

Exercise therapy in women who have had breast cancer: design of the Sheffield women's exercise and well-being project

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Abstract

Recovering from cancer treatment can be a difficult experience, both physically and psychologically. This paper describes a randomized controlled trial that evaluates the effects of exercise therapy upon quality of life in 120 women who have had breast cancer. To facilitate behaviour change, exercise counselling is also included as an integral component in the exercise therapy intervention. Participants are randomized to one of three groups: exercise therapy, body conditioning (placebo control) or a normal care control group. The supervised exercise therapy and body conditioning sessions take place 3 times per week for 8 weeks. Outcome measures include quality of life, physical self-perceptions, depression, satisfaction with life, exercise behaviour, aerobic capacity and percentage body fat. All outcomes are assessed at baseline, 4 weeks during the intervention and at the end of the 8-week intervention. Follow-up assessments of outcomes take place at 3 and 6 months post-intervention. As the number of women surviving breast cancer is increasing and cancer treatment is linked to

reduced quality of life, it is critical to evaluate treatments that improve the quality of life of this population or hasten recovery following treatment.

Introduction

Breast cancer is by far the most common cancer in women with approximately 41 000 new cases diagnosed in the UK in 1999 (Cancer Research UK Breast Cancer Incidence Fact Sheet: <http://www.cancerresearchuk.org>). In terms of modifiable lifestyle variables, being overweight after the menopause, regularly drinking large amounts of alcohol, smoking and physical inactivity have been targeted as risk factors in terms of the incidence and re-occurrence of breast cancer [e.g. (Carpenter *et al.*, 1999; Pinto *et al.*, 2000)]. Breast cancer survivors are also at an increased risk of developing secondary tumours, osteoporosis, cardiovascular diseases and obesity (Demark-Wahnefried *et al.*, 2000), and this heightened threat may be a result of health-related choices (i.e. sedentary lifestyle).

Women diagnosed with breast cancer often experience a host of negative emotions, including anger, fear and hopelessness. Courneya and Friedenreich (Courneya and Friedenreich, 1999a) have commented that some of the most common psychological and emotional consequences of the cancer experience include depression, anxiety, stress, decreased self-esteem and loss of sense of control. The psychological responses often associated with breast cancer are of concern, but are also likely to impinge upon survivors' health behaviours (Greeno and Wing, 1994; Wardle *et al.*, 2000).

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Pinto *et al.* (Pinto *et al.*, 2000) have argued that the diagnosis and treatment of cancer constitute significant stressors *per se* that could hold ramifications for quality of life. Taken together, this has created an increased need for clinicians and researchers to examine issues that promote positive health choices, particularly exercise behaviour, in women recovering from breast cancer, because the outcomes could have implications for the risk of cancer recurrence and, ultimately, survival. It is therefore critical to evaluate treatments that may improve the quality of life of this population or hasten recovery following treatment.

The role of exercise therapy as an adjunctive treatment for quality of life and mental health enhancement has not been extensively investigated with cancer survivors, although the limited evidence that does exist has been positive. Baldwin and Courneya (Baldwin and Courneya, 1997) have reported cross-sectional data, which indicated that exercise participation was positively associated with physical self-esteem in female breast cancer survivors. Likewise, Courneya and Friedenreich (Courneya and Friedenreich, 1997b) reported that breast cancer survivors who exercised during and after treatment reported higher quality of life scores 1 and 2 years later. Furthermore, being able to function normally was perceived as the most important dimension underlying overall satisfaction with life. Recent research by Segal *et al.* (Segal *et al.*, 2001) has reported that self-directed and structured exercise can positively influence quality of life during treatment for breast cancer. Courneya *et al.* (Courneya *et al.*, 2003) have also concluded from the results of their study that home-based moderate intensity exercise may improve quality of life in cancer survivors. Although previous research is strongly suggestive of a positive link between exercise and well-being during and after cancer treatment, these studies are not without their limitations. Many studies have used small sample sizes and have been quasi-experimental, cross-sectional or retrospective designs. Moreover, these studies have offered an initial framework for understanding the exercise and well-being relationship, but they do not provide strong enough evidence of a causal

relationship. Pinto and Maruyama [(Pinto and Maruyama, 1999), p. 8] have stated that there is a 'need to conduct studies with a sample size sufficient enough to detect the outcomes of interest' and a limited number of studies have used a randomized controlled trial to investigate the effects of exercise upon quality of life in women who have had breast cancer. The recent studies by Courneya *et al.* (Courneya *et al.*, 2003) and Segal *et al.* (Segal *et al.*, 2001) are two notable exceptions to this, however. Such studies are needed to minimize bias inherent in previous studies.

Making the case for exercise

A range of psychological interventions (e.g. relaxation, psychotherapy and support groups) is available to assist cancer patients in recovering from cancer diagnosis, treatment and rehabilitation. A common feature of current psychosocial interventions is that their focus is largely psychological, and they are less likely to address adequately the physical and functional problems that breast cancer survivors can experience (e.g. weight gain and insomnia). Additionally, physical and functional problems may, in part at least, underlie some of the psychological distress often experienced by cancer survivors (Williamson and Schulz, 1992). Other researchers have also reported that functional well-being may be the least possessed, but most critical, dimension underlying satisfaction with life in cancer survivors (Courneya and Friedenreich, 1997a,b).

