INVESTIGATING PHYSICAL ACTIVITY AND ASSOCIATIONS WITH SLEEP, FATIGUE AND MOOD AFTER BREAST CANCER TREATMENT: AN EXPLORATORY STUDY AND CLINICAL RESEARCH FOLIO

VOLUME ONE

(Volume Two bound separately)

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CHAPTER ONE

SYSTEMATIC REVIEW

TITLE

The Efficacy of Randomised Controlled Trials of Exercise Interventions on Psychosocial Outcomes after Breast Cancer Treatment – A Systematic Review.

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ABSTRACT

Objective: To systematically review the methodological quality of, and evaluate the evidence from trials assessing the efficacy of exercise interventions for improving sleep, fatigue and mood after breast cancer treatment. *Methods:* The search strategy reviewed the English language literature of randomised controlled trials (RCTs) from four databases (Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials and EBSCO) and hand searched key journals. Seven studies met criteria for inclusion the review. Effects sizes were calculated and methodological quality assessed using the Clinical Trials Assessment Measure. *Results:* One study was rated as high methodological quality. The results suggest that a combined intervention approach incorporating physical exercise and cognitive behavioural strategies may be more effective for improving psychosocial outcomes, than stand alone approaches. However, the lack of studies assessing sleep made it difficult to summarise the evidence. Failure to blind the outcome assessor and intervention contamination were the most prevalent methodological shortcomings. Adverse events were assessed and reported in two studies. *Conclusions:* The trials reviewed suggest that exercise may help to improve sleep, fatigue and mood following breast cancer treatment. However, the beneficial effects of exercise may vary as a function of patient-specific and disease-specific factors, as well intervention type. Future RCTs should use appropriate comparisons of the different intervention elements and pay greater attention to sleep problems following

breast cancer treatment, as this is a much neglected area in this patient group.

Keywords: breast cancer; exercise interventions; sleep; fatigue; anxiety; depression.

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INTRODUCTION

1.1 Description of underlying health problem

Breast cancer affects 41,700 people in the UK each year. There are 12,700 deaths from the disease annually and one in nine women will develop breast cancer. Breast cancer incidence is increasing but improved treatment means that survival is also increasing (Meuser *et al*. 2001). Women who survive breast cancer experience a wide range of disease and treatment-related problems, including sleep difficulties, fatigue, mood disturbance and reduced physical functioning (So *et al*. 2009). The reasons for this are unclear, however, it is likely that when patients receive cancer treatment, damage inevitably occurs to healthy cells and tissues, leading to treatment side-effects and symptoms. Of the various symptoms, fatigue, pain, anxiety and depression are most prevalent among breast cancer patients and result in significant reductions in quality of life (So *et al*. 2009). Importantly, sleep dysfunction may affect more than half of breast cancer patients and can be improved with exercise (Irwin, 2008a). However, few studies have attempted to investigate sleep in a systematic way. In addition to sleep problems, physical activity levels reduce significantly for many women after a diagnosis and remain low after treatment is complete (Irwin *et al*. 2003). Explanations to account for these symptoms include biochemical changes secondary to disease and treatment, impaired nutritional status, psychosocial factors and/or mood disturbance (Sneider *et al*. 2007). Exercise programmes have

been presented as a promising therapeutic strategy to address both the psychosocial and physical concerns of breast cancer patients.

1.2 Current treatment options

Current programmes in cancer settings are mostly limited to physical treatment addressing specific impairments caused by surgery or amputation (Irwin *et al.* 2003). Such programmes do not usually deal with the psychosocial problems encountered by patients. This is despite exercise being shown as a promising strategy for the treatment of these symptoms. Previous reviews support the role of exercise in attenuating these problems, (McNeely *et al*. 2006; Markes *et al*. 2006) however, the results are mixed and often hampered by methodologic limitations that limit interpretation of the results. The most common limitations include the use of small convenience samples, which result in limited statistical power. Wide variability in study interventions and outcome measures also make it difficult to compare results across trials.

1.3 Exercise interventions

Clinical trials of exercise in breast cancer patients primarily prescribe supervised, structured, and often gym-based exercise programmes that meet recommended guidelines. Structured exercise interventions generally

require participants to attend a centre to exercise at a specified duration and frequency (e.g. 30 minutes four times per week). Research in the general population indicates that structured exercise programmes are a difficult challenge for healthy adults and may be even more difficult after a cancer diagnosis and treatment (Markes *et al.* 2006). To overcome these challenges researchers have developed home-based exercise programmes. Pinto *et al*. (2009), for example, found that home-based physical intervention successfully increased physical activity and psychological well-being among stage 0 to II breast cancer patients who had completed treatment. However, sample size treatment fidelity issues and adherence may have limited results. Despite these challenges, emerging evidence confirms that exercise interventions are beneficial for cancer patients and can help to improve both the psychological and physical problems following treatment (Fong *et al*. 2012).

Previous reviews (McNeely *et al.* 2006; Markes *et al*. 2006) included studies up to 2006 and most have focused on outcomes during breast cancer treatment. The focus of the McNeeley *et al*. and Markes *et al* reviews were restricted to trials that focused on physical fitness outcomes and psychological distress during breast cancer treatment. It is well known that the post-treatment period is an important time in terms of adjustment and personal change. However, relatively few studies have focused on this transition. There are now newer studies that focus on this time period, and therefore, there is sufficient research available to justify another review in this area. A recent meta-analysis focusing on outcomes during and after

treatment found that exercise improved psychosocial functioning (Duijts *et al.* 2011). However, this review like many previous studies did not consider sleep as an outcome variable and included metastatic disease, which may have biased results. To address these limitations, there is a need to update previous findings and examine trials published since 2006. The rationale for considering exercise as an intervention to alleviate sleep and mood disturbance is based on the literature which demonstrates aerobic exercise has antidepressant and anxiolytic effects that protect against stress (Spiegal, 1997). Exercise has also been found to increase functional capacity leading to reduced effort and decreased fatigue (de Jong *et al*. 2002). It is hypothesised that these combined effects may alleviate the psychosocial problems associated with cancer-related treatment.

1.4 Aims and objectives

The current review will address the following research questions:

1) Are exercise interventions more effective for improving psychosocial outcomes (i.e., sleep, fatigue, depression, anxiety) following breast cancer treatment, when compared with established therapies in controlled trials?
2) What are the methodological limitations of exercise intervention studies?
3) Are there any adverse events associated with exercise interventions?

METHOD

2.1 Search strategy for identification of studies

The electronic databases from Ovid MEDLINE, Embase, The Cochrane Central Register for Controlled Trials and EBSCO databases (PsycINFO, CINAHL, Health Source: Nursing/Academic Section, PsycARTICLES, Psychology & Behavioural Sciences Collection) were searched from March 2006 to April 2012. The search was supplemented by hand searching the reference sections of those papers which were deemed appropriate for inclusion, as well as those of relevant recent reviews (McNeeley *et al.* 2006; Markes *et al*. 2006; Fong *et al*. 2012; Duijts *et al*. 2011).

2.2 Search terms

Search terms included the following Medical Subject Headings (MeSH) [BREAST CANCER] with [EXERCISE*] or [PHYSICAL ACTIVIT*] and the terms linked to the subject headings: [BREAST NEOPLASMS] and [EXERCISE] or [EXERCISE THERAPY] and [SLEEP] and [FATIGUE] and [AFFECT]. For databases that did not use MeSH headings the search strategy was modified to include the following keywords: (1) (breast cancer)*; (2) (exercise* or physical activit*); (3) (intervention* or therapy* or train*); (4) (sleep); (5) (fatigue or mental fatigue); (6) (psychosocial or emotion* or distress* or affect or mood or anx*). The symbol * denotes database

operators, which include truncations in the term to be included within the search. These six searches were then combined using 'AND'. References were stored and managed using Reference Manager Software.

2.3 Criteria for including and excluding studies

A set of inclusion criteria was applied, regarding study type, participant characteristics, timing of recruitment, intervention and focus of main outcome variables, e.g. sleep, fatigue, depression, anxiety. The review included English language articles and may therefore reflect selective publication bias of English language studies.

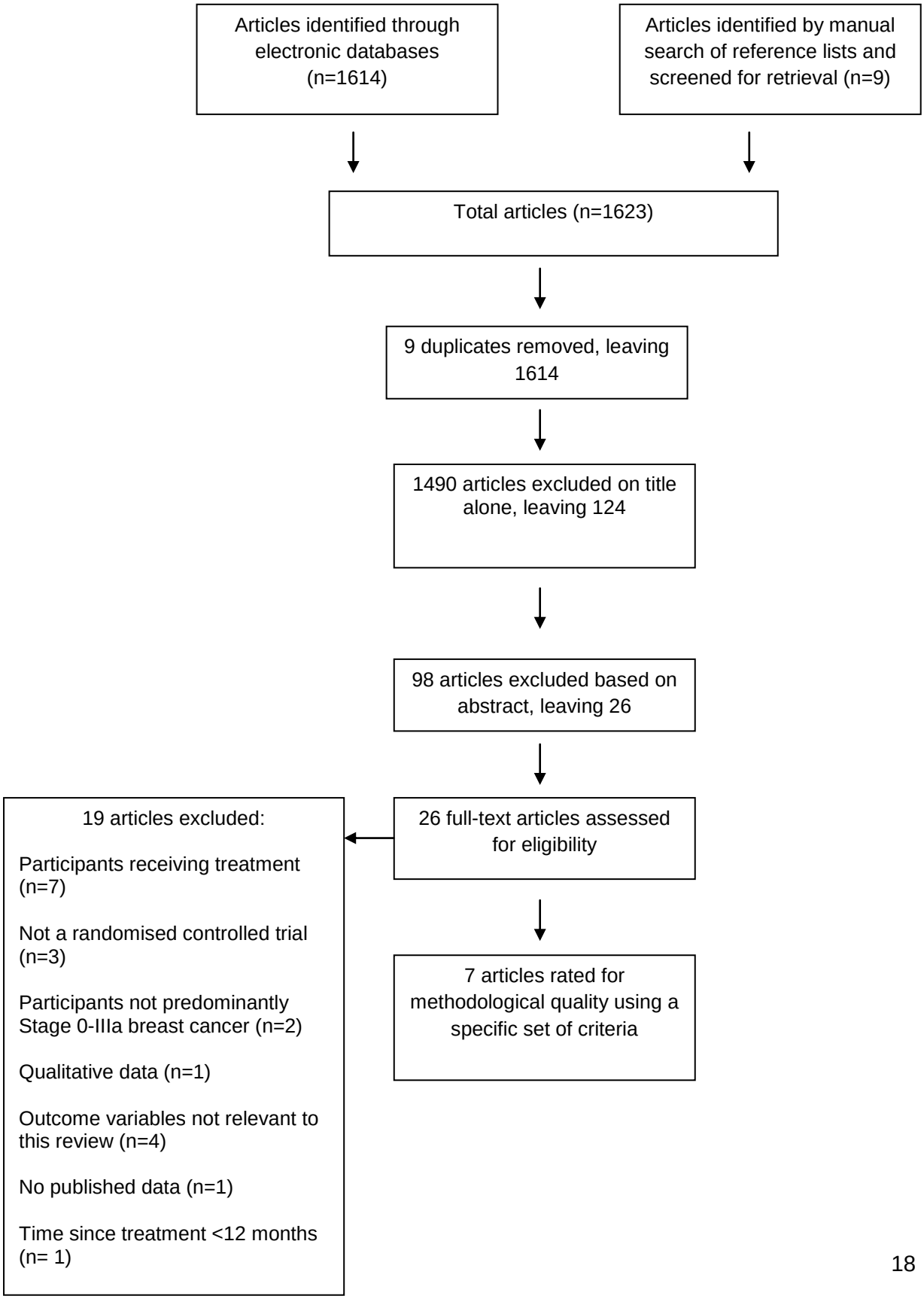
1) Study type: Randomised Controlled Trials.
2) Participants: Women with stage 0-IIIa breast cancer, (excluding metastatic disease) following completion of adjuvant therapy (i.e. radiotherapy or chemotherapy) with the exception of hormonal therapy.
3) Recruitment: 12-months post-treatment (as evidence shows that the majority of cancer patients prefer to start an exercise programme after they have completed initial treatment) (Jones & Courneya, 2002).

4) Intervention: Exercise therapy (including walking of moderate intensity and aerobic or resistance exercise).

5) Outcomes: Measures related to psychosocial distress (i.e. sleep disturbance, fatigue, depression, anxiety).

Exclusion criteria included: (1) research examining unpublished data; (2) no data, preliminary data or qualitative data; (3) review articles; (4) single case reports; (5) rehabilitation programmes with no specific intervention; (6) studies where time since completion of treatment was less than 12 months; (7) articles describing pharmacological interventions and, (8) articles presented in languages other than English. Figure 1 illustrates the article selection for the review.

Figure 1. Flow diagram of papers excluded at each stage of the review



2.4 Methodological quality assessment

The Clinical Trials Assessment Measure (CTAM; see Appendix 1.1; Tarrier & Wykes, 2004) was used to assess the quality of trials. The CTAM was chosen to ensure the scientific rigour of the review process, due to the thoroughness of its 15 included items and its use in previous systematic reviews of randomised controlled trials (Wykes *et al*. 2007). Furthermore, the CTAM shows high inter-rater reliability and good criterion related validity when compared with other scoring systems. The CTAM asks the rater to answer 15 questions about the study, under the headings of: sample, allocation, assessment, control groups, analysis and active treatment. Each question is weighted and scores are summed to reach a total score out of a possible 100. Studies are categorised as scoring high, moderate or low using the arbitrary grading system:

- High score = >70%
- Moderate score = 40-69%
- Low score = <39%

Studies were reviewed in a blinded manner by an independent rater. Overall percentage agreement was high (94%). Individual disagreements were resolved by discussion with the independent reviewer. Effect sizes were calculated for the main outcome variables in five studies (Vallance *et al*. 2007; Daley *et al*. 2007; Fillion *et al*. 2008; Milne *et al*. 2008; Rogers *et al*. 2009) using Cohen's *d* (Cohen, 1992; see Appendix 1.2 for calculation of

effect size). Effect sizes were not computed for two studies due to insufficient information (Payne *et al*. 2008) and null findings (Cadmus *et al*. 2009).

RESULTS

3.1 Summary of results

A total of 1,623 articles were initially identified from electronic databases and manual searches of reference lists. Following removal of nine duplicate studies the literature search identified 1614 articles. Of these, 1,490 studies were excluded on the basis of title alone, mainly because they were not intervention studies or pharmacological intervention studies. A further 98 articles were excluded based on their abstract as they did not fulfil the specified inclusion and exclusion criteria. Again, this was mainly because the studies did not relate to a direct intervention. A full article search was performed on the remaining 26 studies, of which 19 were excluded (refs: Pinto *et al*. 2009; Badger *et al*. 2007; Basen-Engquist *et al*. 2006; Blacklock *et al*. 2010; Courneya *et al*. 2007a; Courneya *et al*. 2007b; Courneya *et al*. 2008; Courneya *et al*. 2009; Hwang *et al*. 2008; Irwin *et al*. 2008b; Jones *et al*. 2010; Latka *et al*. 2009; Mayer *et al*. 2010; McClure *et al.* 2010; Mutrie *et al*. 2007; Ohira *et al*. 2006; Yang *et al*. 2011; Wang *et al*. 2011; Wu *et al*. 2008) for reasons specified in Appendix 1.3. Of the remaining seven included studies, one was rated as being of 'high' methodological quality, five were rated as 'moderate' and the remaining study as 'low' quality. Descriptions of the populations studied, intervention characteristics and study quality are summarised in Table 1. Individual quality assessment ratings for included studies can be found in Appendix 1.4.

