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## **Post-operative exercises after breast cancer surgery: results of a RCT evaluating standard care versus standard care plus additional yoga exercise**

Helena Harder<sup>1</sup>, Carolyn Langridge<sup>1</sup>, Ivonne Solis-Trapala<sup>1</sup>, Charles Zammit<sup>2</sup>, Mokshini Grant<sup>3</sup>, Diane Rees<sup>4</sup>, Lynn Burkinshaw<sup>5</sup>, Valerie Jenkins<sup>1</sup>

1. Sussex Health Outcomes Research & Education in Cancer (SHORE-C), Brighton and Sussex Medical School, University of Sussex, England, UK
2. Park Centre for Breast Care, Brighton & Sussex University Hospitals NHS Trust, Brighton, England, UK
3. Triratna Buddhist Community, Brighton, England, UK
4. Nuffield Health Ltd., Brighton, England, UK
5. Brighton & Sussex University Hospitals NHS Trust, Brighton, England, UK

### **Correspondence**

Dr Helena Harder

Email: [H.Harder@sussex.ac.uk](mailto:H.Harder@sussex.ac.uk)

Telephone: +44 1273 873029

Fax: +44 1273 873022

## **Abstract**

**Introduction:** There is a lack of standardisation in the guidelines for post-operative exercises following breast cancer surgery. Adherence to exercise programmes is low, and complementary therapies such as yoga often appeal to patients and may encourage practise. A step-by-step guide to yoga DVD was evaluated in addition to the standard care exercises (SC) compared to SC alone.

**Methods:** Women with early-stage breast cancer were randomised to SC plus or minus a yoga DVD for 10-weeks. Patient-reported outcomes were collected at baseline, 10 weeks and 6 months. The primary study-endpoint was the Trial Outcome Index (TOI) of the Functional Assessment of Cancer Treatment-Breast; a recognised quality of life (QoL) tool with an arm morbidity subscale (FACT-B+4).

**Results:** 92/103 (89%) women were randomised to the study. The SC group reported practising post-operative exercises more often than the yoga DVD group. There was a 69% improvement from baseline in FACT-B+4 TOI, which included an arm subscale, at 10 weeks and 6 months in the SC group. This was 62% and 81% respectively for the yoga DVD group. Numbness in the affected arm was greater in the SC group (OR= 2.5, 95% CI: 1.1, 5.6) and in patients receiving chemotherapy (OR=2.17, 95% CI: 1, 4.6). Despite no group differences, 74% of women would definitely recommend following the yoga DVD after surgery.

**Conclusions:** Practising post-operative exercises does improve arm and shoulder morbidity following breast cancer surgery. The addition of a self-practise general yoga programme was well received and appeared to improve QoL at 6 months.

**Keywords:** Breast cancer, Yoga, Patient reported outcomes, Arm morbidity, Randomised controlled trial

## **Introduction**

Each year, more than 48,000 women in the UK are diagnosed with breast cancer and the majority (80%) undergo surgical treatment [1], which also involves examination of lymph glands under the arm (axilla). Some women require extensive treatment to the glands in the axilla if they contain cancer cells; this can take the form of further surgery to remove the glands or radiotherapy to the axilla. These treatments often damage lymphatic drainage from the arm and women may subsequently develop shoulder and arm dysfunction including lymphoedema. As well as discomfort, there can be restricted movement, pain, numbness and other sensory problems [2-6]. These side effects interfere with daily activities, impair quality of life (QoL), can be distressing, and are often irreversible [7,8]. Symptoms are costly to the health services in terms of rehabilitative treatments and lymphoedema clinics.

Management of the axilla and post-operative rehabilitation (e.g. upper extremity exercises) are key components in current standard post-operative care. Unfortunately, one disadvantage of early discharge from hospital following breast surgery is that patients in the UK are less likely to be taught specific post-operative arm exercises by a physiotherapist. There is little consensus in the instructions for arm and shoulder mobilisation provided to women [9], and many are only given a leaflet or an information pack with instructions to follow at home (e.g. Breast Cancer Care) [10]. Also, there are few specific training programmes available, and prevention of arm and shoulder impairments depends on self-care and self-management.