According to Demark *et al.* (Demark *et al.*, 2000), cancer survivors are also at increased risk of developing diabetes, osteoporosis and cardiovascular diseases, thus making them an important target population for health-related quality of life interventions. Given that many common psychologically based treatments (e.g. cognitive behavioural therapy, psychotherapy) can be expensive and are often in short supply, there is much to commend other strategies (Fox *et al.*, 2000). Martinsen (Martinsen, 1993) has argued that exercise can be self-sustaining in that individuals can maintain it once the basic skills have been learnt. Long-term, this could help cancer patients feel autonomous and

more 'in control' of their health. Moreover, studies have indicated that at least 50% of the variance in psychosocial adjustment to breast cancer is accounted for by non-medical intra-individual variables [*cf.* (Glanz and Lerman, 1992)].

The use of other standard psychological and quality of life interventions has received modest empirical support. Meyer and Mark (Meyer and Mark, 1995) considered the effectiveness (meta-analysis) of five psychosocial treatment categories on quality of life outcomes among patients with cancer. Beneficial effect sizes were small [effect size (ES) = 0.19–0.26] for all treatments and no significant differences between the treatment categories were recorded. In contrast, effect size values (using cancer specific quality of life scales) for exercise interventions with cancer survivors have been reported to be higher (ES = 0.3–0.67) (Courneya and Friedenreich, 1997b). Furthermore, Courneya *et al.* (Courneya *et al.*, 2003) compared the effects of group psychotherapy with another group that received exercise plus group psychotherapy. These researchers reported that those women assigned to the exercise plus psychotherapy group reported better physical well-being and satisfaction with life those women who only received group psychotherapy. These initial findings highlight the potential role of exercise, and emphasize a need for the development and evaluation of exercise-based interventions for use with cancer survivors. Importantly, these studies suggest that exercise can have a potent effect upon quality of life and mental health beyond the benefits experienced during other standard quality of life interventions, such as group psychotherapy.

The quality of life and psychological outcomes associated with participation in exercise are important, but consideration also needs to be given to long-term implications of individuals' adherence and motivation to exercise. Dropout from exercise has been reported to be a major health issue in both healthy and clinical populations (Dishman, 1991). Unfortunately, most studies that have examined the relationship with exercise and quality of life in cancer patients, and survivors have not included exercise counselling designed to promote exercise behaviour change within exercise interventions.

Unless individuals are given support to change, beyond that provided by exercise facilities or exercise programmes themselves, it seems unlikely that patients of cancer survivors will be unable to maintain their participation once the specified intervention period/research study is completed.

A useful model that may be used to frame exercise counselling interventions is the Trans-theoretical Model (TTM). Prochaska and DiClemente (Prochaska and DiClemente, 1983) in the development of the TTM described exercise behaviour as a series of stages, and this model has been an important theoretical advance in understanding when, how and why people change their health behaviours. The model hypothesizes that individuals progress through a series of stages of change: (1) precontemplation (not seriously considering a change), (2) contemplation (seriously considering a change), (3) preparation (making small changes), (4) action (making changes to an appropriate level) and (5) maintenance (sustaining the change over time). Movement across the stages is thought to be cyclic since many individuals do not succeed in their efforts to establish and maintain lifestyle changes (Prochaska *et al.*, 1992). Implicit in the stages of changes are the processes of change, which consist of strategies and techniques that people use to change their behaviour. These can be either cognitively or behaviourally based. King *et al.* (King *et al.*, 1998) in their randomized controlled trial (comparing a lifestyle physical activity program with a structured exercise program in changing physical activity behaviour) advocated the use of counselling in activity interventions. Long and Haney (Long and Haney, 1986) have found counselling to be a useful strategy in promoting active lifestyles in sedentary women.

The mismatch between stage of change and exercise intervention strategy can lead to high attrition rates. Therefore, it is important that research studies address this problem, and include practical and appropriate strategies as part of exercise interventions that give individuals the physical and psychological tools to sustain their exercise behaviour and thus experience positive psychological gains from long-term exercise. The TTM has been

used successfully to tailor interventions in the domain of addictive behaviours [e.g. (Prochaska *et al.*, 1985, 1999)] and studies have demonstrated its efficacy when examining exercise behaviour [e.g. (Cardinal, 1995; Dunn *et al.*, 1998)]. Specifically, Dunn *et al.* (Dunn *et al.*, 1998) as part of the *Project Active* randomized controlled trial used TTM as a guiding theoretical framework, and reported it to be an effective intervention approach because it increased energy expenditure and physical activity participation in previously sedentary individuals over a 6-month period.