Table 1. Description and methodological quality ratings of included studies

Study and quality rating (%)	Sample (N, age range, disease stage, time since treatment complete)	Design	Intervention	Outcome measures[a]	Effect Size (*d*)	Follow-up	Findings	Adverse events	Limitations
Daley *et al* (2007) *71%* *High*	N=108 breast cancer patients Age 18-65 years Stage I-III 17.5 months post-treatment	RCT comparing the effects of exercise intervention vs. placebo vs. usual care.	Supervised aerobic exercise 3 times a week for 8 weeks plus cognitive-behavioural techniques promoting exercise behaviour change. 2 intervention groups: Supervised aerobic exercise vs. exercise placebo (body conditioning) vs. usual care (control).	Fatigue, RPFS Depression, BDI-II QoL, FACT-G and FACT-B Exercise behaviour, self-report. Aerobic fitness, treadmill walking test	Depression: *d*=0.24 small QoL: FACT-G *d*=0.69 medium to large at 8 wk follow-up. FACT-B *d*=0.72 large	8, 12 wks	No group differences for fatigue at follow-up. Both intervention groups reported lower depression scores compared to control group. QoL significantly improved in the supervised aerobic exercise group compared to usual care at both follow-ups. Aerobic fitness improved in both intervention groups.	Not assessed/reported upon	Intervention contamination in the exercise-placebo and control group. Possible Hawthorne effect - blinding of assessments not possible. Possibility of Type I error - trial underpowered and no adjustments made for multiple comparisons.

Vallance *et al* (2007) *68% Moderate*	N=377 breast cancer patients Age 30-90 years Stage I-IIIa breast cancer 39 months post-treatment	RCT comparing the effects of print materials and step pedometers vs. control.	30mins moderate / vigorous physical activity 5 days a week for 12-weeks using step pedometer / breast cancer- specific print materials. <u>3 intervention Groups</u>: Pedometer group (PED) vs. Print Material (PM) vs. Combination of Step Pedometer and Print Material (COM) vs. Standard Recommendation (SR; control).	Fatigue, FACT-B scale Physical activity and pedometer Aerobic fitness, treadmill walking test	<u>Fatigue:</u> *d*=0.37 small to medium <u>Physical activity:</u> PM *d*=0.25 small PED *d*=0.37 medium COM *d*=0.38 Medium	3 mths	COM group reported improved fatigue compared to SR group. All 3 intervention groups showed significant increases in physical activity compared to SR group.	Not assessed/reported upon	No objective measure of physical activity, self-report only. Possibility of Type I error - no corrections made for multiple comparisons. Failure to blind participants from pedometer step count during baseline and post-intervention.
Fillion *et al* (2008) *58% Moderate*	N=87 Age≥18 years Stage 0-III 24 months post-treatment	RCT comparing group intervention to usual care.	Group intervention using stress/fatigue management , walking exercise of moderate intensity, muscle-relaxation and telephone booster session, once a week for 4-wks vs. usual-care.	Fatigue, MFI Emotional distress, POMS anxiety and depression QoL, SF12 Fitness, treadmill walking test Subjective physical activity, self-administered	<u>Fatigue</u>: *d*=0.48 medium at 3-mth follow-up <u>Emotional distress</u>: *d*=0.46 medium	4, 12 wks	Intervention group showed significant reductions in fatigue and emotional distress at 12wk follow-up compared to control group. Fitness improved equally in both groups.	Not assessed/reported upon	Multilevel aspect of intervention made it difficult to determine which aspects of the intervention were effective. Adherence to walking programme not assessed - limits comparisons and generalisability. Non-specific therapeutic effects.

				questionnaire Objective physical activity, actigraph					Questionnaire measuring subjective physical activity not standardised. Low participation rate.
Milne *et al* (2008) *58% (Moderate)*	N=58 Age ≥18 years Stage I-II breast cancer 13 months post-treatment	RCT 2-armed complete crossover design comparing immediate vs. delayed exercise programme.	Supervised aerobic and resistance exercise training 3 times a week for 12 weeks. <u>2 intervention groups</u>: Immediate Exercise Group (IEG) completed the exercise program from baseline to 12 weeks vs. Delayed Exercise Group (DEG) completed the exercise programme from 13 to 24 weeks	Fatigue, SCFS Social Physique Anxiety, SPAS QoL, FACT-B;FACT-G scale Aerobic fitness, cycle test	<u>Fatigue:</u> *d*=0.42 medium <u>QoL</u>: <u>FACT-B</u> *d*=0.52 medium at 3-mth follow-up. <u>FACT-G</u> *d*=0.46 medium	6, 12, 18, 24 wks	Fatigue scores improved in the IEG compared to no change in the DEG. From weeks 12 to 18 fatigue improved in the DEG. QoL significantly increased in the IEG compared to a reduction in the DEG. Aerobic fitness improved in both intervention groups.	Not assessed/reported upon	Therapist expectancy effects. Long-term treatment gains for fitness not known as participants assessed at post-intervention only. Low adherence rate to exercise programme. Intervention quality not assessed.
Rogers *et al* (2009) *56% Moderate*	N=41 Age 18-70 years Stage I-IIIa 33 months post-	RCT 2-armed comparing intervention to usual care.	Multi-disciplinary physical activity behaviour change intervention incorporating walking of moderate intensity, stress management, counselling and role modelling, on an	Fatigue, FACT-F Sleep, PSQI Objective physical fitness, actigraphy	Physical <u>activity</u>: *d*=0.64 medium to large.	3mths	No significant improvements in fatigue or sleep in the intervention group compared to control. Improved fitness	No adverse events reported however intervention group reported greater increase in joint stiffness. Some non-serious events were	PSQI sleep disturbance scale not included in data collection. Measurement bias - assessors not blind to group allocation.

	treatment		individual and group format, once a week for 12 wks vs. usual care.	Self-reported physical activity, GLTEQ QoL, FACT-B and FACT-G			and social wellbeing in the intervention group.	recorded e.g. wheezing requiring physician evaluation for asthma, sinusitis, back pain related to falling	Study outcomes influenced by different exercise specialists.
Cadmus *et al* (2009) *55% Moderate*	N=75 Age 34-79 years Stage 0-IIIa 12 months post-treatment	RCT comparing supervised exercise intervention to usual care.	Supervised intervention of moderate to vigorous physical activity 3 times a week for 6-mths vs. home-based exercise among breast cancer patients vs. usual care.	Depression, CES-D Anxiety, STAI QoL: FACT-B Physical fitness, Physical Activity Log		6 mths	No improvements were found on measures of depression and anxiety in the intervention group compared to control.	Assessed and none reported.	Small sample size. No formal power calculation. Possible self-selection bias as most participants were higher functioning than overall population of breast cancer patients.
Payne *et al* (2008) *19% Low*	N=58 Age 55- 78 years Stage of disease and time since treatment not reported. Contacted study author who	RCT comparing home-based walking exercise with usual care.	Home-based moderate walking activity for 20 mins 4 times a week.	Sleep, PSQI Fatigue, PFS Depressive, CES-D Exercise, self-assessed activity log	Not reported. Effect size could not be calculated.	2, 12, 14 wks	Intervention group reported better sleep compared to usual care. No significant differences between groups on measures of fatigue and depression.	Not assessed/reported upon	Small sample size may have reduced power. No details of randomisation procedures. No blinding. Adherence to study parameters not assessed.

	confirmed stage I-III and minimum 12 mths post-treatment.								Treatment fidelity not assessed. Reliance on self-reported physical activity despite objective measure (actigraph and step pedometers).

[a]Outcome Measures: BDI-II=Beck Depression Inventory; CES-D=Centres for Epidemiological Studies-Depression Scale; FACT-B=Functional assessment of cancer therapy-breast; FACT-F=Functional Assessment of Cancer therapy-Fatigue; FACT-G=Functional assessment of cancer therapy-general; GLTEQ=Godin Leisure-Time Exercise Questionnaire; MFI=Multidimensional Fatigue Inventory; PFS=Piper Fatigue Scale; PSQI=Pittsburgh Sleep Quality Index; POMS=Profile of Mood States; RPFS=Revised Piper Fatigue Scale; SCFS=Schwartz Cancer Fatigue Scale; SPA=Social physique anxiety; STAI=State-Trait Anxiety Index.

3.2 Study characteristics

All the studies used a randomised controlled design. Participants were women ≥18 years of age with stage 0-IIIa breast cancer who had completed adjuvant therapy. Sample size ranged from 41 participants (Daley *et al.* 2007) to studies containing 377 breast cancer patients (Vallance *et al.* 2007). The mean length of time since completion of treatment was 21.5 months. A variety of physical exercise modalities were employed, which differed in type: walking (Fillion *et al.* 2008; Rogers *et al*. 2009; Payne *et al.* 2008), aerobic resistance exercise (Vallance *et al.* 2007; Daley *et al.* 2007; Fillion *et al*. 2008; Milne *et al*. 2008; Cadmus *et al*. 2009), muscle strengthening (Payne *et al*. 2008) or combined exercise (e.g. physical activity plus cognitive behavioural techniques; Daley *et al.* 2007; Fillion *et al*. 2008; Rogers *et al.* 2009), intensity, with most programs at 75 per cent to 85 per cent of the estimated maximal heart rate (Vallance *et al.* 2007; Daley *et al.* 2007; Fillion *et al*. 2008; Payne *et al.* 2008; Cadmus *et al.* 2009); frequency, which ranged from once a week to five days a week; and duration, ranging from four to 12 weeks. Interventions were delivered on an individual (Vallance *et al*. 2007; Daley *et al.* 2007; Rogers *et al.* 2009; Payne *et al*. 2008; Cadmus *et al*. 2009) or group basis (Fillion *et al*. 2008; Milne *et al*. 2008; Rogers *et al.* 2009) and some were supervised (Vallance *et al*. 2007; Daley *et al.* 2007; Fillion *et al.* 2008; Milne *et al.* 2008; Rogers *et al*. 2009; Cadmus *et al.* 2009) or unsupervised (Vallance *et al* 2007; Payne *et al.* 2008). Examples of control or comparison group activities included body conditioning exercises (Cadmus *et al*. 2009), exercise of a lesser intensity (Rogers *et al*. 2009) and

usual care (Daley *et al*. 2007; Fillion *et al*. 2008; Rogers *et al.* 2009; Payne *et al*. 2008; Cadmus *et al*. 2009). In one study, the comparison group participated in a cross-over trial (Milne *et al*. 2008). Of the two studies that measured sleep, Payne *et al*. found improvements in sleep, whereas Rogers *et al*. found no differences between groups. Mixed results were found for the effect of exercise on fatigue, with three studies reporting significant improvements in fatigue (Vallance *et al.* 2007; Rogers *et al*. 2009; Payne *et al*. 2008) and three finding no differences between groups (Fillion *et al*. 2008; Rogers *et al*. 2009; Payne *et al*. 2008). Four studies investigated the effects of exercise on psychological distress (depression; Daley *et al*. 2007; Fillion *et al.* 2008); anxiety/depression (Fillion *et al.* 2008; Cadmus *et al.* 2009), with two finding improvements in depression (Daley *et al*. 2007; Fillion *et al*. 2008) and anxiety (Fillion *et al.* 2008) and two finding no difference between groups (Payne *et al*. 2008; Cadmus *et al.* 2009). Adverse events related to the intervention were assessed in two studies (Rogers *et al.* 2009; Cadmus *et al.* 2009). No adverse events were reported, however, the intervention group in one study reported a significant increase in joint stiffness (Rogers *et al*. 2009).

3.3 High quality studies

Daley *et al*. examined the effects of aerobic exercise on fatigue and depression in women treated for breast cancer, relative to usual care. A small benefit for depression was noted in the intervention group (d=0.24). No group differences were found for fatigue at follow-up. This paper is of

particular high methodological quality and scored the highest rating of all included studies. Strengths of this study included the inclusion of baseline data, the use of an appropriate comparison group, low attrition and good adherence rates, detailed descriptions of the intervention components and how these were standardised. Blinded assessments of outcomes, however, were not a feature of this study and may have biased the results. Lastly, as no adjustments were made for multiple comparisons, the risk of Type I errors increased.

3.4 Moderate quality

Vallance *et al*. studied the effects of breast cancer print materials and step pedometers on fatigue levels. Participants were randomly assigned to one of four groups: standard public health recommendation for physical activity (SR), print materials (PM), step pedometer (SP) or a combination of PM and SP (COM). The COM group showed the greatest benefits for fatigue, compared to the SR group, with a small to medium effect size noted (d=0.37). Methodological strengths included a large sample size, the use of a SR as a comparison group, high fidelity to the intervention and minimal loss to follow-up. The study was limited, however, by the use of self reported physical activity, failure to blind participants during step pedometer counts and potential false positive findings.

Fillion *et al*. examined the effectiveness of a combined stress management and physical activity intervention on fatigue and emotional distress (i.e.

anxiety and depression). Participants were randomly assigned to either the group intervention or usual-care. Improvements in fatigue and emotional distress were found in the intervention group compared to the control group, with medium effect sizes noted (*d*=0.48; *d*=0.46). Study limitations included the multilevel aspect of the intervention, which made it difficult to determine which aspects of the intervention were effective. Non-specific effects of therapy (i.e. participants in the intervention group spent more time [one-third] with study experts than the control group) and the low participation rate, may also have limited group comparisons and generalisability.

Milne *et al*. studied the effects of a combined aerobic and resistance programme on fatigue and social physique anxiety. A particular strength of this trial was the complete crossover design, which meant that participants in the immediate exercise group (IEG) completed the exercise programme from baseline to 12 weeks. The delayed exercise group (DEG) completed the intervention from 13 to 24 weeks. Reductions in fatigue were found in the IEG from baseline to week 18 and in the DEG from week 12 to 18, with a medium effect size that was statistically significant (*d*=0.42). However, the same professionals treated both groups, therefore, expectancy effects may have biased the results.

Rogers *et al*. examined the effectiveness of a combined intervention on sleep and fatigue. Participants were randomly assigned to either a 12-week physical activity intervention or usual care. No significant differences were found between groups on measures of sleep or fatigue. Limitations of the

study included non-blinding of participants, increased attention with study staff in the intervention group and the omission of the sleep disturbance scale, which may have contributed to a floor effect. Despite these limitations, the study had several strengths, including the use of an objective measure of physical activity, assessment of intervention adherence and monitoring adverse events, of which none were reported.

Cadmus *et al*. examined the effects of a 6-month supervised exercise intervention on anxiety and depression, relative to usual care. The intervention consisted of supervised moderate/vigorous exercise sessions three times a week, at a local health club and an additional two days, either at the health club or in the participants' home. Participants assigned to usual care were told that they could exercise on their own if they chose to do so. Exercise was not associated with improvements in anxiety or depression. To explain these findings, the authors suggest that high levels of psychological well-being at the time of enrolment may have made increases difficult to obtain. The authors attempted to tease this out by conducting secondary analyses on participants who scored in the bottom 50 per cent on each measure, however, no effect of the intervention was found. Despite good adherence rates, the sample size was small which meant the trial may have been underpowered and as this was a pilot study, no formal power calculation was conducted. In addition, no data was collected on ineligible or uninterested participants, may have led to selection bias.

3.5 Low quality

In this pilot study, Payne *et al*. examined the effects of a home-based walking intervention on fatigue, sleep disturbance and depressive symptoms, compared to usual care. Improvements in sleep were found in the intervention group, however, no significant differences were found between groups on measures of fatigue or depression. This study had numerous methodological flaws including small sample size (*n*=20), no information on concealment of allocation or randomisation procedures, high attrition rates and the use of subjective measures of physical activity, despite having objective data. The intervention was poorly described and data analysis did not include the "intention-to-treat" strategy. In addition, as this was a home-based intervention study, treatment fidelity tracking issues were an issue.

DISCUSSION

4.1 General findings

This review provides mixed evidence for the effects of exercise interventions in improving sleep, fatigue and mood after completion of breast cancer treatment. In general, the results suggest that a combined intervention approach (i.e., cognitive-behavioural strategies and physical activity) may be more effective than either approach alone. This may be because a combined approach addresses both the emotional and physical impact of breast cancer, which is important, as we know that the emotional impact of cancer can continue long after physical symptoms have improved (Irwin *et al*. 2008). Seven studies included in the review were of variable quality with only one considered to be of high quality (Daley *et al*. 2007). Of the two studies that investigated sleep, improvements were found in one study (Payne *et al*. 2008), however, due to significant methodological flaws, the results of this study should be interpreted with caution. Improvements in fatigue (Vallance *et al*. 2007; Fillion *et al*. 2008; Milne *et al*. 2008) were consistent with a recent meta-analysis by Duijts *et al.*, which demonstrated moderate effect sizes between exercise and fatigue. The lack of effect in other studies may be related to low fatigue scores at baseline which caused a floor effect (Daley *et al*. 2007; Rogers *et al*. 2009; Payne *et al* 2008). Future studies should consider focusing inclusion criteria or enrolling an adequate sample size to assess intervention effects on the basis of time since treatment or cancer stage (Courneya *et al*. 2007b).

