

CLINICAL PAPER

A randomized controlled trial of the effectiveness of aerobic training for patients with breast cancer undergoing radiotherapy

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Abstract

Adjuvant therapy for patients with breast cancer may cause favourable changes in physical function and quality of life (QOL). The most common complications of breast cancer are fatigue and a reduced capacity for exercise. This study evaluated the relative merits of aerobic training as an intervention to minimize these effects. The objective of the study was to determine the effectiveness of aerobic training plus conventional physiotherapy in postoperative patients with breast cancer who were undergoing radiotherapy. A randomized controlled trial was conducted between 2010 and 2012. Sixty participants with a clinical diagnosis of stage I or II breast cancer were assigned to either aerobic training plus conventional physiotherapy ($n=30$) or conventional physiotherapy alone ($n=30$) for a period of 6 weeks. The outcome measures used were the Brief Fatigue Inventory, the 6-min walk test, maximal oxygen consumption (VO_{2max}) and the short version of the World Health Organization Quality of Life Assessment questionnaire. Statistical analysis showed that aerobic training plus conventional physiotherapy was superior to conventional physiotherapy alone in reducing fatigue, and improving exercise capacity, VO_{2max} and QOL. No adverse events were reported during the course of the study. The intervention was initiated on the same day that the participants began receiving radiotherapy, and therefore, it was possible to achieve a high level of participant adherence to the programme. Aerobic training plus conventional physiotherapy had beneficial effects on fatigue, exercise capacity, VO_{2max} and QOL in participants with breast cancer who were undergoing radiotherapy.

Keywords: aerobic training, breast cancer, maximal oxygen consumption, quality of life, radiotherapy.

Introduction

Breast cancer is a world-wide problem that affects more than 1.2 million women every year (Mutrie *et al.* 2007). In the UK, breast cancer accounts for 15% of all cancers and 30% of cancers in women (Daley *et al.* 2007). In India, it accounts for approximately 25–33% of all cancers in women (NCRP 2011). Breast cancer is characterized by the uncontrolled growth of breast cells. A positive family history, under-

going menarche at an early age, nulliparity, obesity, ageing and a later first pregnancy are the high-risk factors that are associated with this condition (Daley *et al.* 2007; Barakat *et al.* 2009). Breast cancer is staged from I to IV according to tumour mass, node status (negative or positive), and the presence or absence of distant metastases (Barakat *et al.* 2009).

This form of cancer can be treated by surgery and adjuvant therapy. The primary surgical approaches are mastectomy and breast conservation surgery (Lewis *et al.* 2008, pp. 49–52; Barakat *et al.* 2009). An adjuvant therapy is any therapy that is used after the surgical removal of

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a tumour, and may include chemotherapy, radiotherapy, hormonal therapy or combinations of these approaches (Daley *et al.* 2007; Mutrie *et al.* 2007; Lewis *et al.* 2008, pp. 49–52; Barakat *et al.* 2009). After surgery, many patients have chest wall adhesions, which can lead to pain and stiffness in the shoulder on the affected side, as well as postural dysfunction. Physiotherapy treatment after breast cancer surgery can include shoulder exercises, postural advice, transcutaneous electrical nerve stimulation and compression garments.

Adjuvant therapy for early-stage breast cancer improves patient survival rates, but may also cause unfavourable changes in an individual's quality of life (QOL) (Kayl & Meyers 2006; Ogilvy *et al.* 2008, pp. 266–268). The World Health Organization (WHO) defines QOL as an individual's perception of his or her position in life, in the context of their culture and its value systems, and in relation to his or her goals expectations and concerns (Skevington *et al.* 2004). Patients become fearful of overexertion during adjuvant therapy, which leads to a reduction in their physical activity. This further compounds their feelings of fatigue and reduces their capacity for exercise (Mustian *et al.* 2009). Cancer-related fatigue is one of the most common complaints in patients with cancer and has a prevalence of 70–100%. As a symptom, fatigue is characterized as a sensation of weakness, lack of energy or tiredness. As a syndrome, it has been defined as an overwhelming and sustained sense of exhaustion, and a decreased capacity for physical and mental work (Van Weert *et al.* 2010).