Aims and purpose of the study

The aim of this study is to examine the effects of exercise therapy upon quality of life and psychological well-being in women who have had breast cancer. The applicability of the Theory of Planned Behaviour (Prochaska and DiClemente, 1983) for predicting exercise behaviour in women during treatment for breast cancer has been assessed previously by Courneya *et al.* (Courneya *et al.*, 1999b) and Blanchard *et al.* (Blanchard *et al.*, 2002) using retrospective and cross-sectional designs. The present study aims to further investigate the utility of this model in predicting exercise intentions and behaviour over time in this population of women. This project is the first randomized control trial to include exercise counselling as an integral component of the exercise therapy intervention process in cancer survivors, and to adopt a theoretical approach to examine the *combined* effects of exercise and exercise counselling with women who have had breast cancer. To our knowledge, no randomized control trial has included a placebo control group in an attempt to try and account for any possible attention effects that might be associated with exercise interventions. We have hypothesized that the exercise therapy intervention will lead to significant changes in participants' quality of life, and that, over time, exercise therapy participants will engage in increased exercise behaviour compared to the body conditioning and control groups. Study objectives are:

- (1) To determine the differences from baseline to 4 and 8 weeks, and 3 and 6 months after exercise

therapy treatment in women assigned to exercise therapy, body conditioning (attention control) or a normal care control group in relation to quality of life, physical self-perceptions, fatigue, satisfaction with life, exercise attitudes and selected physiological outcomes.

- (2) To investigate the effectiveness of exercise therapy in changing exercise behaviour and attitudes in breast cancer survivors by including 3- and 6-month follow-up assessment of outcomes measures.
- (3) To compare differences in responses to exercise relative to stages of cancer and treatment regime.

Methods

Participants

A total of 120 female breast cancer survivors (defined as having completed some form of breast cancer treatment within the past 12–36 months and no longer undergoing chemotherapy or radiation therapy) are recruited to the study. All participants continue to receive usual care from their health team.

Doctors and other health professionals make the initial approach to survivors and provide medical clearance for them to take part in this project. Members of the research team then contact survivors who express an interest in taking part in the project. Media adverts are also placed in the local community. A standard letter is sent to participants' GPs informing them of their participation in the project. To facilitate recruitment and retention, a £20 sport store voucher is given to participants at the end of the intervention phase and a contribution of £2.50 towards travel expenses is made per visit to the Centre.

Based on current Tamoxifen use and previous chemotherapy treatment, stratified random sampling is used and participants are randomized to one of three groups: (1) supervised exercise therapy, (2) body conditioning (placebo control) or (3) a usual care control group. To minimize bias, a distant random telephone service is used to allocate participants to the groups. Participants are randomized to

the groups after they have completed their baseline assessment. Ethical approval for this study has been gained from the South Sheffield Research Ethics Committee (application number 02/226) and written informed consent is obtained from all participants before they enter the study. The research assistant is not blind to participants' group allocation.

Power calculations are based on The Functional Assessment of Cancer Therapy—General (FACT-G) (quality of life) scale as the primary outcome measure. A recent pilot project in Glasgow (Campbell *et al.*, 2004) reported a mean difference of about 15 units from baseline to 12 weeks post-intervention using the FACT-G scale. Whilst the magnitude of this change is encouraging, the sample used in this study ($n = 22$) was rather homogeneous, with participants tending to be relatively young and socioeconomically advantaged. As we expected to recruit a much larger sample of women across a wider demographic and socioeconomic range it seemed more appropriate to expect a clinically meaningful change of 10 units of FACT-G score between the groups. This change represents a shift from being fully ambulatory with symptoms to being fully ambulatory without symptoms (Brady *et al.*, 1997). With 40 participants in each group, the study should have 80% power at the 0.5 α level. The primary outcome of interest in this study is the change between in FACT-G scores at baseline and 8 weeks post-intervention.

Participant characteristics

Participants are recruited on the basis of the following criteria:

- (1) Female aged 18–65 years.
- (2) Participants must have completed surgery, radiotherapy and chemotherapy between 12 and 36 months prior to joining the study.
- (3) Participants with metastatic breast cancer and inoperable or active loco-regional disease are ineligible.
- (4) Participants on Tamoxifen and other endocrine treatments are included.
- (5) Patients must be an exercise pre-contemplator, contemplator or preparer as defined by the TTM

(Prochaska *et al.*, 1992). For the purpose of this study, exercise is defined as 'planned, structured and repetitive bodily movement done to improve or maintain one or more components of physical fitness' (Health Education Authority, 1998).

- (6) Patients must not have any physical or psychiatric impairment that would seriously influence their physical mobility. Participants who are clinically depressed are not excluded from the study, although baseline depression scores will be used as a covariate in analyses.
- (7) Participants who are suffering from severe nausea, anorexia or other diseases affecting health (e.g. arthritis and multiple sclerosis) are excluded from taking part in this study.
- (8) Patients must be willing to attend supervised exercise sessions 3 times per week for 8 weeks.

Measures and instruments

The physical outcome measures include fitness [using the (Ebbeling *et al.*, 1991) 8-min single-stage walking test], muscle function (as measured by a biodex isokinetic dynamometer), body mass index and percentage body fat (using bioelectrical impedance analysis).

The following questionnaires are used to assess quality of life, psychological well-being and exercise behaviour related outcomes.