The finding of improvements in depression is consistent with previous research (McNeeley *et al.* 2006), though effect sizes were small. High levels of functioning at the time of enrolment or lack of power may have explained the null findings on measures of psychological distress in the other studies included in the review. Only two studies assessed and reported adverse events (Rogers *et al.* 2009; Cadmus *et al*. 2009). Future RCTs should formally monitor and report the incidence of potential adverse events as requested by the CONSORT checklist (Moher *et al.* 2001), as this data could help to inform interventionists identify and overcome potential barriers to adherence. Despite some evidence that exercise interventions are cost-effective in various medical conditions, the number of studies among breast cancer patients is limited and requires further investigation (Roine *et al*. 2009).

4.2 Methodological limitations of included studies

Overall, the trials in this review were of moderate methodological quality. The most common methodological problems were with blinding (Vallance *et al.* 2007; Daley *et al*. 2007; Rogers et al. 2009; Cadmus *et al.* 2009) and intervention contamination (Daley *et al.* 2007; Fillion *et al.* 2008; Milne *et al.* 2008; Payne *et al*. 2008). Blinded assessment of outcome is possible in RCTs but unfortunately was not a feature in most of the studies in this review. Furthermore, the improvements observed in some studies may be

the result of intervention contamination and reflect benefits accrued from group activities and fellow patients, rather than the intervention itself.

4.3 Strengths, limitations and future research

To the author's knowledge, this is the first systematic review to focus specifically on sleep dysfunction following breast cancer treatment. The limited evidence for the effects of exercise on sleep is not surprising, given that only four of the 26 eligible studies, measured sleep as an outcome. Until the volume of literature expands in this area, it is not possible to summarise the evidence for the efficacy of exercise on sleep problems. The review highlights a lack of consistent evidence for the efficacy of exercise in improving psychosocial outcomes after treatment for breast cancer. A potential explanation for these findings relates to treatment stage and variation in intervention type. Future reviews should consider focusing on patient-specific and treatment-specific factors, as well as key characteristics of interventions that clearly differ between studies. Limitations of the current review include the variability in outcome measures and interventions used. Future RCTs should consider standardising both the mode and intensity of exercise used and use a comparable set of outcome measures, as this will allow pooling of data and comparisons across studies.

4.4 Conclusions and implications for NHS policy and practice

In conclusion, the current literature provides some evidence that a combined intervention approach may be more effective in improving psychosocial outcomes after breast cancer treatment, than stand alone approaches. Future studies with appropriate comparisons of different intervention elements are needed to support practitioners in clinical decision-making. There is also a need to increase the evidence base on sleep problems following breast cancer treatment as this is a much neglected area. Disease and treatment-related symptoms can be intense and lead to significant complications that result in reduced psychosocial and physical functioning. Based on the results of this review, integrating psychological strategies into exercise interventions may be necessary to strengthen the effect of exercise in reducing interference with daily life caused by treatment side-effects. Finally, the adoption of exercise as a standard treatment recommendation for breast cancer patients may allow for the above methodological problems to be addressed.

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CHAPTER TWO

MAJOR RESEARCH PROJECT

TITLE

INVESTIGATING PHYSICAL ACTIVITY AND ASSOCIATIONS WITH SLEEP, FATIGUE AND MOOD AFTER BREAST CANCER TREATMENT

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LAY SUMMARY

We know that many women who have had treatment for breast cancer experience a range of symptoms which affects their quality of life. Sleep problems, fatigue, anxiety and depression are just some of the symptoms following treatment. Exercise has been shown to improve some of these symptoms. However, many patients do not perform regular physical activity after treatment is complete. We were interested in the link between activity levels and these symptoms. We collected information about physical activity and common symptoms such as sleep problems, fatigue, anxiety and depression. The results of our study show that most patients were relatively active, but only a few were sufficiently active to meet national guidelines. We also found that activity was not related to sleep, fatigue or depression. There was a positive relationship between anxiety and high levels of activity, indicating that anxiety increased with more vigorous exercise. This information is important as it may help health professionals to target anxiety and include increased physical activity as a component of patients' post-treatment symptom management. We hope this will lead to improved services for cancer patients and help facilitate good post-treatment functioning.

ABSTRACT

Objective: Physical activity has been shown to improve sleep, fatigue and mood among breast cancer patients during treatment. However, few studies have focused on assessing the effect of activity on these symptoms after treatment is complete. Using a correlational design, this study aimed to explore associations between physical activity, sleep, fatigue and mood in women who had completed treatment for breast cancer and to evaluate the reliability and validity of the short-version International Physical Activity Questionnaire.

Methods: Twenty-eight women (aged 43 to 75 years) with stage I and II breast cancer were recruited at 6-months post-diagnosis and after completion of active treatment. Respondents completed measures of activity, sleep, fatigue, depression and anxiety. Six participants also undertook actigraphic monitoring to obtain objective activity levels.

Results: Descriptive analyses suggest the sample was relatively active with 50% of participants engaging in moderate-intensity activities. Despite this, however, only 18% were sufficiently active to meet national guidelines. No significant relationships were found between total physical activity, sleep, fatigue or depression, whereas, anxiety and activity were significantly correlated. Reliability of the IPAQ was low, however, comparison with objective actigraphy data suggests high criterion validity.

Conclusion: These findings have implications for designing interventions to reduce anxiety among breast cancer patients returning to physical activity

after treatment. However, the choice of assessment instrument may have a significant impact on research results.

Keywords: breast cancer; physical activity; sleep; fatigue; depression; anxiety.

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INTRODUCTION

1.1 Breast cancer and symptom distress

Breast cancer is the most commonly occurring cancer among women in the United Kingdom. More than 40,000 new cases are reported each year and this figure is expected to rise[1]. However, with advances in treatment and management, survival rates are increasing. Surviving cancer usually means enduring sequential combinations of treatment modalities which can result in significant reductions in quality of life.[2] During and after breast cancer treatment, many patients experience unpleasant side-effects such as weight gain, sleep disturbance, fatigue and depression.[3] Exercise has been shown to be effective in preventing weight gain and alleviating fatigue and depression.[4,5] However, there is a lack of research looking directly at the role of exercise in reducing sleep disturbance following breast cancer treatment.[6] This is surprising, considering 38% of breast cancer patients experience persistent sleep disturbance, with distress being a significant contributor.[7]

1.2 Physical activity levels in breast cancer patients

Despite the benefits of exercise, a large proportion of breast cancer patients do not perform regular physical activity or meet recommended physical activity guidelines.[8] Similarly, many patients decrease their activity after diagnosis, highlighting the need for intervention.[9] Evidence shows that

these decreases are related to the type of cancer treatment patients receive, with the greatest decrease in activity found among women who are treated with radiation and chemotherapy (50%), compared to women who undergo surgery only (24%).[10] Other reasons include that women are fearful of overexertion or uncertain of what they can do while receiving treatment.[11] A lack of medical advice[12] or reluctance of oncologists to prescribe exercise may also explain low activity levels.[13] Another reason may be that patients lack the confidence or self-efficacy to engage in exercise.[14] Self-efficacy is used within social cognitive theory (SCT) and provides a useful framework for understanding some of the barriers to exercise participation.[15] For example, if an individual feels confident that they can successfully engage in a behaviour, he or she is more likely to engage in that activity, and interventions that improve self-efficacy increase behaviour compliance. A prospective study evaluating SCT demonstrated the importance of self-efficacy for exercise adherence among breast cancer patients.[16] Although the current study did not evaluate specific SCT constructs *per se*, poor self-efficacy may suggest a mechanism to help explain reductions in activity following breast cancer treatment.

Previous reviews of the effects of exercise on breast cancer patients report mixed results for improvements in sleep, fatigue and emotional quality of life. Courneya and Friedenreich,[2] for example, found exercise to be associated with small but statistically significant improvements in fatigue and mood. However, a Cochrane review of exercise interventions exclusively during

treatment for breast cancer, found no improvements in fatigue or mood and limited evidence for an effect of exercise on sleep disturbance.[17] Although some findings were positive, most of these trials had methodological limitations. For example, most recruited small samples (e.g. fewer than 50 participants), used convenience-sampling approaches and recruited cancer patients into non-randomised trials of short duration (e.g. less than 3 months). The majority also focused on the effects of exercise during breast cancer treatment. Relatively few have focused on outcomes after treatment. Importantly, few trials have included sleep as an outcome variable. In one study, Humpel and Iverson,[18] examined the relationship between sleep disturbance and physical activity following a cancer diagnosis. This was a questionnaire-based study in which 32 breast and 59 prostate cancer patients completed questionnaires measuring sleep quality, physical activity and fatigue. The results showed that breast cancer patients experienced more sleep problems (48%) and greater fatigue (65%), compared to prostate cancer patients (17% and 43.%, respectively). The results also suggest lower levels of activity among those reporting poor sleep. However, the inclusion of both breast and prostate cancer patients limits interpretation of the results.

1.3 Measuring physical activity

Another challenge in the exercise literature is the measurement of physical activity. There are numerous methods (objective and subjective), each with characteristic advantages and disadvantages. Objective measures such as

heart rate and motion sensor monitoring can provide very detailed accurate measurement of physiological variables (which can be converted into relevant units such as energy expenditure) and have been shown to be highly reliable and valid measures of physical activity (Cronbach's $\alpha > .80$).[19] However, the equipment involved in these studies can often be expensive making the cost of large-scale studies prohibitive. The use of diary and recall methods are commonplace subjective forms of measuring physical activity, as they are relatively cheap to produce and easy to administer. However, a recent review highlighted the need for researchers to tackle the area of validating and standardising existing tools.[20] The International Physical Activity Questionnaire (IPAQ) has been shown to be quick and easy to complete in a variety of situations (including postal methods). It has been shown to be reliable and hold reasonable concurrent validity, however, further work is required to examine the criterion validity.[21]

1.4 Aims and Hypotheses

The current study aimed to: (1) examine associations between physical activity, sleep, fatigue and mood in women who had completed treatment for breast cancer; (2) evaluate the test-retest reliability of the IPAQ and, (3) examine the criterion validity of the IPAQ by comparing objective levels of activity (actigraphy) with self-reported activity scores (IPAQ) over a 3-week period.

The following predictions were made: (1) lower levels of physical activity, as measured by the IPAQ would be related to poorer sleep quality, as measured by the Insomnia Severity Index; (2) lower levels of physical activity would be related to higher levels of fatigue, as measured by the Fatigue Severity Scale; (3) lower levels of physical activity would be related to higher levels of anxiety and depression, as measured by the Hospital Anxiety and Depression Scale; (4) time 1 (T1) IPAQ scores would correlate with time 2 (T2) and time 3 (T3) IPAQ scores; and (5) self-reported physical activity scores, as measured by the IPAQ would correlate with objective activity data, as measured by actigraphy.

METHOD

2.1 Design

A cross-sectional correlational design was used for the primary analyses. Relationships between physical activity and sleep were examined, while controlling for the effects of fatigue and mood. Secondary analyses included correlations to examine the reliability of IPAQ scores over a 3-week period. Objective data from actigraphy was compared with self-reported levels of physical activity.

2.2 Participants

Participants were female, aged 18 years or older, with stage 0-IIIa breast cancer. All participants had completed treatment for breast cancer (chemotherapy and radiotherapy) with the exception of hormonal therapy. Participants were recruited at six months following diagnosis once active treatment was complete. Participants were excluded if they had an estimated prognosis fewer than six months, confusional problems or drug misuse, evidence of another sleep disorder or an untreated psychiatric disorder. Potential participants were attending and recruited from follow-up clinics at the Beatson West of Scotland Cancer Centre and NHS satellite sites between December 2011 and April 2012.

2.3 Measures

(i) International Physical Activity Questionnaire

The primary outcome was physical activity, which was measured using the short-version IPAQ (Appendix 2.1).[21] The IPAQ is a 4-item self-report instrument which measures physical activity over the preceding week. The short-version IPAQ was selected for use in this study as it is designed for monitoring purposes and is less burdensome than the long-version IPAQ, which is recommended for use in intervention studies. The IPAQ assesses three specific types of activity: (a) walking (b) moderate-intensity activities and (c) vigorous-intensity activities. The IPAQ counts only sessions lasting 10 minutes or longer. This reflects current scientific evidence that the physiological changes associated with health benefits from physical activity require a minimum duration.[22] An additional question measured time spent sitting which was used as an indication of sedentary time. The items on the IPAQ are structured to provide separate scores on walking, moderate-intensity and vigorous-intensity activity. The measure has been validated with breast cancer patients and demonstrates acceptable psychometric properties that are comparable to other established self-report questionnaires (Cronbach's $\alpha = .80$) .[23]

Computation of the total score requires summation of the duration in minutes and/or frequency (days) of walking, moderate-intensity and vigorous-intensity activities (expressed as 'activity minutes'). Algorithms are used to classify

three levels of physical activity into low, moderate or high categories. Each activity on the questionnaire is assigned a metabolic equivalent task (MET) score based on the classification by Ainsworth *et al.*[24] MET scores for specific activities are defined as the ratio of the metabolic rate associated with that activity divided by the resting metabolic rate. For example, walking at an average pace is assigned a MET score of 3.3; moderate intensity activities such as jogging, 4; and vigorous intensity e.g. running, 8. The MET-minutes per week (min/wk) was used in addition to 'activity minutes' because the total energy expenditure, rather than the time spent in specific exercise intensities is associated with improvement in health outcomes.[22] The scores for MET-min/wk for each activity were calculated from the reported minutes per day engaged in that activity multiplied by the assigned MET score. The values from the individual activities were summed for a total MET-min/wk score. For the sitting question, 'Minutes' was used as an indicator to reflect time spent in sitting rather than MET-minutes which would suggest an estimate of energy expenditure. See Appendix 2.2 for IPAQ Scoring Protocol and cut-off values.

(ii) Activity monitor (actigraphy)

Objective measures of physical activity were recorded in a subsample of participants using actigraphy (Cambridge Neurotechnology Ltd).[19] The wrist actiwatch is a nonintrusive device that records movement for 1-minute epochs through a wrist-watch microprocessor that senses motion (see Appendix 2.3 for an illustration of an actiwatch). The actiwatch provides

activity/rest variables which include mesor to represent overall mean activity levels. The sum of accelerations is transformed into counts. Total activity was expressed as counts per recorded time (count-mins week^{-1}) and compared with self-reported MET-minutes from the IPAQ (MET-mins week^{-1}).

(iii) Insomnia Severity Index

Sleep quality was measured using the Insomnia Severity Index (ISI; Appendix 2.4).[25] The ISI is a 7-item self-report questionnaire and is considered to be a core assessment tool in insomnia research studies. Each item is rated on a 0-4 scale, with total scores ranging from 0 to 28. Higher scores indicate more severe insomnia. Scores of between 8 and 14 indicate 'sub-threshold insomnia'; scores of 15-21 indicate 'moderate insomnia' and scores of 21-28 indicate 'severe insomnia'. The instrument has demonstrated good psychometric properties with cancer patients in previous studies (Cronbach's $\alpha = .90$).[26]

(iv) Fatigue Severity Scale

Fatigue was measured using the Fatigue Severity Scale (FSS; Appendix 2.5).[27] The FSS was originally developed as a tool to assess fatigue in patients with multiple sclerosis. The questionnaire has nine statements

enquiring about the severity of fatigue symptoms over the preceding week. Participants are asked to rate their level of agreement (toward seven) or disagreement (toward zero) with the nine statements. A score of 36 and above (out of a maximum of 63) indicates the presence of significant fatigue. The FSS has demonstrated excellent validity and reliability in a number of other studies of patients with medical conditions and sleep disorders (Cronbach's α = .94) .[28]

(v) Hospital Anxiety and Depression Scale

Anxiety and depressive symptoms were measured using the Hospital Anxiety and Depression Scale (HADS; Appendix 2.6).[29] The HADS is a brief 14-item self-report measure, which is widely used to assess anxiety and depression in patients with medical conditions. The scale is quick and easy to administer and consists of two subscales of seven items designed to measure levels of anxiety and depression. Responses are scored on a scale from 3 to 0, with a maximum of 21. The HADS is divided into four ranges to identify caseness: normal (0-7), mild (8-10), moderate (11-15) and severe (16-21). The HADS has demonstrated acceptable psychometric properties with cancer patients in a number of evaluation studies (Cronbach's α = .88; .82 for anxiety and .84 for depression subscale).[30]

2.4 Procedure

Participants were a subset of those who participated in a larger insomnia study being conducted by researchers at the University of Glasgow Sleep Centre (UGSC). The primary researcher/recruitment co-ordinator from the UGSC study, approached patients during routine clinic visits and provided information explaining the study, answered questions and then invited patients to participate. Written informed consent was obtained from all patients who met study criteria and agreed to participate. Data was collected during one clinic visit either face-to-face or remotely by post. This meant study participants were not required to make an additional trip for research study purposes. At the initial visit, eligibility criteria and demographic data were collected (Appendix 2.7). Participants also completed instruments assessing physical activity, sleep, fatigue and mood. To minimise participant burden, data was shared for measures that overlapped with the UGSC study (i.e. ISI, FSS and HADS). Participation in current exercise activity was also examined by asking participants to report whether they engaged in light or moderate exercise (i.e., light exercise was defined as less than five days of walking of 30 minutes per day; moderate exercise was defined as 30 minutes of moderate activity, five or more days per week).