Combination adjuvant chemotherapy and radiotherapy for early-stage breast cancer may also cause unfavourable changes in physical functioning and body composition, leading to fatigue caused by alterations in pulmonary and heart function, and red blood cell count. These changes result in reduced oxygen transport and utilization, which brings about further alterations in the muscular energy systems and results in physical fatigue (Dimeo *et al.* 1998; Kayl & Meyers 2006; Courneya *et al.* 2007). A reduction in cardiac output increases cardiac and respiratory work, and therefore, a higher energy consumption is needed in order to sustain an adequate oxygen supply to the cells during rest and physical work. These changes lead to a reduction in aerobic capacity. Maximal oxygen consumption (VO_{2max}) is an important factor in determining aerobic capacity (Ogilvy *et al.* 2008, pp. 266–268).

There is little evidence from clinical trials to support the use of exercise to manage fatigue in cancer patients (Mock *et al.* 1997; Mustian *et al.* 2009). Aerobic training generally includes activities that are light to moderate in intensity and are sufficiently supported by the aerobic metabolism so that these can be performed for extended periods of time (McArdle *et al.* 2006, p. 204; Plowman & Smith 2007, p. 61). A number of studies have shown that many of the physical and psychological components of QOL are positively affected by exercise (Young-McCaughan & Sexton 1991; McNeely *et al.* 2006). Therefore, there is a need for research pertaining to treatments that focus on such problems and comprehensive evaluations of the effects of these interventions.

The purpose of the present study was to determine the effectiveness of aerobic training along with conventional physiotherapy in breast cancer. The authors hypothesized that aerobic training plus conventional physiotherapy would be more effective than conventional physiotherapy alone. The study compared the effectiveness of aerobic training and conventional physiotherapy with conventional physiotherapy alone on fatigue, exercise capacity and QOL.

Participants and methods

The present study received approval from the Institutional Ethical Committee of the Pravara Institute of Medical Sciences, Loni, Taluka Rahata, Ahmednagar, Maharashtra, India. Participants were screened based on the inclusion and exclusion criteria described below. Those individuals who were willing to participate were briefed about the nature of the study in the language best understood by them, and written informed consent was obtained.

Study setting

The research was conducted at a rural tertiary medical centre, i.e. in the Department of Community Health and Rehabilitation, College of Physiotherapy, Pravara Rural Hospital, Loni. The data were obtained from the Department of Oncology. The study was conducted between January 2011 and November 2011.

Participants

Participants were eligible for the study if they met the following criteria: women aged between 30 and 60 years with a clinical diagnosis of stage I or II breast cancer who had undergone

unilateral modified radical mastectomy and were receiving radiotherapy. Participants were excluded if they had: any cardiovascular abnormality; impaired cognitive function; musculoskeletal disorders; neurological disorders; emotional instability; and/or a very low level of activity. The latter would be rated as category 3 or 4 according to Winningham's (1991) classification, a scale that determines the activity levels of participants using a five-point scale: (0) active, no limitations; (1) ambulatory, decreased leisure activity; (2) ambulatory more than 50% of the time; (3) ambulatory 50% or less of the time; and (4) confined to bed (Van Weert *et al.* 2010).

Design, randomization and allocation

The study was a randomized controlled trial. Eligible participants were randomly assigned to a group that received aerobic training combined with conventional physiotherapy or a group that received conventional physiotherapy alone, and were then scheduled for baseline measurements. The participants were blinded to the intervention that they were allocated to receive. The physiotherapists were not blinded because they had to schedule the intervention sessions. The demographic data, the Brief Fatigue Inventory (BFI; Mendoza *et al.* 1999), the 6-min walk test (6MWT), VO_{2max} and the short version of the WHO Quality of Life Assessment questionnaire (WHOQOL-BREF; WHOQOL Group 1998) were assessed before and immediately after 6 weeks of intervention. A general assessment of the cardiovascular, musculoskeletal and neurological systems was done that consisted of inspection, palpation, sensory and motor examination, chest expansion, and assessment of posture, the range of movement (ROM) of the joints and soft tissue tightness.

Intervention

Aerobic training was conducted five times a week for 6 weeks. This was supervised by a physiotherapist. The intensity of aerobic training, or target heart rate [HR_{target} (bpm)], was 40–60% of the reserve HR (bpm), which is the difference between the maximum and resting HR ($HR_{reserve} = HR_{max} - HR_{rest}$), and was calculated using the Karvonen Formula (ACSM 2000, p. 145):

$$HR_{target} = [(HR_{max} - HR_{rest}) \times 40-60\% \text{ intensity}] + HR_{rest}$$

where HR_{max} (bpm) is calculated as $220 - \text{age}$ (years).