FACT-G (primary outcome measure) and *The Functional Assessment of Cancer Therapy—Breast* (*FACT-B*) (Cella *et al.*, 1993) are used to assess quality of life. *FACT-G* is intended for use with all cancer patients and *FACT-B* is intended for use with breast cancer patients. *FACT-G* and *FACT-B* collectively measure five aspects of quality of life: physical, functional, emotional, social and additional concerns (breast cancer-specific *FACT-B* module). The subscales have been tested with large patients groups, and have proved reliable, valid, responsive, brief and easy to administer (Cella *et al.*, 1993). Other researchers [i.e. (Courneya and Friedenreich, 1997b)] have also reported the internal consistencies of these subscales to be acceptable. Each item is rated on a five-point scale from 'not at all' to 'very much'.

The *Physical Self-Perception Profile (PSPP)* developed by Fox and Corbin (Fox and Corbin, 1989) assesses self-perceptions in the physical domain. The 30-item inventory consists of five, six-item subscales: perceived sports competence, attractiveness of body, physical condition, physical strength and general physical self-worth. This scale has been found to demonstrate acceptable coefficient α s and test-re-test coefficients [see (Fox and Corbin, 1989; Sonstroem *et al.*, 1992)].

The *Revised Piper Fatigue Scale (PFS)* (Piper, 1998) is a 22-item, 10-point self-report scale that measures overall fatigue and four fatigue dimensions: temporal, severity, affective, and sensory. Each question was scored on an 11-point numerical scale. The overall score and each subscale score is given on a scale of 0–10, with 0 indicating no fatigue and 10 indicating the most severe fatigue. The PFS has demonstrated validity and reliability in a number of other studies of patients with cancer [e.g. (Mock *et al.*, 2001)].

Satisfaction with Life Scale (SWL) (Diener *et al.*, 1985). The SWL was developed to assess satisfaction with participants' life as a whole and this short scale allows people to assess their quality of life based on their own unique criteria without reference to a specific domain. The scale contains five items that are rated on a seven-point scale from 'strongly disagree' to 'strongly agree'. It has been shown to be a highly reliable and valid measure of overall quality of life (Pavot and Diener, 1993).

The *Beck Depression Inventory—II (BDI-II)* (Beck *et al.*, 1996) is a 21-item self-report instrument for measuring severity of depression in adults. The BDI-II consists of 21 items to assess the intensity of depression in clinical and normal patients. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. The BDI has become one of the most widely accepted instruments for assessing the severity of depression. A full description of the development, reliability and validity of the BDI-II has been reported by Beck *et al.* (Beck *et al.*, 1996), and the reader is directed to this source.

The *stage of change ladder* (Biener and Abrams, 1991) is used to assess current exercise behaviour.

The anchor labels represent the five items from the standard stages of change for exercise questionnaire (Marcus *et al.*, 1992). The change ladder is a visual-analogue measure. The labels at each stage represent the minimum requirements for membership of a particular stage of exercise change.

Past exercise behaviour is assessed by asking participants to consider how often they have participated in one or more physical activities for 20–30 min per session during their free time in the last 3 months? This method for assessing behaviour was based on previous validated studies (Godin and Shephard, 1985; Godin *et al.*, 1986; Gionet and Godin, 1989).

Participants complete brief questionnaires that relate exercise behaviour to components of the Theory of Planned Behaviour (Ajzen, 1991): attitude, subjective norm, and perceived behavioural control and intention. Example statements include 'I am going to take part in physical exercise as much as I can every week', 'If I wanted to, I could easily take part in regular physical exercise', 'Most people who are important to me encourage me to participate in regular physical exercise' and 'Exercise is enjoyable'. For a more in-depth description of these subscales and their use with cancer patients, readers are directed to Blanchard *et al.* (Blanchard *et al.*, 2002) and Courneya and Friedenreich (Courneya and Friedenreich, 1999b).

Participant assessments and design

The study is a pragmatic intention-to-treat 3 (group) \times 5 (time points) randomized controlled trial. Therefore, all eligible patients, regardless of compliance with the protocol, will be included in the analysis. Outcome measures are completed at baseline, 4 weeks during the intervention, at the end of the 8-week intervention, and 3 and 6 months after the completion of the exercise therapy programme (Figure 1). For the 6-month follow-up assessment, only questionnaire data is collected and these are mailed to participants at the appropriate time. All other outcomes measures are completed in the presence of the research assistant (third author). An independent medical statistician is responsible for data analysis.

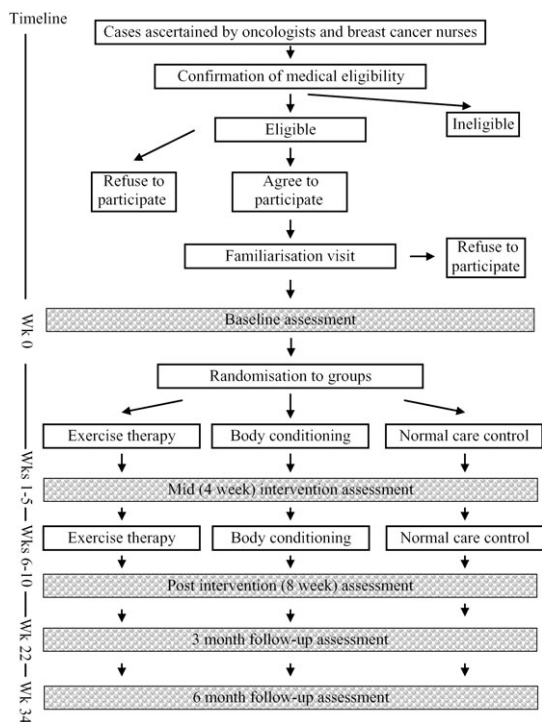


Fig. 1. Intervention flow chart.