For the actigraphy component, participants were asked to wear a wrist actiwatch for seven consecutive days. The monitors were initialised before the recording period began and placed on the participant's non-dominant wrist. Participants also completed the IPAQ at three time-points over a 3-

week period, Time 1 as test, Time 2 as re-test (plus actigraphy) and Time 3 as re-test (no actigraphy). It was therefore possible to test reliability of the IPAQ during the same 7-day period that the activity monitor was worn. Participants returned the actiwatch and questionnaires when the measurement period was complete. Actigraphy data was uploaded from the monitors to a computer using Actiwatch Analysis software (version 5.03, Cambridge Neurotechnology Ltd, UK).

2.5 Ethical Issues

Informed consent was obtained from all participants by the primary researcher before initiation of any study measurements. Ethical approval was granted from Greater Glasgow and Clyde NHS ethics committee (Appendix 2.8) and local Research and Development Management Office (Appendix 2.9).

2.6 Statistical Power and Data Analysis

Few studies have investigated physical activity and sleep in breast cancer patients, therefore, a study of related constructs was used to estimate the sample size needed to obtain power of 0.8, at an alpha of 0.05. Humpel and Iverson,[18] compared breast cancer and prostate cancer patients on measures of sleep and physical activity. Results showed statistically significant differences between groups, in that a greater proportion of breast cancer patients reported sleep problems and lower levels of activity,

compared to prostate cancer patients. A small to medium effect size was found (r = 0.30) for mean scores of activity and sleep. For the present study, GPower analysis estimated that a sample size of 82 would be required to detect an effect of this magnitude and 26 participants would be required to detect a large effect size (r = 0.50). Given that the current study used individuals of the same gender and cancer site (women with breast cancer), it was anticipated that a sample size of 26 would be sufficient to detect these associations if they existed. Effect sizes for the current study were calculated by dividing the z-score by the square root of the total number of observations.[31]

All analyses were performed using a Statistical Package for the Social Sciences (SPSS, version 18.0; SPSS Inc., Chicago, IL, USA). A two-tailed hypothesis was used for all statistical analysis with an alpha level set at 0.05. The normality of the frequency distributions of all continuous variables were evaluated by the Kolmogorov-Smirnov statistic; only age was normally distributed. As the assumptions for parametric tests were not met, Spearman's correlations were used to assess relationships between variables. Due to the skewed distribution of the IPAQ data, medians were presented to aid interpretation of the data. Partial correlations were conducted between physical activity and sleep while controlling for the effects of fatigue and mood. Secondary analyses included test-retest correlations to examine the reliability of IPAQ scores. Correlations between IPAQ scores and actigraphy data were conducted to assess criterion validity.

RESULTS

3.1 Participant characteristics

Thirty-five breast cancer patients were invited to take part in the study. A total of 31 took part resulting in a response rate of 88%. However, data is only presented on 28 as three participants did not return questionnaires. Four participants declined due to work/family commitments (*n*=3) and health issues (*n*=1). There were no significant differences between responders and non-responders on demographic variables and medical characteristics (see Appendix 2.10 for statistical analyses and significance levels). Participants were recruited at six-months beyond diagnosis, following completion of breast cancer treatment. The sample included women between the ages of 43 and 75 (*M* = 58.3 years, *SD* = 8.8), 76% were married and 28% retired. Over half the sample had received a diagnosis of stage I breast cancer (54%) and almost a third stage II (29%). The majority of women received a combination of surgery and radiotherapy/chemotherapy (92%); the remaining 8% received surgery alone. Fifty-five per cent engaged in light exercise and a minority reported no exercise activity (13%). More than a third reported insomnia of moderate severity (40%) and exactly half reported symptoms of fatigue (50%). The majority were within the normal range for anxiety and depression (68% and 82%, respectively). Sixteen per cent discussed exercise with their oncologist/surgeon prior to treatment ending. See Appendix 2.11 for percentage of individuals meeting diagnostic criteria. Table 1 provides demographic and medical information of the sample.

Table 1. Participants' demographic and medical characteristics (*N*=28)

Characteristic	Mean	*SD*	*N*	(%)
Age (years) mean (SD)	**58.3**	**8.8**		
Marital status				
Married			22	76
Single			1	4
Divorced			2	8
Widowed			1	4
Co-habiting			2	8
Employment status				
Employed			16	57
Not employed			1	4
Retired			8	28
Sick leave			3	11
Breast cancer stage				
0			1	4
1			17	54
II			7	29
III			3	13
Treatment received				
Surgery alone			2	8
Combination			26	92
Current exercise activity				
None			3	13
Light			16	55
Moderate			9	32

3.2 Current levels of Activity

Table 2 describes the weekly minutes of physical activity for the three IPAQ categories. The median score for minutes of total physical activity was 585. The majority of the sample participated in walking (93%), with a median of 420 min/wk. The second most commonly reported activities were of moderate-intensity, with 68% participating in these activities, with a median of 95 min/wk. Less common was participation in vigorous-intensity activities, with only 32% of women reporting these activities. The median score for time spent sitting was 300 minutes, which was the equivalent of approximately 5 hours a day. Participants who engaged in moderate-intensity activities reported higher mean scores on measures of sleep (*M* = 12.6), fatigue (*M* = 35.9), anxiety (*M* = 7.6) and depression (*M* = 5.6), compared to those who participated in high and low-intensity activities (see Appendix 2.12 for descriptive statistics of the ISI, FSS and HADS categorised by activity level).

Table 2. Minutes of weekly physical activity and sedentary time[a] reported by women following completion of breast cancer treatment based on the IPAQ (*N*=28)

Activity type	%	Median (*IQR**)	Min, max
Total physical activity		585 (1018)	0, 2550
Walking	93	420 (690)	0, 1260
Moderate	68	95 (536)	0, 1260
Vigorous	32	0 (0)	0, 180
Sitting	100	300 (5)	60, 780

[a] Time spent sitting = total weekday daily minutes.

* *IQR*: Interquartile Range.

3.3 Physical Activity Categories

Based on IPAQ scores, 50% of the sample were categorised as engaging in 'moderate' levels of physical activity and 25% met criteria for 'high' and 'low' categories. Since sample size was small and data were not normally distributed, a Kruskal-Wallis test was performed to examine differences in activity minutes between the three IPAQ categories (low, moderate, high). The analysis showed that the groups were significantly affected by the number of daily minutes engaged in physical activity (H (3) = 20.9, $p < 0.001$, see Figure 1). Appendix 2.13 shows *post hoc* analysis and median values for the IPAQ categories. In brief, a Jonckheere test revealed a significant trend in the data: as participants engaged in more vigorous-intensity

activities, the median minutes of activity also increased (J = 238.5, z = 5.020, r = .8).

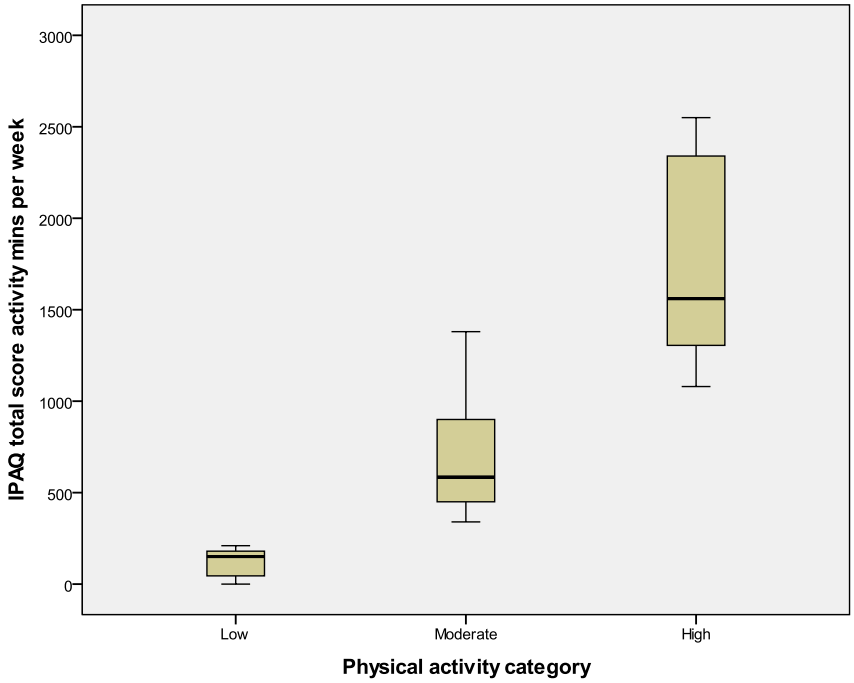

Figure 1. Boxplot of daily activity minutes for individuals engaging in different levels of physical activity per week

3.4 Hypotheses 1, 2 and 3 - Physical activity and associations with sleep, fatigue and mood

To examine associations between physical activity, sleep, fatigue and mood, Spearman's correlations were carried out on total IPAQ scores (activity minutes and metabolic equivalent [MET] value), ISI, FSS scores and HADS anxiety and depression subscale scores.

IPAQ activity minutes

The analysis showed that the predicted association between IPAQ activity minutes and sleep was statistically not significant (r_s = .1, N = 28, p > 0.05). Similarly, IPAQ activity minutes were not significantly correlated with fatigue (r_s = .1, N = 28, p > 0.05) or depression (r_s = .2, N = 28, p > 0.05). A significant positive correlation was found between IPAQ activity minutes and anxiety scores (r_s = .4, N = 28, p < 0.05), indicating that higher levels of anxiety were moderately related to higher levels of activity (see Figure 2).

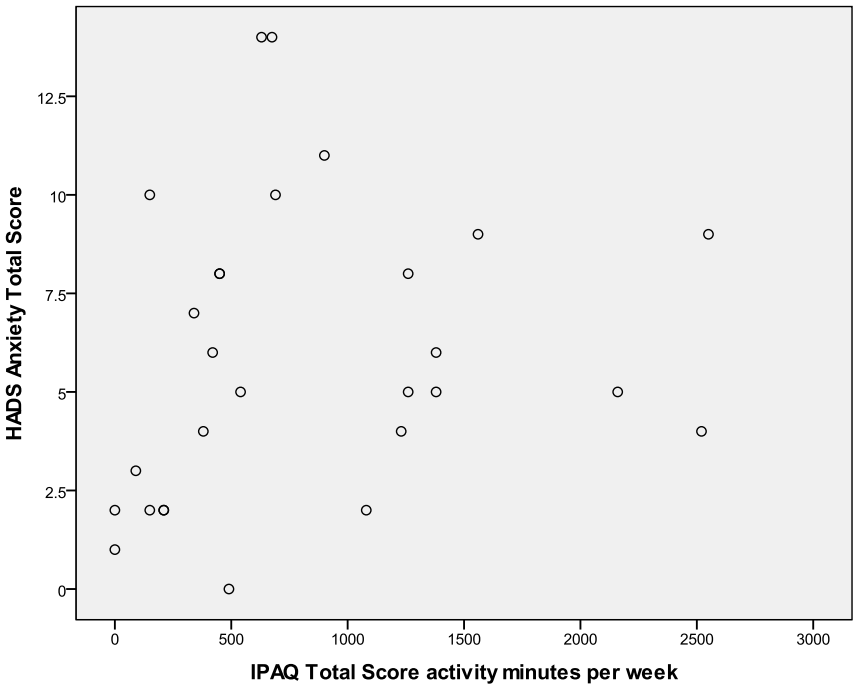

Figure 2. Scatterplot showing a moderate positive correlation between IPAQ activity min/wk and HADS anxiety scores

The correlation coefficient of .4 suggests that 16% of the variation in activity levels may be accounted for by the variation in anxiety scores. As there was no predicted association between physical activity and sleep, partial correlations controlling for the effects of fatigue and mood were not carried out. Appendix 2.14 shows correlation coefficients and significance levels for IPAQ activity minutes, measures of sleep, fatigue and mood.

IPAQ MET-minutes

Calculated MET-mins from the IPAQ were not significantly correlated with sleep ($r_s = .1$, $N = 28$, $p > 0.05$), fatigue ($r_s = .1$, $N = 28$, $p > 0.05$), anxiety ($r_s = .3$, $N = 28$, $p > 0.05$) or depression ($r_s = .2$, $N = 28$, $p > 0.05$; see Appendix 2.15 for correlation coefficients and significance levels). These findings, therefore, do not support the hypotheses that lower levels of activity were related to poor sleep, worse fatigue and depression. The IPAQ activity minutes data, however, provides partial support for the hypothesis that physical activity and anxiety were related, though not in the predicted direction.

Table 3 shows the median values for the total MET-min/wk for each of the activities measured by the IPAQ. As demonstrated by the means and medians, most variables were skewed. Among walking, moderate and vigorous activities, the highest percentage of energy expenditure was related to walking, with a median value of 1386. Using reported physical activity levels from the IPAQ, women were categorised according to national

physical activity guidelines. Only 18% were sufficiently active to meet recommended guidelines.

Table 3. IPAQ* MET-mins[a] of walking, moderate and vigorous-intensity activity and proportion of women meeting physical activity guidelines[b] following breast cancer treatment (*N*=28)

	%	Median MET-min/wk (*IQR*)	Mean (*SD*)	Min, max
Walking		1386 (2277)	1745.5 (1397.7)	0, 4158
Moderate		380 (2145)	1102.1 (1442.0)	0, 5040
Vigorous		0 (0)	158.6 (383.7)	0, 1440
Meeting guidelines	18	7758		2415, 9198
Not meeting guidelines	82	2079		0, 5652

*IPAQ = International Physical Activity Questionnaire.

[a] MET-mins = metabolic equivalents * min/wk.

[b] Physical activity guidelines defined as 30 min of moderate activity, 5 or more days per week, or 20 min of vigorous activity on 3 or more days per week.

3.5 Internal reliability of measures

A reliability analysis was undertaken for each of the self-report measures. All measures excluding the IPAQ demonstrated an acceptable level of internal consistency (Cronbach's α = .53 for the IPAQ; ISI = .90; FSS = .94; .81 and .87 for the HADS anxiety and depression subscales respectively). In view of the relatively low reliability of the IPAQ, further analysis showed that

removing item 3 from the scale (which represented vigorous-intensity scores), resulted in an increase in Cronbach's alpha from .14 to .77 (see Appendix 2.16 for IPAQ, ISI, FSS and HADS mean and median scores).

3.6 Hypothesis 4 – IPAQ reliability

To evaluate the test-retest reliability of the IPAQ, Spearman's correlations were carried out between T1 (test), T2 (retest) and T3 (retest) total IPAQ scores (i.e., activity minutes and MET-mins/week). Table 4 shows no significant associations between test and retest results. However, the moderately positive correlation between time spent sitting at T1 and T3 was marginally significant (r_s = .6, n = 6, p = 0.07). At T2 the magnitude of this relationship remained strong but did not reach significance (r_s = .8, n = 6, p >0.05). The latter coefficient may reflect fluctuations in test-retest reliability levels. The hypothesis that T1 IPAQ scores would correlate with T2 and T3 IPAQ scores was, therefore, not supported by the results. This effect, however, may have been due to limited power.

Table 4. Time 2 and Time 3 Spearman rank correlation coefficients for IPAQ activity minutes and MET-minutes per week (*n*=6)

Variable	r_s	Sig.	*p*
T2 Activity minutes	-.1	NS*	0.803
T3 Activity minutes	.3	NS	0.577
T2 Walking MET-mins	-.3	NS	0.612
T3 Walking MET-mins	.4	NS	0.381
T2 Moderate MET-mins	.4	NS	0.473
T3 Moderate Met-mins	.7	NS	0.144
T2 Vigorous MET-mins	.7	NS	0.125
T3 Vigorous MET-mins	.6	NS	0.178
T2 Sitting minutes	.6	NS	0.245
T3 Sitting minutes	.8	NS	0.072

*NS = not significant (p > 0.05, two-tailed).

