. Attrition from home-based programs has also been low with rates of less than 10% [18, 21, 37]. However, Coleman and colleagues [40] had a 42% retention rate in their home-based combined aerobic and strength exercise program for multiple myeloma patients receiving high dose chemotherapy and peripheral blood stem cell transplant.

Follow up/Maintenance of Effects

The current literature in exercise interventions in oncology patients is lacking in terms of long-term follow-ups, leaving unanswered questions regarding persistence and maintenance of exercise and its associated benefits. Of the studies reviewed, six included follow-up after the period of the intervention [11, 16, 21, 26, 37, 41]. At a one-year follow-up, Berglund and colleagues [12] found that benefits in physical training, physical strength and fighting spirit were maintained in a mixed cancer sample. However, as is the case with exercise interventions in the general population [1], oncology patients also find it difficult to maintain exercise after the intervention has ended [26, 55]. Clearly, the data on the maintenance of effects is lacking and more research is necessary in this area in order to make definitive conclusions. No studies to date have examined the long-term effect of exercise interventions on cancer recurrence and survival.

Strengths

The field has grown tremendously since the earliest studies in the late 1980s[27, 43, 44]. Although a preponderance of interventions has been offered to breast cancer patients, some researchers have tested interventions among prostate cancer patients [16, 40], colorectal [18], multiple myeloma [17] as well as stomach cancer patients [33]. In the early studies, patients on adjuvant treatments were offered on-site supervised exercise; since then, there has been an interest in home-based programs with safeguards in place to monitor exercise participation and patients' health. For home-based programs, efficacy tests have been strengthened by the efforts to go beyond self-reported PA participation by using objective activity monitoring or fitness testing[17, 19, 28, 32, 37, 42]. Attention has been paid to confounding variables in research designs that include stratification variables such as disease or treatment variables such as stage of disease [26, 37], cancer treatments [15, 20, 39], intent of treatment (curative vs. palliative) [40], baseline motivational readiness for exercise [55] or functional capacity [14, 27, 43, 44],

baseline body fat percentage [38], baseline QOL [14] or demographic variables such as age [37, 38], race/ethnic minority background [21] and gender [21]. In terms of the research questions, a few trials examined the potential benefits of exercise in attenuating specific side effects of treatment such as nausea [43] and were offered to patients during adjuvant treatments; consequently these programs tended to be shorter in duration. However, if the researcher is interested in more global effects such as psychological well-being, QOL and physical functioning, the length of programs may need to be longer. Some investigators have focused on teaching behavioral skills for the adoption and maintenance of PA [13, 16] and this is an appropriate direction given the anticipated challenge of maintaining exercise after structured programs have ended. In keeping with the AHRQ [1] recommendations to track adverse events associated with exercise adoption, explicit statements about adverse events have been reported in recent studies [14, 20, 39] and it is important for researchers to continue tracking and reporting of such events.

Limitations

There are several limitations of the completed exercise intervention studies which should guide future research in this area. Studies should use interventions that are guided by and based on theory. Theory-based interventions are preferable because they allow for results that are replicable and generalizable. Additionally, theories provide guidance in the development of interventions, what the appropriate outcomes should be as well as the mechanisms of change. Given the current literature, we know that exercise interventions are feasible and appear to be beneficial in cancer populations. The methodological rigor of studies has improved but more is needed. Studies should have larger sample sizes, based on power calculations and be RCTs with complete reporting according to Consort guidelines. Intent-to-treat analyses should be used where appropriate. Studies should clearly define their primary outcomes and avoid making multiple comparisons, particularly when underpowered. The majority of studies have been conducted among breast cancer patients. Future studies should investigate exercise interventions among patients diagnosed with other cancers. The majority of studies to date have been composed of samples that are primarily White, middle-aged, highly educated and mostly female due to the large number of studies of breast cancer patients. Exercise intervention research should be conducted among more diverse populations.