All participants are asked to attend the Centre for Sport and Exercise Science for an accustomization session with the research assistant/exercise specialist before the start of the study. This session provides participants with an opportunity to meet the staff involved in the project and ask questions. All participants are informed that the project is designed to investigate the effects of exercise upon well-being.

At baseline, participants provide informed consent (collected by the research assistant), and undergo standardized assessments of aerobic capacity, muscle strength, body mass, percentage body fat and blood pressure. Participants also complete pre-screening exercise and lifestyle questionnaires. Demographic data including age, ethnicity, marital status, medical history, and previous and current exercise behaviour are collected. Additional clinical information regarding the extent and nature of disease, and years free from cancer is requested from participants and their treating oncologist. The research team includes two exercise and health

psychologists, one physiologist, one exercise therapist, one consultant oncologist, and an administrator.

Exercise therapy

The exercise sessions take place in a designated exercise room that contains a variety of aerobic exercise equipment. All exercise therapy sessions are on a 'one-to-one' basis with an exercise specialist and each session lasts 50 min (30 min exercise and 20 min exercise counselling). As suggested by Biddle *et al.* (Biddle *et al.*, 2000) and Friedenreich and Courneya (Friedenreich and Courneya, 1996), participants are offered a range of exercise modalities (e.g. stepping, cycling and walking) 3 times a week for 8 weeks. The American College of Sports Medicine (American College of Sports Medicine, 2000) recommends that adults should exercise between 3 and 5 times per week at moderate intensity, and Courneya *et al.* (Courneya *et al.*, 2000) in their exercise prescription guidelines for cancer survivors recommend 20–30 min of continuous exercise on at least 3–5 days per week. The exercise therapy sessions have been structured with these guidelines in mind. The exercise programme is designed to last 8 weeks because there is some evidence [e.g. (Mock *et al.*, 1997)] that exercise can be effective in improving quality of life outcomes in cancer patients during this time frame and it provides sufficient time/opportunities to encourage exercise group participants to become independent exercisers. Table I outlines the exercise intervention in more detail. Participants are encouraged to use their preferred exercise mode to provide a degree of self-determination.

Participants wear heart rate monitors throughout exercise and are normally given at least 24–48 h rest between sessions. To account for differences in participants' daily patterns of fatigue and minimize attrition, participants are also offered a range of times and days to attend exercise sessions, including evenings and weekends. Heart rate and ratings of perceived exertion [RPE (Borg, 1977)] are assessed every 2 min during exercise.

In accordance with the principles of the TTM, the exercise therapy sessions use a variety of

Table I. *Exercise intervention*

Exercise	Weeks 1–2	Weeks 3–4	Weeks 5–6	Weeks 7–8
Duration (min)	10–20	15–20	15–20	20–30
Type	aerobic exercise ^a	aerobic exercise ^a	aerobic exercise ^a	aerobic exercise ^a
Intensity (%; age-adjusted maximum)	60–75	60–75	75–85	75–85
Frequency (times per week)	3	3	3	3

Exercise sessions commence and conclude with a 5-min warm-up and cool-down period. As the intervention progresses, and when medically appropriate, women are encouraged to participate in continuous, rather than intermittent exercise bouts.

^aFor example, treadmill walking, cycling, rowing.

cognitive-behavioural techniques for promoting positive exercise attitudes and experiences. Weeks 1–4 focus on cognitively based intervention strategies (e.g. cognitive reappraisal and consciousness raising). During weeks 5–8, more behaviourally based interventions are introduced (e.g. goal setting, self-monitoring and finding social support). Participants follow a broad curriculum of topics over the course of the exercise therapy treatment. At the end of the 8-week intervention the exercise therapy group participants are guided into maintaining an exercise regime through a personalized plan that is tailored to suit their individual needs and experiences. Refer to Table II for a detailed description of the exercise-counselling curriculum.

Body-conditioning intervention (placebo control)

A body-conditioning group has been included in this project in an attempt to control the potential for attention effects that might be associated with exercise interventions. We hope that the inclusion of this group will allow us to begin to disentangle the ‘real’ effects of aerobic exercise from the influence that attention or other modes of exercise might cause. This is particularly important in the current study because the exercise therapy group receive one-to-one sessions with the researcher. Any attention control condition must be relevant and meaningful, and we have tried to achieve this by presenting an alternative ‘exercise’ group that does not involve aerobic exercise. In this way, and similar to the exercise therapy group, participants who are assigned to the body-conditioning group also attend the Centre 3 times per week for 8 weeks

and participate in ‘one-to-one’ 50-min sessions. Thus, participants have the perception that they are ‘exercising’, although RPE is maintained below 12 (low-intensity exercise) and heart rate kept typically less than approximately 100 b.p.m. The body conditioning placebo control condition focuses on flexibility, body control, range of motion and posture through the use of a mini-circuit of exercises. Examples of exercises completed include shoulder rotation (flexibility), balance (body control) and passive stretching. The physical exertion of each exercise is kept to a minimum, but involves activities that are engaging, which is important for compliance. Heart rate and RPE are assessed every 5 min during these sessions. Participants assigned to this condition are asked to continue with their sedentary lifestyle as normal for the duration of the study. The body-conditioning group does not receive exercise counselling.