IPAQ = International Physical Activity Questionnaire; ISI = Insomnia Severity Scale; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

3.7 Hypothesis 5 – IPAQ construct validity

IPAQ versus Actigraphy

To examine the criterion validity of the IPAQ, self-reported energy expenditure (MET-mins week^{-1}), was compared with objective activity counts (count-mins week^{-1}). Eight participants were initially invited to wear a wrist actiwatch, however, two declined due to health reasons. Data is therefore presented on six participants. Due to the small sample size, the strength of the relationship between IPAQ scores and actigraphy data was analysed using Spearman's correlation. The analysis showed a significant strong positive correlation between IPAQ MET-mins week^{-1} and actigraph count-mins week^{-1} (r_s = 0.8, n = 6, p < 0.001). This suggests that subjective minutes of activity increased with objectively measured recording time (see Figure 3). These findings support the hypothesis that the IPAQ and actigraph were measuring similar constructs and suggests the IPAQ may hold strong criterion validity.

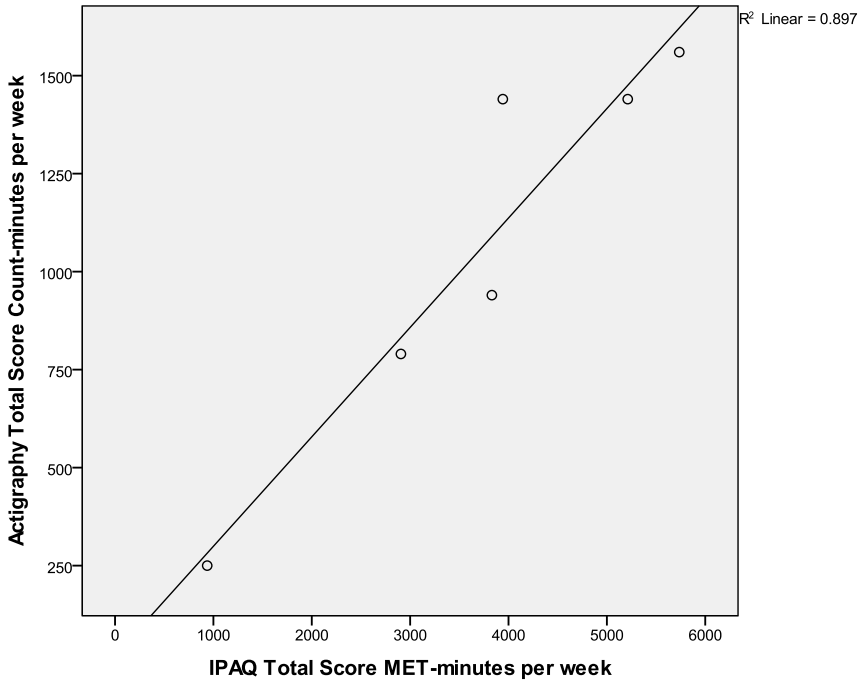

Figure 3. Scatterplot showing a strong positive correlation between IPAQ MET-mins/week and Actigraphy count-mins/week

DISCUSSION

4.1 Summary of results

This study aimed to explore the relationships between physical activity, sleep, fatigue and mood in women who had completed treatment for breast cancer. Secondary aims included examining the reliability and criterion validity of the IPAQ. The results of the study showed that walking was the most common form of physical activity, with more than 90% preferring it as their primary mode of exercise. The sample was relatively active with 50% of participants reporting moderate levels of physical activity. Despite this, only 18% met recommended physical activity guidelines. Contrary to the study hypotheses, no significant associations were found between physical activity, sleep, fatigue or depression. However, a moderately positive association was found between IPAQ activity minutes and anxiety, though not in the predicted direction. Results of the IPAQ reliability data were poor with low correlation coefficients ranging from 0.1 to 0.3. The criterion validity data showed a strong correlation between IPAQ scores and actigraphy data, suggesting high agreement between the two measures.

4.2 Comparison with previous studies

The findings that physical activity was not related to sleep, fatigue or depression, do not agree with previous research,[2,18] which found that poor sleep, worse fatigue and depression were negatively associated with less

physical activity. To explain these findings, the women in the study were functioning well, with only a minority meeting clinical cut-off for insomnia, fatigue and depression. This restricted range of scores may have had a ceiling effect on the results, which may account for the inconsistency with previous studies. Also, half the sample reported lower levels of fatigue when compared with levels in the general population and previous research.[4] The non-significant correlation between depression and physical activity is, however, consistent with Mock *et al.*,[32] who found no evidence that exercise was effective in reducing depression in breast cancer patients. This discrepancy may have been due to relative high quality of life, as mean Total Depression scores in the current study were fairly low, suggesting that the sample was relatively free from distress. Moreover, the literature suggests that the benefits of exercise towards reducing distress are stronger among individuals reporting higher levels of mood disturbance.[33]

An important contribution of this study to the literature was the unexpected finding that increased anxiety significantly correlated with higher levels of activity. While this finding conflicts with previous research of a negative relationship between anxiety and activity,[33] it may provide support for Social Cognitive Theory in helping us understand some of the barriers to exercise participation. It is possible, for example, that anxiety increased with more vigorous activities due to uncertainty about what was safe to do after breast cancer treatment.[10] In addition, study participants confirmed a lack of medical advice, with the majority (84%) reporting that their oncologist/surgeon had not discussed exercise with them. It is therefore

possible that a lack of confidence or self-efficacy led to increased anxiety as participants attempted to return to pre-diagnosis activity levels. Evidence confirms this, as it is well established that the post-treatment period is a time of uncertainty with new challenges, higher stress levels and changed social influences.[14] It is also possible that situational factors such as anticipatory anxiety associated with clinic attendance or psychosocial concerns relating to adjustment and coping impacted on anxiety levels.[34] For example, participants were recruited 6-months post-diagnosis and a short time after treatment was complete. The impact of psychosocial adjustment on physical activity is important to consider during this time, as the post-treatment period can be a time of instability and uncertainty about the future. To capture the transition period's acute nature, however, the study focused on a well-defined time interval (diagnosis to 6-months post-diagnosis). As a consequence, the study gives new perspectives for physical activity promotion by reporting the positive association with anxiety. An examination of the influence of anxiety on activity could illuminate additional areas to target in breast cancer patients facing the prospect of returning to "normal" life after treatment.

The test-retest reliability data for the IPAQ was low and although statistically non-significant is consistent with previous research.[21] These results may be due to fluctuations in test-retest reliability levels or measurement error.[20] The high correlation coefficient of 0.8 between self-reported activity scores and objective actigraph data, suggests the IPAQ may hold strong criterion

validity. However, the small sample size precludes a high criterion validity of the questionnaire and requires further validation with a larger sample.

4.3 Study strengths, limitations and future research

A particular strength of the study was the choice of activity monitor as an objective and valid criterion measure of physical activity.[19] Objective activity measurements were performed during the same time period as the questionnaire, therefore, there is no reason to believe that respondents did not refer to the same day when answering the questionnaire. However, the activity monitor and IPAQ captured only one week of activity. It is, therefore, possible that activity during the week prior to completion of these measures, may be markedly different from a "normal" week and activity level may not have been fully captured. The study is strengthened by its unique focus on sleep and physical activity among breast cancer patients after treatment. Only one study has examined this association among breast cancer patients[18] and few studies have measured this following treatment.

The current study is not without its limitations. First, since the study was cross-sectional in design the findings cannot be regarded as providing a cause-effect relationship. The findings should be confirmed by longitudinal analyses. Nevertheless, the study documents the relationship between increased anxiety and activity for the first time in the breast cancer literature. Second, the study was limited by the use of self-reported activity, creating the possibility for recall bias and measurement error. It is difficult to obtain a

good measure of low and moderate physical activity using self-administered questionnaires, because these activities are being accumulated throughout the day and, the number and diversity of these activities is enormous, resulting in poor recall.[35] It has also been reported that people tend to overestimate time spent in high-intensity activities and underreport time spent in light and moderate-intensity activities, resulting in measurement error.[35] However, the current study used the IPAQ short-version, which produces more accurate estimates than the IPAQ long-version, as it does not enquire about physical activity undertaken in specific domains (e.g. leisure time; domestic and gardening; work-related physical activity; transport-related). Another limitation of self-report, is that a single estimate of the energy cost of a specific activity is taken from a published compendium and applied to all individuals.[24] This does not allow for inter-individual variation in energy expenditure for a given intensity or through variations in mechanical and metabolic efficiency.

The study is also limited by the small sample size and potential loss of power. However, consideration was given to effect size estimation and power analysis indicated that a sample of 26 would be sufficient to detect a large effect size. Attempts were made to recruit as many participants as possible, however, numbers were limited due to timescales to complete the study. It is also possible that the likelihood of Type I errors was increased as adjustments were not made to control for multiple comparisons.

Importantly, the study did not gather data on what activity was like prior to a breast cancer diagnosis. Future studies should consider gathering baseline information on individual characteristics such as fitness level and history of physical activity, as these factors may influence participation in exercise. Lastly, participants in the study were primarily married, employed and most were diagnosed with early-stage tumours and, therefore, may not constitute a representative sample of the overall population of breast cancer patients. Additionally, it is very possible that those women who elected to participate in the study were coping better than breast cancer patients in general. Although the study collected demographic data on non-responders, the study did not collect activity data for potential participants who were not interested in participating in the study. Therefore the possibility of a psychosocial self-selection bias cannot be verified, but is plausible.

4.4 Clinical implications and conclusion

This is one of the first studies to find a relationship between high levels of anxiety and increased activity in patients following breast cancer treatment. The results are suggestive of a relationship but prospective data involving a larger sample size are required to adequately understand the direction and magnitude of the relationship. The findings, however, have implications for improving health outcomes among breast cancer patients, as the majority of women did not meet national recommendations. Future exercise programmes for breast cancer patients should include patient education and guidance by clinical staff. While reliability of the IPAQ was low, there was

high agreement between the activity monitor and IPAQ, suggesting strong criterion validity. Given the small sample size and possible selection effects, however, future studies should examine the reliability and validity of the IPAQ in a larger population of breast cancer patients.

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CHAPTER THREE

ADVANCED CLINICAL PRACTICE I

REFLECTIVE CRITICAL ACCOUNT (ABSTRACT)

TITLE

WORKING THERAPEUTICALLY WITHIN THE CONSTRAINTS OF THE CRIMINAL JUSTICE SYSTEM: A REFLECTIVE ACCOUNT

Trainee: Trudi Dickson

Matriculation Number: 0905128

Word Count: 3,286 words (including references)

Date of Submission: 17 April 2012

ABSTRACT

This reflective account describes my development working within a multi-disciplinary team in a specialist adult mental health setting. Particular reference is made to my developing competencies in relation to ethical and clinical practice as well as relational processes such as communicating psychological knowledge to others. The account will draw on Rolfe's framework for reflective practice (2001) and Schon's model of reflection (1991). These models of reflection were chosen as they help to capture the fluid and dynamic nature of reflective practice across time. The account will begin with a reflection of the impact of recent policy developments on the profession and wider National Health Service (NHS). It will then provide a brief outline of a clinical case before moving on to describe my experiences, analysis of learning and action plan for future practice.

CHAPTER FOUR

ADVANCED CLINICAL PRACTICE II

REFLECTIVE CRITICAL ACCOUNT (ABSTRACT)

TITLE

MULTI-DISCIPLINARY AND MULTI-AGENCY WORKING – STRONGER TOGETHER THAN APART: A REFLECTIVE ACCOUNT

Trainee: Trudi Dickson

Matriculation Number: 0905128

Word Count: 3,053 words (including references)

Date of Submission: 27 June 2012

ABSTRACT

This reflective account describes my development working within a multi-disciplinary team in a specialist learning disability service. Particular reference is made to my developing competencies in relation to research skills and service evaluation, as well as staff training and management. The account will draw on Gibbs' framework for reflective practice and Schon's model of reflection. These models of reflection were chosen because they help to capture the meaning of experiences and allow conceptual perspectives to change. The account will begin with a reflection of the impact of recent policy developments on the identification and management of gender-based violence within learning disability services. It will then provide a description of events before moving on to describe the stages of self-awareness, evaluation and analysis of learning, synthesis and action plan for my future practice.

VOLUME ONE – APPENDICES

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APPENDIX 1.1

CLINICAL TRIALS ASSESSMENT MEASURE (CTAM)

Sample – two questions: maximum score = 10

Q1	Is the sample a convenience sample (score 2) or a geographic cohort (score 5), highly selective sample, e.g. volunteers (score 0); convenience sample, e.g. clinic attendees, referred patients or geographic cohort – all patients eligible in a particular area	__
Q2	Is the sample size greater than 27 participants in each treatment group (score 5) or based on described and adequate power calculations (score 5)	__

Allocation – three questions: maximum score = 16

Q3	Is there true random allocation or minimisation allocation to treatment groups (if yes score 10)	__
Q4	Is the process of randomisation described (score 3)	__
Q5	Is the process of randomisation carried out independently from the trial research team (score 3)	__

Assessment (for the main outcome) – five questions: maximum score = 32

Q6	Are the assessments carried out by independent assessors and not therapists (score 10)	__
Q7	Are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms (score 3)	__
Q8	Are assessments carried out blind (masked) to treatment group allocation (score 10)	__
Q9	Are the methods of rater blinding adequately described (score 3)	__
Q10	Is rater blinding verified (score 3)	__

Control groups – one question: maximum score = 16

Q11	TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)	__

Analysis – two questions: maximum score = 15

Q12	The analysis is appropriate to the design and the type of outcome measure (score 5)	__
Q13	The analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)	__

Active treatment – two questions: maximum score = 11

Q14	Was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)	__
Q15	Was adherence to the treatment protocol or treatment quality assessed (score 5)	__

- Where the criterion is not reached for any question score = 0
- Total score: maximum score = 100

APPENDIX 1.2

EFFECT SIZE CALCULATION

Effect sizes were calculated by authors in five studies (Vallance *et al*., 2007; Daley *et al*., 2007; Fillion *et al*., 2008; Milne *et al*., 2008; Rogers *et al*., 2009) using Cohen's *d* (1992). Cohen's *d* was used as the preferred procedure for calculating effect sizes, namely the difference between two group outcomes divided by the population standard deviation. This is represented in the following formula:

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s}$$

Effect sizes were not computed for two studies due to insufficient information (Payne *et al*., 2008) and null findings (Cadmus *et al*., 2009). A meta-analysis was not felt to be appropriate due to the small number of studies, differences in methodological design and measurement of different psychosocial domains. Related to this, the review did not address the 'file drawer' problem i.e. bias attributable to the tendency for studies with large effect sizes to be published. Statistical methods have been developed for dealing with this issue within meta-analyses, however, this only becomes an issue when many of the studies remain unpublished. This is unlikely to be the case within the emerging evidence base described in the review.