Figure 1. Warm-up (lower extremity muscle stretching).



Figure 2. Pectoral muscle stretching.

The duration of each session was 30–50 min (Buckley *et al.* 1999, pp. 77–83; Dimeo 2001; Watson & Mock 2004). Aerobic training consisted of warm-up exercises for 10 min and included mild stretching of the large muscle groups (Figs 1–5). The aerobic training consisted of treadmill walking (Fig. 6).

Initially, treadmill walking was performed for 10 min at self-adjusted speeds. The walking time was progressively increased to 30 min over the period of 6 weeks and the speed was chosen by the participants according to their comfort. The whole intervention programme was carried out with zero inclination of the treadmill.



Figure 3. Shoulder muscle stretching.

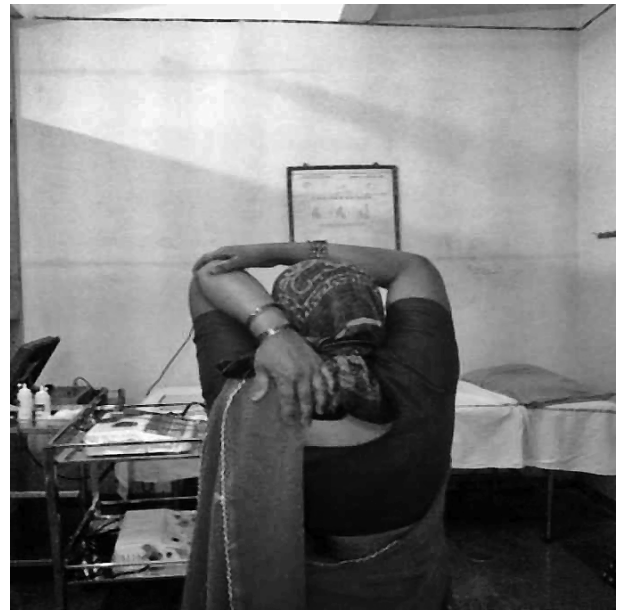


Figure 5. Triceps stretching.



Figure 4. Forward bending.

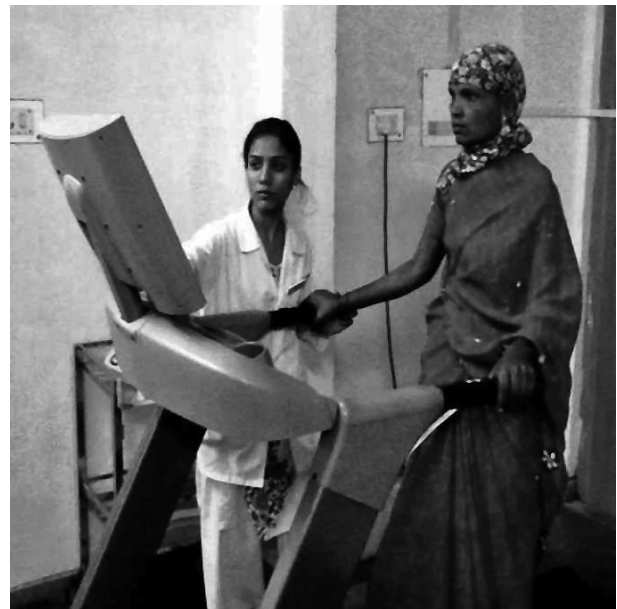


Figure 6. Treadmill walking.

Cool-down exercises were done for 10 min, first by slowing the pace of treadmill walking and then by mild stretching of the large muscle groups (Figs 1–5).

Conventional physiotherapy

Conventional physiotherapy was performed five times a week for 6 weeks and was supervised by a physiotherapist. These sessions consisted of shoulder active ROM exercises for flexion, extension, abduction, and external and internal rotation. All sessions involved 10 repetitions of each exercise, postural advice, skin care advice and compression garments (Brook *et al.* 2008, pp. 134–135; Hwang *et al.* 2008).

Outcome measures

Brief Fatigue Inventory. The BFI is a questionnaire with nine items, each measured on a numeric scale from 0 to 10. It was used to assess the severity of fatigue and its impact on daily functioning in the participants before and after the intervention. The global score for the BFI was calculated as the mean value of the nine items ranging from 0 to 10. The highest reported reliability for this measure is 0.97 (Mendoza *et al.* 1999).