For on-site exercise programs, researchers have reported adherence data, but this is not common among tests of the efficacy of home-based trials. It is particularly important for home-based exercise interventions to include self-report exercise logs to help assess adherence to the intervention; devices such as pedometers or actigraphs should also be considered to obtain corroboration for self-reported exercise. Measures of exercise participation (or fitness when appropriate), psychological well-being, QOL as well as cancer-related biomarkers should be included as outcomes of exercise interventions among oncology patients. As is true of exercise trials for healthy individuals, there is variability in the outcome measures used across studies (e.g., exercise, physical functioning, fitness, mood, QOL). Using standardized, well-accepted measures consistently across studies will certainly help to reach definitive conclusions about the effects of exercise. Importantly, longer term follow-up is needed after the completion of exercise interventions to assist in determining the maintenance of effects.

While there are many research studies of exercise interventions in cancer patients, there has been very little focus on the translation of this research into clinical practice. This is a place where nurses could play a major role, as they often have more contact time with patients. As is clear from this review, underserved groups (e.g., elderly, rural residents, ethnic minority patients) have not generally participated in exercise intervention trials; yet these are groups that oncology nurses encounter in clinical care. These patients may be receptive to

recommendations to become physically active and assistance from nurses. In addition, nurses can help provide referrals to specialists when appropriate.

Future Directions

There is a vast scope for oncology nurses to encourage, advise and support exercise participation among those patients for whom exercise is not contraindicated. Patients develop a relationship with their healthcare providers and their advice is respected and may indeed be acted on.[56] The new guidelines issued by the American Cancer Society [57] specify several aspects of physical activity promotion that are relevant to healthcare providers.

For researchers and clinicians, there are several questions that need to be addressed before definitive recommendations can be made:

A. WHAT?

1. What type of exercise (modalities such as aerobic, resistance, or both; as well as the exercise dose) yields benefits specifically for treatment sequelae, physiological status, functional status, psychological benefits, and QOL?
2. What types of exercise (aerobic, resistance or both; on-site, home-based or both?) are safe and provide benefits? What mechanism(s) provide these benefits?
3. What programs are needed for those at various points of the cancer trajectory: soon after diagnosis, during treatment, post-treatment or palliative care?
4. What types of programs are needed for subgroups of cancer patients/ survivors such as the elderly, young, low income or those residing in rural areas?
5. What types of programs can help prevent co-morbidities associated with cancer treatments (e.g., cardiovascular disease, osteoporosis)?

B. WHEN?

1. When is the optimal time to promote exercise after cancer diagnosis?
2. Are there opportunities during cancer treatments or at follow-up visits that are “teachable moments” when patients are receptive to such recommendations?

C. WHERE?

1. When is it necessary to provide on-site supervised exercise vs. home-based/ distance programs?

D. WHO?

1. Who will be responsive to exercise recommendations?
2. How best to tailor the message that it is effective for patients with various cancers and also for subgroups of patients such as the elderly?

In addition, there are large system or macro-level issues to be considered such as:

1. How to integrate evidence-based programs into oncology care?
2. How will exercise promotion by healthcare providers be reimbursed?

3. How to involve professionals from multi-disciplines (e.g., physicians, exercise physiologists, nurses, behavioral scientists, physical therapists) to establish and offer such programs within cancer care facilities?

Finally, there has been progress in offering interventions to promote exercise adoption among those diagnosed with cancer but little work has been done on examining exercise maintenance. It is intriguing to speculate whether cancer survivors are more or less likely to maintain a healthy behavior such as exercise and the variables associated with better maintenance. Maintenance of the behavior would appear to be more relevant to outcomes such as QOL, weight, physical functioning or survival but perhaps less relevant if the goal is to alleviate specific treatment-related side-effects such as nausea that subside over time.

Conclusion

Exercise programs have much promise in addressing concerns of cancer patients after diagnosis, across the cancer trajectory, to palliative care. The field has made many advances over the past 1 ½ decades; but many questions still need to be addressed. Overall cancer mortality rates have decreased in the U.S. [58] and there are over 10.5 million cancer survivors[59]. Evidence suggests that exercise can contribute to the well-being (physical functioning, fatigue, QOL) of these survivors. It is clear that, in research and in providing clinical services, oncology nurses can contribute to efforts to reduce sedentary behavior among cancer patients.

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