APPENDIX 1.3 Characteristics of excluded studies

Badger 2007	Not a randomised controlled trial
Basen-Engquist 2006	Participants not predominantly Stage I-III (included Stage IV breast cancer)
Blacklock 2010	Not a randomised controlled trial
Courneya 2007a	Participants receiving treatment
Courneya 2007b	6-month follow-up study of Courneya 2007a
Courneya 2008	Qualitative data
Courneya 2009	Participants receiving treatment
Hwang 2008	Participants receiving treatment
Irwin 2008	Outcome measures not relevant to this review (biological markers)
Jones 2010	No published data, design paper
Latka 2009	Outcomes not relevant to this review (adherence study)
Mayer 2010	Outcomes not relevant to this review (pharmacological intervention)
McClure 2010	Participants not predominantly Stage I-III (included breast-cancer related lymphoedema)
Mutrie 2007	Participants receiving treatment
Ohira 2006	Time since treatment <12 months
Pinto 2009	Outcomes not relevant to this review (adherence study)
Yang 2010	Participants receiving treatment
Wang 2011	Not a randomised controlled trial
Wu 2008	Participants receiving treatment

APPENDIX 1.4 **Quality Assessment Ratings for Included Studies**

Study	1	2	**Sample Score**	3	4	5	**Allocation Score**	6	7	8	9	10	**Assessment Score**	11	**Control Group Score**	12	13	**Analysis Score**	14	15	**Active Treatment Score**	**Total CTAM Score**
Daley *et al* 2007	2	5	**7/10**	10	3	3	**16/16**	0	6	0	0	0	**6/32**	16	**16/16**	5	10	**15/15**	6	5	**11/11**	**71/100**
Vallance *et al* 2007	5	5	**10/10**	10	3	0	**13/16**	0	6	0	0	0	**6/32**	16	**16/16**	5	10	**15/15**	3	5	**8/11**	**68/100**
Fillion *et al* 2008	2	5	**7/10**	10	3	0	**13/16**	0	6	0	0	0	**6/32**	6	**6/16**	5	10	**15/15**	6	5	**11/11**	**58/100**
Milne *et al* 2008	2	5	**7/10**	10	3	0	**13/16**	0	6	0	0	0	**6/32**	6	**6/16**	5	10	**15/15**	6	5	**11/11**	**58/100**
Rogers *et al* 2009	5	0	**5/10**	10	0	3	**13/16**	0	6	0	0	0	**6/32**	6	**6/16**	5	10	**15/15**	6	5	**11/11**	**56/100**
Cadmus *et al* 2009	5	5	**10/10**	10	3	0	**13/16**	0	6	0	0	0	**6/32**	6	**6/16**	5	10	**15/15**	0	5	**5/11**	**55/100**
Payne *et al* 2008	2	0	**2/10**	0	0	0	**0/16**	0	6	0	0	0	**6/32**	6	**6/16**	5	0	**5/15**	0	0	**0/11**	**19/100**

Key:
Item 1. Is the sample a convenience sample (score 2) or a geographic cohort (score 5), highly selective sample, e.g. volunteers? (score 0)
Item 2. Is the sample size greater than 27 participants in each treatment group (score 5) or based on described and adequate power calculations? (score 5)
Item 3. Is there true random allocation or minimisation allocation to treatment groups? (score 10)
Item 4. Is the process of randomisation described? (score 3)
Item 5. Is the process of randomisation carried out independently from the trial research team? (score 3)
Item 6. Are the assessments carried out by independent assessors and not therapists? (score 10)

Item 7. Are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms? (score 3)
Item 8. Are assessments carried out blind (masked) to treatment group allocation? (score 10)
Item 9. Are the methods of rater blinding adequately described? (score 3)
Item10. Is rater blinding verified? (score 3)
Item11.TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment? (score 10)
Item12.The analysis is appropriate to the design and the type of outcome measure? (score 5)
Item13.The analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15%? (score 4)
Item14. Was the treatment adequately described (score 3) and was a treatment protocol or manual used? (score 3)
Item15.Was adherence to the treatment protocol or treatment quality assessed? (score 5)

Note: Where the criterion is not reached for any question score = 0

APPENDIX 1.5

GUIDELINES FOR SUBMISSION TO PSYCHO-ONCOLOGY

Manuscript Preparation

Address manuscripts to the Editor: *Journal of Psychosocial Oncology* receives all manuscript submissions electronically via their Scholar One Manuscripts website located at: http://mc.manuscriptcentral.com/WJPO. Scholar One Manuscripts allows for rapid submission of original and revised manuscripts, as well as facilitating the review process and internal communication between authors, editors and reviewers via a web-based platform. For Scholar One Manuscripts technical support, you may contact them by e-mail or phone support via http://scholarone.com/services/support/. If you have any other requests please contact the journal at mailforkrish@gmail.com.

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All parts of the manuscript should be typewritten, double-spaced, with margins of at least one inch on all sides. Number manuscript pages consecutively throughout the paper. Authors should also supply a shortened version of the title suitable for the running head, not exceeding 50 character spaces. Each article should be summarized in an abstract of not more than 100 words. Avoid abbreviations, diagrams, and reference to the text in the abstract.

References. References, citations, and general style of manuscripts should be prepared in accordance with the APA Publication Manual, 4th ed. Cite in the text by author and date (Smith, 1983) and include an alphabetical list at the end of the article.

Illustrations. Illustrations submitted (line drawing, halftones, photos, photomicrographs, etc.) should be clean originals or digital files.

Digital files are recommended for highest quality reproduction and should follow these guidelines:

300 dpi or higher

Sized to fit on journal page

EPS, TIFF, or PSD format only

Submitted as separate files, not embedded in text files

Color Illustrations. Color illustrations will be considered for publication; however, the author will be required to bear the full cost involved in color art reproduction. Color art can be purchased for online only reproduction or for print+online

reproduction. Color reprints can only be ordered if print+online reproduction costs are paid. Rates for color art reproduction are: Online Only Reproduction: $225 for the first page of color; $100 per page for the next three pages of color. A maximum charge of $525 applies. Print + Online Reproduction: $900 for the first page of color; $450 per page for the next three pages of color. A custom quote will be provided for articles with more than 4 pages of color.

Tables and Figures. Tables and figures (illustrations) should not be embedded in the text, but should be included as separate sheets or files. A short descriptive title should appear above each table with a clear legend and any footnotes suitably identified below. All units must be included. Figures should be completely labelled, taking into account necessary size reduction. Captions should be typed, double-spaced, on a separate sheet.

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APPENDIX 2.1

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (7-day recall)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives following a diagnosis of breast cancer. The questions are about the time you spent being physically active in the last 7 days. They include questions about activities you do at work, as part of your house and garden work, to get from place to place, and in your spare time for recreation, exercise or sport.

Please answer each question even if you do not consider yourself to be an active person.

In answering the following questions,

- **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal.
- **Moderate** physical activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

1. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   Think about *only* those physical activities that you did for at least 10 minutes at a time.

   _____ days per week

   How much time did you usually spend doing vigorous physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ No vigorous physical activities

2. Again, think *only* about those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ days per week

How much time did you usually spend doing moderate physical activities on one of those days?

_____ hours per day

_____ minutes per day

☐ No moderate physical activities

3. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place and any other walking that you did solely for recreation, sport, exercise or leisure.

   _____ days per week

   How much time did you usually spend walking on one of those days?

   _____ hours per day

   _____ minutes per day

   ☐ No walking

The last question is about the time you spent **sitting** on weekdays during the last 7 days. Include time spent at work, at home and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television.

4. During the **last 7 days**, how much time in total did you usually spend *sitting* on a week day?

   _____ hours per day

   _____ minutes per day

APPENDIX 2.2

IPAQ SCORING PROTOCOL

According to the published IPAQ scoring protocol, the cut-off point values for the three levels of physical activity are: Category 1 [Low], which is the lowest level of physical activity and includes individuals who do not meet criteria for Categories 2 or 3, Category 2 [Moderate], includes individuals engaging in three or more days of vigorous-intensity activity of at least 20 minutes per day OR five or more days of moderate-intensity activity and/or walking of at least 30 minutes per day OR five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum Total physical activity of at least 600 MET-minutes/week and, Category 3 [High], includes those individuals engaging in vigorous-intensity activity on at least three days achieving a minimum Total physical activity of at least 1500 MET-minutes per week OR seven or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes per week.

APPENDIX 2.3

EXAMPLE OF A WRIST ACTIWATCH

APPENDIX 2.4

INSOMNIA SEVERITY INDEX

Please respond to these questions, even if you do not have a sleep problem currently.

1. Please rate the current (i.e., last month) severity of your insomnia problem(s).

	None	Mild	Moderate	Severe	Very severe
a. Difficulty falling asleep:	0	1	2	3	4
b. Difficulty staying asleep:	0	1	2	3	4
c. Problem waking up too early:	0	1	2	3	4

2. How satisfied/dissatisfied are you with your current sleep pattern?

Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
0	1	2	3	4

3. To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc)?

Not at all interfering	A little	Somewhat	Much	Very much interfering
0	1	2	3	4

4. How noticeable to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all interfering	A little	Somewhat	Much	Very much interfering
0	1	2	3	4

5. How worried/distressed are you about your current sleep problem?

Not at all interfering	A little	Somewhat	Much	Very much interfering
0	1	2	3	4

APPENDIX 2.5

FATIGUE SEVERITY SCALE

Read each statement and circle a number from 1 to 7, depending on how appropriate you feel the statement applies to you over the preceding week. A low value indicates that the statement is not very appropriate whereas a high value indicates agreement.

FSS Questionnaire								
During the past week, I have found that:	**Score**							
1. My motivation is lower when I am fatigued.	1	2	3	4	5	6	7	
2. Exercise brings on my fatigue.	1	2	3	4	5	6	7	
3. I am easily fatigued.	1	2	3	4	5	6	7	
4. Fatigue interferes with my physical functioning.	1	2	3	4	5	6	7	
5. Fatigue causes frequent problems for me.	1	2	3	4	5	6	7	
6. My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7	
7. Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3	4	5	6	7	
8. Fatigue is among my three most disabling symptoms.	1	2	3	4	5	6	7	
9. Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7	

APPENDIX 2.6 HOSPITAL AND ANXIETY DEPRESSION SCALE

The next part of the questionnaire asks about how you have been feeling. Please read each item below and <u>circle one number opposite</u> the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long thought-out response.

1. I feel tense or "wound up"

Most of the time 3
A lot of time 2
Time to Time, Occasionally 1
Not at all 0

2. I still enjoy the things I used to enjoy

Definitely as much. 0
Not quite as much. 1
Only a little. 2
Hardly at all 3

3. I get a sort of frightened feeling as if something awful is about to happen

Very definitely and quite badly . . . 3
Yes, but not too badly 2
Time to Time, Occasionally 1
Not at all 0

4. I can laugh and see the funny side of things

As much as I always could 0
Not quite so much now 1
Definitely not so much now 2
Not at all 3

5. Worrying thoughts go through my mind

A great deal of the time 3
A lot of the time 2
From time to time but not too often 1
Only occasionally 0

6. I feel cheerful

Not at all 3
Not often 2
Sometimes 1
Most of the time 0

7. I can sit at ease and feel relaxed

Definitely 0
Usually 1
Not Often 2
Not at all 3

8. I feel as if I am slowed down

Nearly all the time 3
Very often 2
Sometimes 1
Not at all 0

9. I get a sort of frightened feeling like butterflies in the stomach

Not at all . . . . . ☐
Occasionally . . . . . ☐
Quite often . . . . . ☐
Very often . . . . . ☐

10. I have lost interest in my appearance

Definitely . . . . . ☐
I don't take so much care as I should ☐
I may not take quite as much care . . ☐
I take just as much care as ever . . . . ☐

11. I feel restless as if I have to be on the move

Very much indeed . . . . . ☐
Quite a lot. . . . . ☐
Not very much. . . . . ☐
Not at all . . . . . ☐

12. I look forward with enjoyment to things

As much as ever I did . . . . . ☐
Rather less than I used to . . . . . ☐
Definitely less than I used to . . . . . ☐
Hardly at all . . . . . ☐

13. I get sudden feeling of panic

Very often indeed . . . . . ☐
Quite often . . . . . ☐
Not very often . . . . . ☐
Not at all . . . . . ☐

14. I can enjoy a good book or radio or TV programme

Often . . . . . ☐
Sometimes . . . . . ☐
Not Often. . . . . ☐
Very seldom . . . . . ☐

APPENDIX 2.7

ELIGIBILITY INTERVIEW

Investigating Everyday Physical Activity with

Sleep, Fatigue and Mood in Patients with Breast Cancer.

ID ☐ **Date:** ☐ (for office purposes)

***Please answer <u>all</u> of the questions**. All information will be treated in the strictest confidence.*

Gender: Male Female

Age: _____

Marital status: married single divorced widowed

Occupation: _____

Retired: Yes No

Which type of cancer have you been diagnosed with?_____

Have you started anti-cancer treatment? Yes No

What treatment? (Chemotherapy; Radiotherapy; Hormone treatment; Surgery)

_____

Do you have any further cancer treatment planned? (please give details)

_____

_____

Have any of the clinicians talked to you about physical activity levels during/after treatment?

Yes No

We are interested in how you have been sleeping. Firstly, please answer the following questions in relation to your sleep in the month BEFORE you were diagnosed with breast cancer.

1. In the month prior to your diagnosis, did you have problems with any of the following:

- Difficulty falling asleep Y N
- Difficulty staying asleep Y N
- Problem waking too early Y N

If you answered yes to one or more of the above, please answer questions 2 to 7 If not, please go to question 8

2. How many days a week were you bothered with these sleeping problems?

_____

3. When did these sleeping problems start? _____

4. Did this sleep problem affect how you felt and functioned during the day? (e.g. fatigue, sleepiness, concentration, memory, mood, motivation, irritable, work/social functioning etc.)

_____

_____

5. How worried or distressed were you about these sleeping problems?

_____

6. Were you satisfied with your sleep?_____

7. Were you taking any *prescribed* **OR** *over-the-counter* medicines for your sleep during this period? Yes No

What medication?_____

How many nights a week were you taking this?_____

The next set of questions will ask about your sleeping habits in the last few weeks, FOLLOWING your breast cancer diagnosis

8. What time do you normally go to bed?_____

9. What time do you normally get up?

_____

10. How much sleep do you normally get each night (hours/minutes)?

_____

11. How long does it normally take you to fall asleep? (minutes)

_____

12. Do you tend to take naps during the day? Yes No

If yes, on average, how many days per week do you take naps?

_____

Roughly how long do you tend to nap for?

_____

13. Are you currently satisfied with your sleep?

_____

14. Are you currently taking any *prescribed* **OR** *over- the-counter* medicines to help with your sleep?

Yes No

If yes, please give medicine name and dose

_____

How many nights per week are you taking them?

_____

15. Have you ever attended therapy for insomnia or any other sleep problem?

_____

16. Do you work shifts or night shifts?

_____

17. Do you CURRENTLY have any problems sleeping? Yes No

If you ARE currently having problems with your sleep, the next few questions will ask you a few more detailed questions to establish the nature of your sleep problem. If you do not currently have any problems with your sleep, please go to question 42.

18. Have you always been a poor sleeper? Yes No

19. How long have you had problems with your sleep (months)?_____

20. On average, how many nights per week do you have difficulties sleeping?

_____

21. On average, how many nights per week do you have difficulty falling asleep?

_____

22. On average, how many nights per week do you have difficulty staying asleep?

_____

23. If you can't stay asleep, how long are you usually awake during the night?

_____

24. Does your sleep problem affect how you feel and function during the day? (e.g. fatigue, sleepiness, concentration, memory, mood, motivation, irritable, work/social functioning etc.)

_____

_____

_____

25. Do you know the main cause(s) of your sleeping problem? If so, please explain. For example, did this occur at a time of stress or life changes?

_____

_____

26. Has your sleep problem been constant over the years or does it come in spells?

_____

27. Does pain or physical discomfort interrupt your sleep at night?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

28. Does taking pain medication help this?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

29. Do you think that pain is the main cause of your sleeping problem (if yes, please specify the nature of the pain)?

_____

Do you snore during your sleep?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

30. If you do, how do you know? For example, has your partner been awoken?

---

31. Do you hold your breath, have breathing pauses or stop breathing in your sleep?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

32. If you do, how do you know? For example, has your partner noticed this?

---

33. Do you think breathing difficulties may be the main cause of your sleeping problem?

---

35. Why do you think this is the case?

---

36. Do you experience repeated, uncontrollable leg jerks or leg twitches during your sleep?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

37. Do you think such uncontrolled limb movements may be the main cause of your sleeping problem?

---

38. Do you experience restless or "crawling" feelings in your legs at night which go away if you move your legs?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

39. Do you think such restless legs may be the main cause of your sleeping problem?

---

40. Do you fall asleep unintentionally or have to fight to stay awake during the day?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

41. How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation.

0 = would *never* doze

1 = *slight* chance of dozing

2 = *moderate* chance of dozing

3 = *high* chance of dozing

Situation	**Chance of dozing**
Sitting and reading	.....
Watching TV	.....
Sitting, inactive in a public place (e.g. a theatre or a meeting)	.....
As a passenger in a car for an hour without a break	.....
Lying down in the afternoon to rest when circumstances permit	.....
Sitting and talking to someone	.....
Sitting quietly after lunch without alcohol	.....
In a car, while stopped for a few minutes in the traffic	.....

The next set of questions will ask about how you have been feeling emotionally in the last few weeks

42. Have you felt particularly worried or anxious about things recently? If so, when did this start? What are you worrying about?