Six-minute walk test. The 6MWT was used to assess exercise capacity. The highest reported reliability for this measure is 0.94. The test

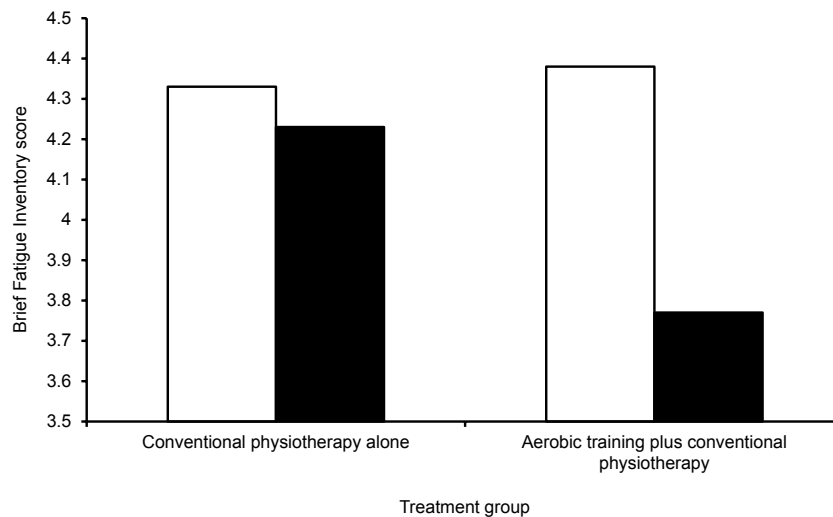


Figure 7. Differences in Brief Fatigue Inventory scores between the treatment groups before (□) and after (■) the intervention.

was conducted according to the standardized protocol (ATS 2002).

Maximal oxygen consumption. The level of VO_{2max} was measured using a formula based on HR (bpm) (Uth *et al.* 2004):

$$VO_{2max} = 15.3 \times (HR_{max}/HR_{rest}),$$

where $HR_{max} = 208 - 0.7 \times \text{age (years)}$.

Short version of the WHOQOL questionnaire. The WHOQOL-BREF consists of 26 items: 24 involve four facets, including physical, psychological, social relations and environmental QOL; one relates to overall health; and one measures overall QOL. Each item is scaled from 1 to 5. The average WHOQOL-BREF score, which is the sum of its 26 items divided by 26, was used and ranged from 1 to 5. The higher the score, the more positive the QOL (WHOQOL Group 1998; Skevington *et al.* 2004; Hwang *et al.* 2008).

Results

The present study included 54 female participants with breast cancer with a mean age [\pm standard deviation (SD)] of 45.59 ± 7.332 years. The baseline characteristics of the participants in both the groups are shown in Table 1 and reveal that both the groups were comparable. Four participants from the conventional physiotherapy group and two from the aerobic training plus conventional physiotherapy group dropped out of the study, but 90% completed the entire 6-week intervention. No adverse events were noted during the study period.

Fatigue was assessed with the BFI. Participants treated with conventional physiotherapy alone showed an average difference (\pm SD) of -0.05 ± 0.18 . The average difference in the fatigue of the participants who underwent aerobic training plus conventional physiotherapy group was 0.46 ± 0.11 . There was a significant difference in the fatigue levels of the participants in these two groups, as shown in Fig. 7 ($P < 0.001$, $t = 12.688$, d.f. = 52).

Exercise capacity was assessed by the 6MWT. Figure 8 shows the changes in 6MWT results for participants in both groups.

Maximal oxygen consumption was measured with the help of the formula based on resting heart rate (Uth *et al.* 2004). The average difference (\pm SD) in VO_{2max} after 6 weeks of conventional physiotherapy alone was 0.272 ± 0.6881 , whereas this figure was 2.071 ± 0.4642 for those who underwent aerobic training plus conventional physiotherapy. Thus, there was a significant difference ($P < 0.001$, $t = 11.339$, d.f. = 52) in VO_{2max} between participants treated with conventional physiotherapy alone and those who underwent aerobic training plus conventional physiotherapy, as shown in Fig. 9.