Usual care control group

The members of control group are encouraged to continue with their lives as usual. At the end of the 8-week exercise intervention they are offered an exercise consultation and a personalized exercise plan.

Concluding remarks

As outlined earlier, this study will make several important contributions to the published literature. In particular, this study will enable us to assess the quality of life and psychological health benefits of exercise therapy in women who have had breast cancer. Should suggestive evidence be obtained, this

Table II. *Exercise counselling protocol*

Weeks	Process of change	Exercise counselling framework: examples of skills and techniques used
1–2 (Cognitive)	consciousness raising dramatic relief decisional balance	<p><i>(a) Review first session</i> How did it feel? Was it difficult/easy? Did you enjoy it? Importance of exercise; information about the importance of warming up and cooling down Heart rate monitoring, what to wear, what and when to drink What to expect in the coming weeks Any questions Finding time of exercise—fitting it in the gaps. Try an activity log for a day Your exercise preferences; consider previous exercise experiences</p> <p><i>(b) Healthy eating</i> What is it? When should I eat? What type of foods are good/not so good? Hand out standard dietary information sheet</p> <p><i>(c) Benefits of exercise</i> How often? How hard? Where and when? Contra-indications to exercise</p>
3–4 (Cognitive)	self re-evaluation decisional balance consciousness raising	<p><i>(d) Which physical exercises do I prefer?</i> Previous exercise experiences, why this worked/failed. What other exercises might you like to try?</p> <p><i>(e) Do you know?</i> Benefits of exercise Importance of healthy eating How are you managing—review pros and cons of exercise? How comfortable are you now with exercising?</p> <p><i>(f) Are you enjoying the sessions?</i> What do you like? What do you dislike? What would you change? Is it what you had expected?</p>
5–6 (Cognitive and Behavioural)	self re-evaluation goal setting/ self-regulation social support	<p><i>(g) Active and healthy living</i> Food groups, choices, portion sizes; the 5-per-day, fruit and vegetable challenge (week); hand out food diary (1 week). Try a Pedometer for a week—just how active are you? Food labelling</p> <p><i>(h) Introduce goal setting</i> What is it? How might it help? Set one exercise goal and one healthy eating goal for the week</p> <p><i>(i) Findings support for exercise</i> Thinking of other who might encourage participation in exercise Finding someone to talk to when exercising is difficult Consider ways in which to exercise with other people</p>

Table II. *Continued*

Weeks	Process of change	Exercise counselling framework: examples of skills and techniques used
7–8 (Behavioural)	goal setting/ self-regulation stimulus control reinforcement management self-liberation	<p>(j) <i>Review goals</i> Did you achieve them? If yes then well done! If not then why not? What can we do to help change this?</p> <p>(k) <i>Cues for action</i> Think of tasks that might prompt participation in exercise</p> <p>(l) <i>Thinking about moving on from the programme</i> Avoiding relapse Future exercise options</p> <p>(m) <i>Looking and planning ahead. SWOT analysis</i> (i.e. strengths weakness', opportunities and threats) What will help me to exercise in the future? What will stop me?</p> <p>(n) <i>What have I achieved so far</i> Review exercise Review healthy eating What do I want to achieve from here? Thinking positively and taking positive action What has been learned</p>

data could be used to develop clinical guidelines for the promotion of exercise therapy in women who have had breast cancer. The cost of such a programme is modest, yet it might result in significant improvements in the quality of life of women who have survived cancer. This study also provides the opportunity to relate theoretical health behaviour processes to quality of life and other health outcomes to advance our understanding of how exercise interventions might improve quality of life outcomes in female cancer populations. Given that physical inactivity has been targeted as a risk factor in terms of the incidence and re-occurrence of breast cancer, the findings from this project may have important public health consequences. Finally, this study should lead to estimates about typical adherence rates to supervised exercise programmes and such information can also be used to inform future exercise promotion policies and strategies in cancer populations. A unique aspect of this research is that, unlike previous studies, it includes an attention control condition and this is considered to be an important methodological strength of the study.