_____

_____

_____

43. Have you felt particularly 'down' or 'sad' or 'empty' about things in the past two weeks?

❒ Never ❒ Sometimes ❒ Usually ❒ Always

44. Does your doctor know about this?

_____

45. Are these low feelings a change from what is normal for you?

_____

46. When did these low feelings start?

_____

47. In the past <u>two weeks</u> :

Have you lost pleasure in your usual activities? _____

Has your appetite changed? _____

Have you lost or gained weight? _____

Have you lacked energy? _____

Have you felt agitated? _____

Have you felt slowed down? _____

Have you thought about harming yourself? _____

Have you felt excessively guilty or worthless? _____

Has your concentration been poor? _____

48. Are you currently being treated for depression? If yes, please give details.

_____

49. Have you ever been diagnosed with any psychiatric disorder?

Yes No

If yes, are you currently receiving any treatment for this? Please give details

_____

The next questions relate to your lifestyle and aspects of your general health

50. Do you smoke tobacco? If yes, how many cigarette's/cigars per day?

_____

51. Do you drink alcohol? Yes No
If yes, roughly how many units of alcohol do you drink per week?

(Remember: One standard (175ml) glass of wine = 2 units

One pint of standard lager = 2.3 units

Spirit & mixer = 1 unit)

_____

52. Do you take any non prescription drugs? If yes please give details

_____

_____

53. Do you exercise? If yes, how often and what types of activity?

Number of times per week: _____

Average time per session: _____

Types of activity (e.g. walking, cycling, swimming, jogging, aerobics):
_____

54. Has your oncologist/surgeon discussed physical activity with you?

54. Do you have any other health problems?

_____

_____

_____

55. What medicines do you take for your physical health?

_____

_____

Dr N Britton, R+D

R & D

03 OCT 2011

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Date 29 September 2011
Direct line 0141-211-1722
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Dear Dr Fleming

Study title:	**Investigating the relationship between everyday physical activity with variables of sleep, fatigue and mood in women with breast cancer**
REC reference:	**11/WS/0048**

The Research Ethics Committee reviewed the above application at the meeting held on 20 September 2011.

Ethical opinion

The Chair thank you for attending the meeting to discuss her study.

You confirmed that the participants for this study are already taking part in the existing sleep study (REC ref 10/S0709.68 "Understanding the development of persistent insomnia in breast cancer patients")

You advised that the main outcome of this study is physical activity but it overlaps with the first study in relation to mood and fatigue. Therefore participants w on't be asked to complete the questions relating to these issues again but you will use the data from the first study. The REC suggested that you concentrated on physical activity only since mood and fatigue are already covered in the first study.

There was discussion about the relevance of some questions in the Questionnaires. However, since this topic will no longer be explored, the questions from the REC are no longer relevant.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of

the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Other Conditions Specified by the REC

There were concerns that 26 participants will not be enough and a correlation of 0.5 is too high. It is suggested that the upper limit is left open and the researcher tries to recruit as many people as possible. It is noted that the numbers have been limited by timescales to complete the study.

You should check whether the GPs are being contacted in the original study but the REC felt for this study that GP contact was not necessary.

Participant Information Sheet:

References to obesity and mood etc that are now not relevant to the study should be removed from the document.

The document should start by inviting the participant to join the trial and should thank them for reading the document. The researcher should refer to the NRES Guidance for writing Participant Information Sheets.

There would be personal safety concerns if the contact mobile number stated is a personal number. If so, it is suggested that a business landline is used instead.

Using Cancer Research UK or Macmillan Cancer Support as independent contacts is too general and vague. It is suggested that a specific contact, such as another member of staff within the Sleep Clinic, is given.

Consent Form:

In statement 3, it should be clear that data will be shared from the first study. Also, "research team" should be added before "clinicians" and the word "only" removed.

Study Leaflet.

There were concerns that the title of the leaflet "Are you as active as you used to be?" may only attract women who are not fit. Therefore the study group won't be representative of the general population.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		01 September 2011
GP/Consultant Information Sheets	1	07 July 2011
Investigator CV		23 August 2011
Other: CV Student - Trudi Dickson		30 August 2011
Other: CV Supervisor - Professor C Espie		23 August 2011
Other: CV Co-Investigator - K Randell		30 August 2011
Other: Study Leaflet	2	23 August 2011
Participant Consent Form	2	23 August 2011
Participant Information Sheet	2	23 August 2011
Participant Information Sheet: Health Professional	1	23 August 2011
Protocol	2	23 August 2011
Questionnaire: App A Eligibility Interview	2	23 August 2011
Questionnaire: App B - International Physical Activity	2	23 August 2011
Questionnaire: App C - Internatioinal Physical Activity - 7 day recall	2	23 August 2011
Questionnaire: App D - Sleep Diary	2	23 August 2011
Questionnaire: App E - Insomnia Severity Index	2	23 August 2011
Questionnaire: App F - Fatigue Severity Scale	2	23 August 2011
Questionnaire: App G - Hospital and Anxiety Depression Scale	2	23 August 2011
REC application		30 August 2011
Referees or other scientific critique report		05 September 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/WS/0048 **Please quote this number on all corresponder**

With the Committee's best wishes for the success of this project.

Yours sincerely

Evelyn Jackson

Dr Sue Langridge
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"

Copy to: ✓Dr Nathaniel Brittain, R&D Office, Tennent Building, Western Infirmar

APPENDIX 2.9

RESEARCH & DEVELOPMENT NHS GG&C APPROVAL LETTER

Greater Glasgow and Clyde
R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT

Coordinator: NB/BR
Telephone Number: 0141-211-8544
E-Mail: Nathaniel.Brittain@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

25 October 2011

Ms Trudi Dickson
Trainee Clinical Psychologist
Department of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

NHS GG&C Board Approval

Dear Ms Dickson

Study Title:	**Investigating the relationship between everyday physical activity with variables of sleep, fatigue and mood in women with breast cancer**
Principal Investigator:	**Ms Trudi Dickson**
GG&C HB site	**BWoSCC, WIG, NVH, Stobhill & RAH sites**
Sponsor	**NHS Greater Glasgow & Clyde**
R&D reference:	**GN11ON293**
REC reference:	**11/WS/0048**
Protocol no: (including version and date)	**Version 2 dated 23/08/2011**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.

NHS
Greater Glasgow and Clyde

a. Recruitment Numbers on a quarterly basis
b. Any change of staff named on the original SSI form
c. Any amendments – Substantial or Non Substantial
d. Notification of Trial/study end including final recruitment figures
e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

N Brittain

Dr Nathaniel Brittain
Research Co-ordinator

Cc: Dr Leanne Fleming, Research Associate, University of Glasgow Sleep Centre, Sackler Institute, SGH

APPENDIX 2.10

Statistical Analysis of Demographic Variables and Medical Characteristics (*N*=35)

Variable	Test	Value	*M* (*SD*)	*df*	Sig.	*p*
Age	*t*	0.559	57.8 (8.4)	33	NS*	.580
Marital status	χ^{2**}	7.318		4	NS*	.093
Employment	χ^{2**}	4.571		4	NS*	.406
Tumour stage	χ^{2**}	1.872		3	NS*	.588
Treatment	χ^{2**}	0.530		1	NS*	.635

*NS = not significant (p > 0.05, two-tailed).
** The analysis showed that 2 cells had expected counts less than 5, therefore Fisher's Exact Test was selected for Pearson's Chi-square.

APPENDIX 2.11

Percentage of participants meeting diagnostic criteria for insomnia, fatigue, anxiety and depression (*N*=28)

Variable		%
ISI		
	No insomnia	32
	Subthreshold insomnia	40
	Clinical insomnia	21
	Severe insomnia	7
FSS		
	Fatigue present	50
	No fatigue	50
HADS anxiety subscale		
	Normal	68
	Mild	21
	Moderate	11
	Severe	0
HADS depression subscale		
	Normal	82
	Mild	11
	Moderate	0
	Severe	4

ISI = Insomnia Severity Scale; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

APPENDIX 2.12

Descriptive Statistics for Outcome Variables categorised by Physical Activity level* (*N*=28)

Outcome variable	Mean (*SD*)	Min, Max
ISI		
Low PA	9.4 (5.7)	2, 20
Moderate PA	12.6 (6.8)	3, 28
High PA	9.7 (7.1)	2, 22
FSS		
Low PA	31.7 (15.5)	9, 57
Moderate PA	35.9 (13.5)	14, 63
High PA	32.3 (18.4)	11, 55
HADS Anxiety subscale		
Low PA	3.1 (3.1)	1, 10
Moderate PA	7.6 (3.8)	0, 14
High PA	5.4 (2.6)	2, 9
HADS Depression subscale		
Low PA	3.0 (2.2)	0, 7
Moderate PA	5.6 (5.1)	0, 19
High PA	4.1 (3.7)	0, 9

*Based on the International Physical Activity Questionnaire; ISI = Insomnia Severity Scale; PA = Physical Activity; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

APPENDIX 2.13

POST-HOC ANALYSIS OF IPAQ CATEGORIES

Participants categorised in the lowest level of activity had the least number of physical activity minutes (median = 150.0) and those individuals who met criteria for higher levels of participation had the most minutes (median = 1560). Participants classified as 'moderate' had a median of 585 minutes of physical activity. *Post hoc* Mann-Whitney tests were used to test for differences between the three groups. A Bonferroni correction was applied and so all effects are reported at a 0.017 level of significance. The analysis showed that activity minutes were significantly affected by intensity level. Participants who engaged in higher levels of activity reported significantly more minutes of activity, compared to those engaged in moderate-intensity (U = 111, z = 3.174, p < 0.01, r = .7) and lower levels of activity (U = 28, z = 3.141, p < 0.01, r = .8). Similarly, individuals who engaged in moderate levels of activity reported significantly more minutes of activity than those who engaged in lower levels of activity (U = 87, z = 3.662, p < 0.01, r = .7). Effect sizes were large indicating fairly substantive findings.

APPENDIX 2.14

Spearman correlation coefficients for IPAQ activity minutes per week and measures of Sleep, Fatigue and Mood (*N*=28)

Variable	r_s	Sig.	*p*
ISI	.1	NS*	0.568
FSS	.1	NS	0.519
HADS Anxiety	.4	Sig**	0.040
HADS Depression	.2	NS	0.275

*NS = not significant (p > 0.05, two-tailed).

** Correlation is significant at the 0.05 level (two-tailed).

IPAQ = International Physical Activity Questionnaire; ISI = Insomnia Severity Scale; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

APPENDIX 2.15

Spearman's correlation coefficients for IPAQ MET-minutes per week and measures of Sleep, Fatigue and Mood (*N*=28)

Variable	r_s	Sig.	*p*
ISI	.1	NS*	0.620
FSS	.1	NS	0.662
HADS Anxiety	.3	NS	0.082
HADS Depression	.2	NS	0.362

*NS = not significant (p > 0.05, two-tailed).
IPAQ = International Physical Activity Questionnaire; ISI = Insomnia Severity Scale; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

APPENDIX 2.16

Descriptive Statistics of the IPAQ, ISI, FSS and HADS

Variable	Mean	*SD*	Min, Max	Median	IQR
IPAQ	826.9	723.2	0, 2550	585.0	1018
ISI	11.1	10.5	2, 28	10.5	10
FSS	33.9	10.3	9, 63	34	19
HADS Anxiety	5.9	3.7	0, 14	5.0	7
HADS Depression	4.6	4.3	0, 19	3.0	6

IPAQ = International Physical Activity Questionnaire; ISI = Insomnia Severity Scale; FSS = Fatigue Severity Scale; HADS = Hospital and Anxiety Depression Scale.

APPENDIX 2.17

GUIDELINES FOR SUBMISSION TO CANCER NURSING

Manuscript Preparation

Manuscripts must adhere to the following instructions or they will be rejected before undergoing peer review.

Abstract: The Abstract is attached as a Word document during the submission process.
Please use the following format for all abstracts; ALL SIX SUBHEADINGHS ARE REQUIRED:

Background: 1 to 3 statements describing existing knowledge and significance of study

Objective: 1 to 3 statements regarding study aims

Interventions/Methods: 1 to 3 statements describing intervention or data collection methods

Results: 1 to 3 statements about sample and findings

Conclusions: 2 to 3 statements about how findings can be interpreted

Implications for Practice: 2 to 3 statements regarding how one or more study findings can be translated into clinical care or practice. Identify both dated information that needs to be released and information that is confirmed or new.

Word limit: 250 words

Do not cite references in the abstract. Limit the use of abbreviations and acronyms.

Key words: Key words are inserted into a designated box during the submission process. Provide up to ten key words, separated by semicolons, that describe the contents of the manuscript like those that appear in Cumulative Index to Nursing & Allied Health Literature (CINAHL) or The National Library of Medicine's Medical Subject Headings (MeSH). The key words are used in indexing your manuscript when it is published.

Title page*:* The title page will be submitted as a separate file when you are instructed to attach files to your submission. Compose your title page using your word processor, then attach this file when you reach the “attach files” step in the submission process. The title page should be formatted according to the example at AMA STYLE (10th ed.) STANDARDIZATION under “Author Resources” on our website. Include on the title page (a) complete manuscript title; (b) all authors’ full names, highest academic degrees, and affiliations; (c) corresponding author's name, affiliation(s), address, and e-mail address; and (d) any acknowledgements, credits or disclaimers. Include acknowledgement of all sources of funding.

The title page must also include disclosure of funding received for this work from

any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).

Manuscript: The manuscript will be submitted as a separate file when you are instructed to attach files to your submission. Compose your manuscript using your word processor, then attach this file when you reach the "attach files" step in the submission process.

Please note the following guidelines for preparing your manuscript:

- Prepare the manuscript double spaced in Microsoft Word. Leave a one-inch margin on all sides. Do not right justify.
- Type all headings on a separate line.
- Number all manuscript pages consecutively in the upper right-hand corner (text and references, followed by illustrations on separate pages).
- All legends for Tables and Figures are to be included with the manuscript; include these at the end of manuscript after the list of references. Tables and Figures are attached as separate files when you reach "attach files" in the submission process. Prepare tables and figures in a format ready for reproduction. Further instructions for preparing figures are given below.
- Manuscript length (excluding all references, tables, figures) should be no more than 20 pages (standard 8.5 x 11 inch page size).
- Use the *American Medical Association Manual of Style*, 10th edition, copyright 2007, for citations and references. See examples for citations and references below.
- No identifying information (authors' names) should be included on the manuscript.

Abbreviations: Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.

References: The reference list is not to exceed 50 entries. Authors are responsible for the accuracy of the references. Key the references (double-spaced) at the end of the manuscript. Cite the references in text in the order of appearance. Cite unpublished data—such as papers submitted but not yet accepted for publication and personal communications, including e-mail communications—in parentheses in the text.
The citations and reference list is to be styled according to the *American Medical Association Manual of Style*, 10th edition, copyright 2007, AMA.

Figures: Figures will be submitted as a separate file when you are instructed to attach files to your submission. Electronic art should be created/scanned and saved and submitted as either a TIF (tagged image file format), an EPS (encapsulated postscript) file, or a PPT (Power Point) file. Figures submitted as Word documents (suffix=.doc) will be rejected. DO NOT USE COLOR, SHADING, SCREENS OR FINE LINES. Line art must have a resolution of at least 1200 dpi (dots per inch), and scanned images must have a resolution of at least 300 dpi. If fonts are used in the artwork, they must be converted to paths or outlines or they must be embedded in the files. Please note that artwork generated from office suite programs such Corel Draw and MS Word and artwork downloaded from the Internet (JPEG or GIFF files) cannot be used. Cite figures consecutively on the site, and number them in the order in which they are discussed.

Figure legends: Include legends for all figures. They should be brief and specific, and they should appear on a separate manuscript page after the references.

Tables

Tables will be submitted as a separate file when you are instructed to attach files to your submission. Tables must be formatted according to the example at AMA STYLE (10th ed.) STANDARDIZATION under "Author Resources" on our website. Create tables using the table creating and editing feature of your word processing software. Do not use Excel or comparable spreadsheet programs. Group all tables in a separate file. Cite tables consecutively in the text, and number them in that order. Each table should appear on a separate page and should include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used). Do not embed tables within the body of the manuscript. They should be self-explanatory and should supplement, rather than duplicate, the material in the text.