Quality of life was assessed with the WHOQOL-BREF questionnaire. It was observed that there were significant differences in the QOL of both participants who were treated with conventional physiotherapy alone ($P = 0.0002$, $t = 4.280$, d.f. = 25) and those who underwent aerobic training plus conventional physiotherapy ($P < 0.001$, $t = 19.046$, d.f. = 27). However, there was a greater improvement in the QOL of the latter group ($P < 0.0007$, $t = 3.58$, d.f. = 52).

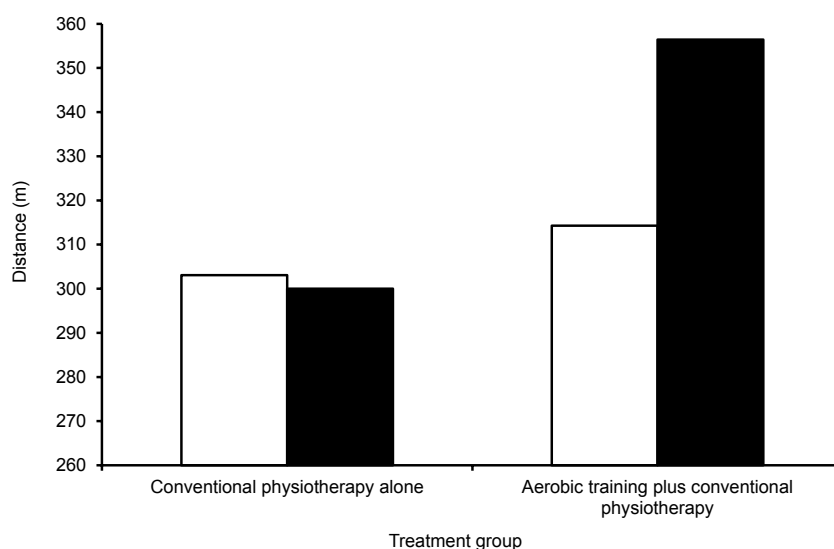


Figure 8. Differences in 6-min walk test scores between the treatment groups before (□) and after (■) the intervention.

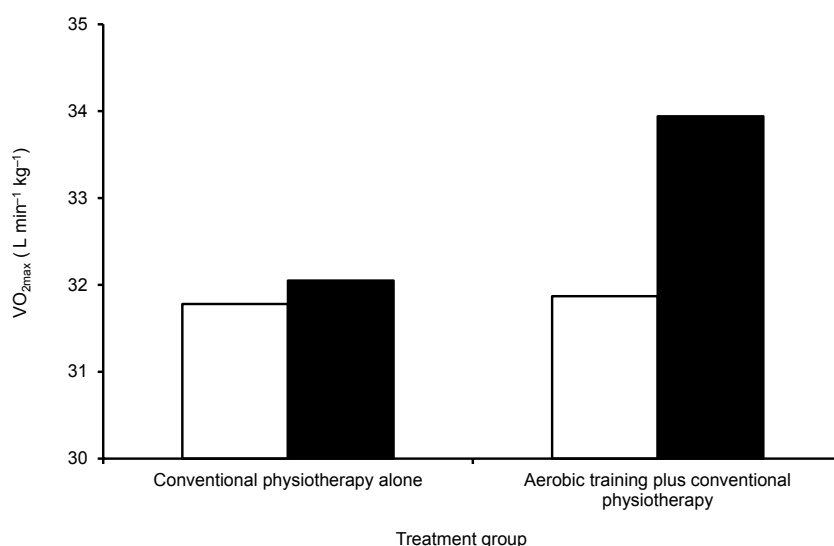


Figure 9. Differences in maximal oxygen consumption (VO_{2max}) scores ($L\ min^{-1}\ kg^{-1}$) between the treatment groups before (□) and after (■) the intervention.

Table 1. Demographic characteristics of the participants

Variable	Treatment group		P-value
	Conventional physiotherapy	Aerobic training plus conventional physiotherapy	
Age (years)	46.42 ± 8.286	44.82 ± 3.370	0.4277
Height (cm)	157.92 ± 2.682	158.03 ± 3.237	0.8903
Weight (kg)	49.73 ± 4.601	51.14 ± 5.930	0.3354
Body mass index ($kg\ m^{-2}$)	19.93 ± 1.526	20.42 ± 1.872	0.3061