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References

- American College of Sports Medicine (2000) *Guidelines for Exercise Testing and Prescription*, 6th edn. Lea & Febiger, Philadelphia, PA.
- Ajzen, I. (1991) The theory of planned behaviour. *Organisational Behaviour and Human Decision Processes*, **50**, 179–211.
- Baldwin, M.K. and Courneya, K.S. (1997) Exercise and self-esteem in breast cancer survivors: an application of the Exercise and Self-esteem Model. *The Journal of Sport and Exercise Psychology*, **19**, 347–359.
- Beck, A.T, Steer, R.A. and Brown, G.K. (1996) *Beck Depression Inventory—Manual*. The Psychological Corp., San Antonio, TX.
- Biener, L. and Abrams, D.B. (1991) The contemplation ladder: validation of a measure of readiness to consider smoking cessation. *Health Psychology*, **10**, 360–365.
- Biddle, S.J.H., Fox, K., Boutcher, S.H. and Faulkner, G. (2000) The way forward for physical activity and the promotion of psychological well-being. In Biddle, S.J.H, Fox, K. and Boutcher, S.H. (eds), *Physical Activity and Psychological Well-being*. Routledge, London, pp. 154–168.

- Blanchard, C.M., Courneya, K.S., Rodgers, W. and Murnaghan, D.M. (2002) Determinants of exercise intention and behaviour in survivors of breast and prostate cancer: an application of the theory of planned behaviour. *Cancer Nursing*, **25**, 88–95.
- Borg, G. (ed.) (1977) *Physical Work and Effort*. Pergamon Press, New York.
- Brady, M.J., Cella, D., Mo, F., Bonomi, A.M., Tulskey, D.S., Lloyd, S.R., Deasy, S., Cobleigh, M. and Shiimoto, G. (1997) Reliability and validity of the Functional Assessment of Cancer Therapy Breast quality of life assessment. *Journal of Clinical Oncology*, **15**, 974–998.
- Campbell, A., Mutrie, N., White, F., McGuire, F. and Kearney, N. (2004) A pilot study of a supervised group exercise programme as a rehabilitation treatment for women with breast cancer receiving adjunctive treatment. *European Journal of Oncology Nursing*, in press.
- Carpenter, C.L., Ross, R.K., Paganini-Hill, A. and Bernstein, L. (1999) Lifetime exercise activity and breast cancer risk among post-menopausal women. *British Journal of Cancer*, **80**, 1852–1858.
- Cardinal, B.J. (1995) The stages of exercise scale and stages of exercise behaviour in female adults. *Journal of Sports Medicine and Physical Fitness*, **35**, 87–92.
- Cella, D.F., Tulskey, D.S., Gray, G., Serafin, B., Linn, E., Bonomi, A., Silberman, M., Yellen, S.B., Wincour, P. and Brannon, J. (1993) The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *Journal of Clinical Oncology*, **11**, 570–579.
- Courneya, K.S. (2000) Coping with cancer: can exercise help? *The Physician and Sports Medicine*, **28**, 49–73.
- Courneya, K.S. and Friedenreich, C.M. (1997a) The relationship between exercise pattern across the cancer experience and current quality of life in colorectal cancer survivors. *Journal of Alternative Complementary Medicine*, **3**, 215–226.
- Courneya, K.S. and Friedenreich, C.M. (1997b) Relationship between exercise during treatment and current quality of life among survivors of breast cancer. *Journal of Psychosocial Oncology*, **15**, 35–57.
- Courneya, K.S. and Friedenreich, C.M. (1999a) Physical exercise and quality of life following cancer diagnosis: a literature review. *Annals of Behavioural Medicine*, **21**, 171–179.
- Courneya, K.S. and Friedenreich, C.M. (1999b) Utility of the theory of planned behaviour for understanding exercise during breast cancer treatment. *Psycho-Oncology*, **8**, 112–122.
- Courneya, K.S., Friedenreich, C.M., Sela, R.A., Quinney, H.A., Rhodes, R.E. and Handman, M. (2003) The group psychotherapy and home-based physical exercise (group-hope) trial in cancer survivors: physical fitness and quality of life outcomes. *Psycho-Oncology*, **12**, 357–374.
- Demark-Wahnefried, W., Peterson, B., McBride, C., Lipkus, I. and Clipp, E.C. (2000) Current health behaviours and readiness to pursue lifestyle change among men and women diagnosed with early-stage prostate and breast cancer. *Cancer*, **88**, 674–684.
- Diener, E., Emmons, R.A., Larsen, R.J. and Griffin, S. (1985) The satisfaction with life scale. *Journal Personality Assessment*, **49**, 71–75.
- Dishman, R.K. (1991) Increasing and maintaining exercise and physical activity. *Behaviour Therapy*, **22**, 345–378.
- Dunn, A.L., Garcia, M.E., Marcus, B.H., Kampert, J.B., Kohl, H.W. and Blair, S.N. (1998) Six-month physical activity and fitness changes in *Project Active*, a randomised trial. *Medicine and Science in Sport and Exercise*, **30**, 1076–1083.
- Ebbeling, C.A., Ward, A., Puleo, E.M., Widrick, J. and Rippe, J.M. (1991) Development of a single-stage submaximal treadmill walking test. *Medicine and Science in Sport and Exercise*, **23**, 966–973.
- Fox, K.R. and Corbin, C.B. (1989) The physical self perception profile: development and preliminary validation. *Journal of Sport and Exercise Psychology*, **11**, 408–430.
- Fox, K.R., Boutcher, S.H., Faulkner, G.E. and Biddle, S.J.H. (2000) The case for exercise in the promotion of mental health and psychological well-being. In Biddle, S.J.H., Fox, K. and Boutcher, S.H. (eds), *Physical Activity and Psychological Well-being*. Routledge, London, pp. 1–9.
- Friedenreich, C.M. and Courneya, K.S. (1996) Exercise as rehabilitation for cancer patients. *Cancer Nursing*, **15**, 254–263.
- Glanz, K. and Lerman, C. (1992) Psychosocial impact of breast cancer: a critical review. *Annals of Behavioural Medicine*, **14**, 204–210.
- Godin, G. and Shephard, R.J. (1985) A simple method to assess exercise behaviour in the community. *Canadian Journal of Applied Sport Sciences*, **10**, 141–146.
- Gionet, N.J. and Godin, G. (1989) Self-reported exercise behaviour of employees: a validity study. *Journal of Occupational Medicine*, **31**, 969–973.
- Godin, G., Jobin, J. and Bouillon, J. (1986) Assessment of leisure time exercise behaviour by self-report: a concurrent validity study. *Canadian Journal of Public Health*, **77**, 359–361.
- Greeno, C.G. and Wing, R.R. (1994) Stress-induced eating. *Psychological Bulletin*, **115**, 444–464.
- Health Education Authority (1998) *Young and Active: Framework for Young People and Health Enhancing Physical Activity*. Health Education Authority, London.
- King, A.C., Taylor, W.L., Haskell, W.L. and Debusk, R.F. (1988) Strategies for increasing early adherence to and long-maintenance of home-based exercise training in healthy, middle-aged men and women. *American Journal of Cardiology*, **61**, 628–632.
- Long, B.C. and Haney, C.J. (1986) Enhancing physical activity in sedentary women: aerobic exercise: information, locus of control and attitudes. *Journal of Sport Psychology*, **8**, 8–24.
- Marcus, B.H. (1992) Self-efficacy and the stages of exercise behaviour change. *Research Quarterly in Exercise and Sport*, **63**, 60–66.
- Martinsen, E.W. (1993) Therapeutic implications of exercise for clinically anxious and depressed patients. *International Journal of Sports Psychology*, **24**, 185–199.
- Meyer, T.J. and Mark, M.M. (1995) Effects of psychosocial interventions with adult cancer patients: a meta-analysis of randomised experiments. *Health Psychology*, **14**, 101–108.
- Mock, V., Dow, K., Meares, C.J., Grimm, P.M., Dienemann, J.A., Haisfield Wolfe, M.E., Quitasol, W., Mitchel, S. and Chakravarthy, A. (1997) Effects of exercise on fatigue, physical functioning and emotional distress during radiation therapy for breast cancer. *Oncology Nursing Forum*, **24**, 991–1000.
- Mock, V., Pickett, M., Ropka, M.E., Muscari, E., Stewart, K., Rhodes, V., McDaniel, R., Grimm, P.M., Krumm, S. and McCorkle, R. (2001) Fatigue and quality of life outcomes of