On-line Manuscript Submission. All manuscripts must be submitted on-line through the CN Editorial Manager Web site at: https://www.editorialmanager.com/cn

After Acceptance

Page proofs and corrections: Corresponding authors will receive electronic page proofs to check the copyedited and typeset article before publication. Portable document format (PDF) files of the typeset pages and support documents (e.g., reprint order form) will be sent to the corresponding author by e-mail. Complete instructions will be provided with the e-mail for downloading and printing the files and for faxing the corrected page proofs to the publisher. It is the author's responsibility to ensure that there are no errors in the proofs. Changes that have been made to conform to journal style will stand if they do not alter the authors' meaning. Only the most critical changes to the accuracy of the content will be made. Changes that are stylistic or are a reworking of previously accepted material will be disallowed. The publisher reserves the right to deny any changes that do not affect the accuracy of the content.

APPENDIX 3

MAJOR RESEARCH PROJECT PROPOSAL

MAJOR RESEARCH PROJECT PROPOSAL

PROJECT TITLE

INVESTIGATING THE RELATIONSHIP BETWEEN EVERYDAY PHYSICAL ACTIVITY WITH SLEEP, FATIGUE AND MOOD IN PATIENTS WITH BREAST CANCER

Research Supervisors: Dr Leanne Fleming / Professor Colin Espie

Trainee: Trudi Dickson

Matriculation Number: 0905128

Word Count: 3,482 words (including references)

Date of Submission: 19 July 2011

ABSTRACT

Background: Obesity and a sedentary lifestyle are highly prevalent in breast cancer survivors. A growing number of publications show significant associations between low levels of physical activity, obesity and increased mortality. Sleep problems, fatigue, mood disturbance and weight gain are common side-effects of a cancer diagnosis and adjuvant treatment. While many studies include measures of fatigue and mood, few studies have examined the direct relationship of physical activity with level of sleep disturbance.

Aims: The present study aims to examine the relationship between physical activity and sleep, as well as variables of fatigue and mood following a breast cancer diagnosis.

Methods: A cross-sectional correlational design will be used. Twenty-six breast cancer patients will be recruited from hospital sites within NHS Greater Glasgow and Clyde and asked to complete questionnaires assessing physical activity, sleep quality, fatigue and mood. Actigraphy will be used as an objective measure of physical movement in a subsample of patients.

Applications: Findings will highlight the importance of enquiring about physical activity levels following a breast cancer diagnosis and educating patients about the health benefits that participation may provide both during and after active treatment.

Introduction

Breast cancer is the most commonly occurring cancer among women in the United Kingdom. More than 40,000 new cases are reported each year, and breast cancer accounts for 30% of the cancer burden in women (excluding non-melanoma skin cancer). Surviving cancer usually means enduring sequential combinations of treatment modalities (surgery, radiotherapy, chemotherapy and hormone therapy), which can result in significant reductions in quality of life.[1] Common side effects of breast cancer treatment include fatigue, which can result in substantial physical, psychosocial and socioeconomic consequences.[2] During and after adjuvant chemotherapy the prevalence of fatigue is high and fluctuating, with a frequency of 60% to 90%.[3] Persistent sleep disturbance is also associated with fatigue and depression,[4] with estimates of 38% among breast cancer patients[5], compared to 20% in the general population[6].

In the past, cancer patients were advised to rest and avoid physical effort, however, it is now well established that excessive rest and lack of physical activity can result in severe physical deconditioning and reduced functional capacity. Moreover, recent systematic reviews and meta-analyses report clear benefits of physical activity for cardiovascular fitness among breast cancer survivors, with modest outcomes for reducing fatigue, improving mood and quality of life.[7,8] The results are mixed, however, with a recent Cochrane review[9] examining the effects of exercise on breast cancer

patients finding no improvements in quality of life, whereas, an earlier review concluding that exercise is effective for improving quality of life.[10]

Despite these and other well documented benefits of physical activity, a large proportion of breast cancer survivors do not perform regular physical activity.[11] Similarly, many breast cancer patients decrease their physical activity level after diagnosis, highlighting the need for intervention. These decreases tend to be associated with the type of adjuvant treatment they receive, with the greatest decreases in physical activity observed among women who are treated with radiation and chemotherapy (50% decrease), compared to women who undergo surgery only (24% decrease). Other reasons for reductions in activity levels include that women may become fearful of overexertion and are uncertain of what they can do while receiving treatment. This often means that most physical activity ceases, which further contributes to the debilitation of the person and compounds the fatigue attributable to adjuvant therapy. Furthermore, physical activity tends to be largely neglected within cancer care and is not an inherent part of rehabilitation programmes.[12] This is a stark contrast to cardiac settings where exercise is considered an essential component of cardiac rehabilitation.

While many studies include measures of fatigue and mood, relatively few studies have examined the direct relationship of physical activity levels with

sleep quality. One study that was identified, examined the relationship between the level of physical activity and sleep problems in a sample of cancer survivors.[13] The results suggest that poorer sleep quality was found among breast cancer survivors (65.7%) compared to prostate cancer survivors (43%). The results also show higher levels of fatigue in those participants who reported no physical activity (M=31), compared to those who reported high levels of physical activity (M=42).

The aim of the current study is to explore the relationship between levels of physical activity and sleep, as well as variables of fatigue and mood. A secondary aim will be to contribute to the literature on exercise in breast cancer patients by including an additional measure of physical activity. The "stages of behaviour change" model will be used as a theoretical framework to help understand the stages people go through as they attempt to change behaviour following a cancer diagnosis.[14] The proposed study is an extension of a prospective quantitative study (NHS REC Ref no. 10/S0709/68) being conducted by researchers at the University of Glasgow Sleep Centre (UGSC). Funded by Breast Cancer Campaign, the core study aims to identify prognostic factors for the development of persistent insomnia post cancer treatment. It does not however include physical activity as a mediating factor, which is important, as we know that exercise can lead to improvements in patient well-being and quality of life. A practical and effective focus upon physical activity may be something that would significantly improve patients' ability to cope with the stress of cancer diagnosis and treatment and also result in better post-treatment well-being.

Aims and Hypotheses

Primary Aims

1. To examine the relationship between physical activity levels and sleep, as well as variables of fatigue and mood following a breast cancer diagnosis.
2. To contribute to the findings of the core study by including physical activity as an additional measure.

Secondary Aims

1. To evaluate the test-retest reliability of the International Physical Activity Questionnaire (IPAQ).
2. To validate the use of the IPAQ in a subsample of patients by comparing self-reported physical activity levels (IPAQ) with objective levels of physical movement (actigraphy).

Hypotheses

(i) Lower levels of physical activity, as measured by the IPAQ will be related to poorer sleep quality, as measured by the Insomnia Severity Index (ISI).

(ii) Lower levels of physical activity will be related to higher levels of fatigue, as measured by the Fatigue Severity Scale (FSS).

(iii) Lower levels of physical activity will be related to higher levels of anxiety and depression, as measured by the Hospital Anxiety and Depression Scale (HADS).

(iv) Time 1 IPAQ scores will correlate with T2 and T3 IPAQ scores.

(v) Time 1 IPAQ scores will add to the prediction of Time 2 IPAQ and actigraphy scores.

(vi) Episodes of vigorous physical activity will correlate with higher levels of activity as measured by actigraphy.

Plan of Investigation

Participants

Participants will have a diagnosis of breast cancer and be receiving anti-cancer treatment (chemotherapy, radiotherapy or hormone-therapy). For inclusion in the study, participants will be female and over 18 years old, have a current diagnosis of breast cancer and commenced anti-cancer treatment. Participants will be excluded if they have an estimated prognosis fewer than six months, confusional problems or drug misuse, evidence of another sleep disorder or untreated psychiatric disorder.

Recruitment Procedures

Participants will be recruited from the Beatson West of Scotland Cancer Centre (BWoSCC) and NHS GG&C satellite sites. All newly diagnosed breast cancer patients will be given an information leaflet about the study by their clinical care team. Patients will then be approached by a clinical research nurse (employed by the core project), who will provide additional study information and answer questions. Leaflets will have an opt-in section and telephone number so that those willing to participate can identify themselves. The trainee will obtain informed consent and conduct participant interviews at a location most convenient to the patient. Due to the sensitivity around recruitment at the acute end of cancer care, breast care nurses will provide support to all participants at each site.

Measures

Data collection comprises assessments of physical activity, sleep quality and psychosocial functioning, obtained at a single time-point six to nine months post treatment. Actigraphy will be used to provide validation data and objective levels of physical movement. Demographic (age, marital status and occupation) and clinical information will also be obtained from all participants.

(i) Glasgow Sleep Centre Interview

A full sleep history will be taken using the Glasgow Sleep Centre Interview. The GSCI is a semi-structured measure which gathers qualitative information

about sleep quality and sleep behaviour and takes approximately 20 minutes to complete.

(ii) International Physical Activity Questionnaire

The International Physical Activity Questionnaire (IPAQ) short form will be used as the primary outcome measure in the study.[15] The IPAQ short form is a 4-item self-report instrument that measures physical activity over the past seven days. The short version of the IPAQ was selected for use in this study as it is designed primarily for monitoring purposes, whereas the long IPAQ form is a more detailed assessment recommended for use in intervention studies. To reduce any additional burden placed on participants, the scale will be adapted for use in the cross-sectional part of the study by asking participants to indicate the number of hours and minutes for each physical activity in a 'typical day', rather than the past seven days. The 7-day recall version of the IPAQ will be used in a subsample of participants for the validation study. The IPAQ short form assesses three specific types of activity: (a) walking (b) moderate-intensity activities and (c) vigorous-intensity activities and only counts sessions lasting 10 minutes or longer. This reflects current scientific evidence that the physiological changes associated with health benefits from physical activity require a minimum duration. An additional question measures time spent sitting which can be used as an indication of sedentary time. The items on the short IPAQ form are structured to provide separate scores on walking, moderate-intensity and vigorous-intensity activity. Computation of the total score requires

summation of the duration (in minutes) and/or frequency (days) of walking, moderate-intensity and vigorous-intensity activities. Algorithms are used to classify three levels of physical activity into low, moderate or high categories. The IPAQ instruments have been tested extensively in countries around the world and have acceptable measurement properties that are comparable to other established self-report questionnaires.

(iii) Actigraphy and Sleep Diary

Actigraphs will be used to provide an objective measure of physical movement. The actigraph is a nonintrusive device that records movement for 1-minute epochs through a wrist-watch microprocessor link.[16] Activity/rest variables include mesor to represent overall mean activity levels, amplitude to represent the ability to meet both higher and lower activity/rest requirements, and night time awakenings as indicators of restlessness and interruptions during sleep. Resourcing 82 wrist actigraphs at any one time is outwith the scope of the current study, however, providing 10 actigraphs is feasible. A subsample of approximately 10 participants will be invited to wear a wrist actigraph on their non-dominant wrist for a period of seven days. Participants will also be asked to complete a sleep diary over the same 7-day period as a measure of subjective sleep pattern.

(iv) Insomnia Severity Index

The Insomnia Severity Index (ISI)[17] will be used to examine the proportion of participants that reach threshold for a significant sleep disturbance. The ISI

is a brief self-report instrument and is considered to be a core assessment tool for use in insomnia research studies.

(v) Fatigue Severity Scale

The Fatigue Severity Scale (FSS)[18] will be used to evaluate the impact of fatigue. The FSS was originally developed as a tool to assess fatigue in patients with multiple sclerosis. The questionnaire has nine statements inquiring about the patient's sleep habits over the preceding week. Participants will be asked to rate their level of agreement (toward seven) or disagreement (toward zero) with the nine statements. A score of 36 and above (out of a maximum of 63) indicates the presence of significant fatigue.

(vi) Hospital Anxiety and Depression Scale

Mood will be measured using the Hospital Anxiety and Depression Scale (HADS).[19] The HADS is a brief 14-item self-report measure, which is widely used to assess anxiety and depression in patients with medical conditions. The scale is quick and easy to administer and consists of two subscales of seven items designed to measure levels of anxiety and depression, each of which has cut-off points to identify caseness.

The questionnaires have satisfactory internal consistency (Cronbach's α of ≥ .70) and in total, completion time for these measures will be around 20 minutes.

Design

A cross-sectional correlational design will be used to examine the relationship between physical activity, sleep, fatigue and mood at a single time point, six to nine months post-treatment. To test the reliability of the IPAQ a subsample of participants will be asked to complete the IPAQ at Time 1 (baseline) and again at Time 2 (1-week later) and Time 3 (3-weeks later). To assess concurrent validity of the IPAQ, objective data from actigraphy will be compared with IPAQ scores at Time 2.

Research Procedures

Participant screening interviews and assessments will be carried out by the trainee. Due to the anticipated poor health of this group all participants will have the opportunity to complete assessments online from their own homes. This will be done using a secure online data collection system which will be set up and maintained by the UGSC. Face to face assessments will also be available should participants prefer this.

Justification of Sample Size

There is a lack of research directly measuring the relationship between physical activity and sleep disturbance in women with breast cancer. Studies of related constructs were therefore used to estimate sample size needed to obtain power of 0.8 at an alpha of 0.05, prior to commencing this study.

Humpel and Iverson[20] compared 32 breast cancer patients with 59 prostate cancer patients and found statistically significant differences on measures of physical activity and sleep quality. A greater proportion of breast cancer (36.7%) than prostate cancer patients (15.5%) reported poor sleep latency and sleep disturbance (48.4% vs. 17.2%). Additionally, the mean minutes of moderate physical activity were lower among those reporting poor sleep quality.

Using data from this study, effect sizes were calculated by dividing the *F*-ratio by the square root of the residual degrees of freedom.[21] The effect size of the difference in mean scores on measures of physical activity and sleep quality were medium (r = 0.30). For the present study, GPower analysis estimates that 82 participants will be required to detect an effect of this magnitude (r = 0.30, with 80% power and $\alpha = p>0.05$, two-tailed). For a large effect size (r = 0.50) the study will require 26 participants. Given that it is intended to use individuals of the same gender and similar cancer site (women with breast cancer), it is expected that a sample size of 26 will be sufficient to detect associations if they exist.

Settings and Equipment

The study will take place at the BWoSCC, the UGSC and NHS GG&C satellite sites. An online data collection system will be used as well as the measures outlined above.

Data Analysis

If the assumptions for parametric tests are met, primary analyses will include Pearson's correlations to assess the relationship between physical activity with variables of sleep, fatigue and mood. Partial correlations will also be carried out between physical activity and sleep while controlling for the effects of fatigue and mood. Secondary analyses will include test-retest correlations over a 3-week interval to examine the reliability of T1 and T2 measures. If participant numbers allow, multiple regression analyses will be conducted to examine predictors of physical activity (age, type of cancer treatment, sleep quality, fatigue and mood). Correlations between IPAQ scores and actigraphy data will be conducted to assess concurrent validity.

Health and Safety Issues

Researcher Safety Issues

The project will be based within a safe environment with Dr Leanne Fleming (University Co-Supervisor) and Professor Colin Espie (University Supervisor) providing supervisory support.

Participant Safety Issues

Participant screening interviews and assessments will be conducted under the supervision of the university supervisors. Should participants express any distress during interviews, the researcher will ensure that a member of the clinical team is available for consultation.

Ethical Issues

Informed consent will be obtained from all participants by the trainee after ensuring full understanding of the study. Should any participant express distress during interviews, the researcher will ensure that a member of the clinical team is available for consultation. Ethical approval and local research and development permissions will be obtained from NHS GG&C.

Financial Issues

Equipment costs, travel etc.

The online data collection system and supply of test materials will be undertaken by the UGSC project team at no additional cost.

Timetable

Time in months	Principal tasks
0-3	Submit MRP Outline (13.12.10); submit MRP Draft Proposal (31.01.11)
4-6	Submit MRP Proposal (16.05.11)
7-10	Submit Systematic Review Outline (26.08.11); apply for ethics and R&D approval; order materials
10-14	Commence participant recruitment; prepare data sheets and files
15-19	Data entry; preliminary analysis
18-19	Complete data analysis; final write-up; prepare papers for publication

Practical Applications

It is anticipated that the study will provide preliminary evidence of a relationship between low levels of physical activity with poor sleep quality, greater fatigue and mood disturbance after a breast cancer diagnosis. This is important, as being physically active post-diagnosis could help improve quality of life and prevent the development of chronic insomnia and other cancer-related symptoms, such as depression and fatigue in an already vulnerable population. The findings from this pilot study could also be used to determine the feasibility of conducting a large-scale national study.

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