Discussion

The results of the present study show that aerobic training plus conventional physiotherapy was more effective than conventional physiotherapy alone in reducing fatigue, and improving exercise capacity, VO_{2max} and QOL. The authors found a decline in fatigue in the aerobic

training plus conventional physiotherapy group, whereas the participants who received conventional physiotherapy alone showed no significant change in fatigue over the period of the study. One explanation for this may be that an improvement in the level of physical activity may alter self-esteem, preventing deconditioning

and enhancing performance in activities of daily living (Schwartz *et al.* 2001). This would be in accordance with a study by Hsieh *et al.* (2008), who carried out a moderate-intensity individualized exercise programme for 6 weeks and reported an improvement in cardiopulmonary function with a concomitant reduction in fatigue. In addition to this, Dimeo (2001) reported that physical activity produces adaptive changes in muscle mass and plasma volume, improves lung ventilation and perfusion, and increases cardiac reserve and the concentration of oxidative muscle enzymes. Therefore, aerobic exercises can greatly reduce an individual's fatigue level by normalizing physical performance. An explanation for the finding that conventional physiotherapy treatment was not helpful in reducing fatigue might be that it was not focused on fatigue.

In terms of the 6MWT and VO_{2max} , the improvement in exercise capacity was significant with aerobic training plus conventional physiotherapy, but not with conventional physiotherapy alone. These results provide evidence that aerobic training improves exercise capacity, which may be the result of an increase in cardiac output and the increased oxygen uptake capability of the skeletal muscles. This finding is in line with recent studies suggesting that the accessibility of oxygenated blood, fluids and nutrients for active muscles during exercise helps with the drainage of metabolic waste products. Therefore, more oxygen is available to the muscles being exercised, and these are better able to extract and use the oxygen to produce more work (Knobf *et al.* 2007; Plowman & Smith 2007, p. 61).

Other studies investigating the effectiveness of aerobic training in survivors of breast cancer found that an improvement in VO_{2max} can occur after between 6 and 10 weeks of regular exercise training as a result of an increase in the numbers of capillaries, myoglobins and mitochondria (Mock *et al.* 1997; Schwartz *et al.* 2001). In addition to this, exercise done at an intensity of 40–65% of VO_{2max} for 30–50 min per session, 5 days a week, enhances exercise capacity (Dimeo 2001). Several studies have demonstrated that aerobic training improves body composition, physical fitness, confidence and self-esteem. Therefore, it has a beneficial effect on QOL in survivors of breast cancer (McNeely *et al.* 2006; Courneya *et al.* 2007). In the present study, aerobic training plus conventional physiotherapy was more effective in improving QOL

than conventional physiotherapy alone, which may be a result of improved physical and psychological functioning during radiotherapy. Daley *et al.* (2007) conducted an 8-week study of supervised exercise training in survivors of breast cancer and concluded that QOL was improved by this programme in terms of the functional assessment of cancer therapy. In the present study, the intervention was initiated on the same day that the participants began to receive radiotherapy, and therefore, it was possible to achieve a high level of participant adherence to the programme. After 6 weeks of intervention, both groups showed substantial improvements in shoulder joint ROM and posture, while there were no chest wall adhesions, only minimal tightness of the soft tissues and no instances of lymphoedema. There was a tendency for the aerobic training plus conventional physiotherapy group to perform better than the participants who received conventional physiotherapy alone on all patient-rated outcomes. Although the conventional physiotherapy group showed improvements on a few of the study parameters, the treatment had no additional effects on other parameters such as fatigue and exercise capacity. Therefore, conventional physiotherapy alone was not helpful in improving the overall physical status of the participants. Furthermore, it is difficult to generalize the results of the present study to the global population since the institutional physiotherapy treatment offered to such patients is generally far less than the five sessions per week for 6 weeks that were offered to these participants.

Clinical implications for practice

In this study, aerobic training plus conventional physiotherapy was beneficial for patients with breast cancer. Since fatigue levels were reduced and VO_{2max} improved, aerobic training can be recommended along with conventional physiotherapy while this patient group undergoes radiotherapy.

Limitations

The sample size of this study was small, and on the basis of previous research, it had been expected to have a sample of more than 100 participants. The follow-up of the patients who had participated in the study was limited, varying from none at all to 6 weeks, and therefore, it is difficult to know whether the effects of the intervention were sustained over time.

Conclusion

Aerobic training was effective in reducing fatigue, and improving exercise capacity and QOL in patients with breast cancer who were undergoing radiotherapy. Future research in this area should involve larger samples and longer-term follow-up.

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