- exercise during cancer treatment. *Cancer Practice*, **9**, 119–127.
- Pinto, B.M. and Maruyama, N.C. (1999) Exercise in the rehabilitation of breast cancer survivors. *Psycho-Oncology*, **8**, 191–206.
- Pinto, B.M., Eakin, E. and Maruyama, N.C. (2000) Health behaviour changes after a cancer diagnosis: what do we know and where do we go from here. *Annals of Behavioural Medicine*, **22**, 38–52.
- Piper B.F., Dibble S.L., Dodd, M.J., Weiss, M.C., Slaughter, R. and Paul, S. (1998) The revised Piper Fatigue Scale: psychometric evaluation in women with breast cancer. *Oncology Nursing Forum*, **25**, 677–684.
- Pavot, W. and Diener, E. (1993) Review of the satisfaction with life scale. *Psychological Assessment*, **6**, 164–172.
- Prochaska, J.O. and DiClemente, C.C. (1983) Stages and processes of self-change of smoking: towards an integrative model of change. *Journal of Consulting and Clinical Psychology*, **51**, 390–395.
- Prochaska, J.O., Norcross, J.C., Fowler, J., Follick, M. and Abrams, D.B. (1992) Attendance and outcomes in a work-site weight control program: processes and stages of change as process and predictor variables. *Addictive Behaviours*, **17**, 35–45.
- Segal, R., Evans, W., Johnson, D., Smith, J., Colletta, S., Gayton, J., Woodard, S., Wells, G. and Reid, R. (2001) Structured exercise improves physical functioning in women with stages I and II breast cancer: results of a randomised controlled trial. *Journal of Clinical Oncology*, **19**, 657–665.
- Sonstroem, R.J., Speliotis, E.D. and Fava, J.L. (1992) Perceived physical competence in adults: an examination of the Physical Self-perception Scale. *Journal of Sport and Exercise Psychology*, **10**, 207–221.
- Wardle, J., Steptoe, A., Oliver, G. and Lipsey, Z. (2000) Stress, dietary restraint and food intake. *Journal of Psychosomatic Research*, **48**, 195–202.
- Williamson, G.M. and Schulz, R. (1992) Pain, activity restriction and symptoms of depression among community-residing elderly adults. *Journal of Gerontology*, **47**(6A), P367–P372.

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