Yoga as a stress reduction intervention or complementary treatment is increasingly popular among breast cancer patients and also offered at some cancer centres. Reviews and meta-analyses evaluating the effect of yoga in randomised controlled trials (RCT) in women with breast cancer conclude there is moderate to good evidence that yoga may be a useful practice during recovery from treatment [11-13]. Despite an emerging number of large RCTs measuring the effectiveness of yoga on fatigue [14, 15], sleep quality [16], QoL [17], and during radiotherapy [18], there is scope for more investigation into its physical benefits, in particular its role following breast cancer surgery.

Preliminary results of yoga interventions for arm and shoulder morbidity demonstrate improvements in physical function and symptom relief [19], in shoulder abduction and flexion [20], and decreased arm volume in women with breast cancer related lymphoedema [21].

However, these studies were observational and have small sample sizes (6-18 participants). Here we report the results of a RCT that examines the use of a specially developed self-practise yoga DVD on QoL and arm and shoulder morbidity in women who had breast cancer surgery.

## Methods

### Study Design

A RCT of the standard care post-operative exercises (SC) alone versus SC plus a 10-week self-practise general yoga programme (i.e. yoga DVD). Primary and secondary outcome measures were collected at baseline (after surgery), 10 weeks (at completion of the intervention) and at 6 months. The study received local ethical approval (REC: H10/1111/57) and written informed consent was provided by participants.

### Standard care

SC comprised of post-operative exercise materials distributed by the hospital prior to surgery. This usually is written instructions for arm and shoulder mobilisation or an exercise leaflet, poster or DVD (e.g. Breast Cancer Care publications [10]). Women allocated to SC were offered the yoga-DVD after the last follow-up assessment (i.e. at 6 months).

### The yoga DVD

The self-practise yoga DVD was developed with members of the Brighton Breast Cancer Support Group (BBCSG), breast surgeons, specialist nurses, physiotherapists and yoga practitioners [22]. The DVD incorporated 16 postures that were used in a 10-week course of general yoga with BBCSG members as part of a feasibility study. The DVD has 2 parts:-

**Disc 1** comprises an introduction from a specialist in breast cancer QoL explaining why women have surgery to the arm pit as well as the breast. A short introduction to yoga from a certified yoga teacher, plus a section with her demonstrating 16 poses in a graduated way from basic to advanced level practice (levels 1-3).

**Disc 2** features a one-hour yoga class (based on Iyengar Yoga© and restorative yoga) led by the yoga teacher with BBCSG members of different ages and physical abilities.

Participants were shown how to use the DVD and follow the poses (at level 1) by the yoga teacher prior to participation. They were asked to use the DVD at least once per week for 10 weeks at level 1 and were given yoga materials to use during the intervention period.

#### Participants and recruitment method

Women aged 18 to 80 years of age with early-stage breast cancer (stages I to III), scheduled for axillary surgery and fluent in English were eligible for the study. They were given study information by the clinical team during their pre-operative assessment appointment. Women who showed an interest in the study (by returning an expression of interest form) were contacted by the researchers to provide further information. A home-visit was arranged to obtain informed consent, demographics, level of previous yoga experience, and details of the hospital post-operative exercises [SC]. After this visit participants were randomised and informed about group-allocation.

#### Yoga Teachers and Physiotherapists

Two trained yoga teachers and 2 registered physiotherapists were involved in the study. Prior to the start of the study they met with the investigators to devise a protocol of yoga practice (based on the pilot study and contents of the DVD), and standard operating procedures for method of data collection and measurements by the physiotherapists. Regular research meetings (2-3 times a year) were held to assess practice.

#### Randomisation and blinding

Randomisation was conducted using a computer-generated program for producing variable sized, balanced permuted blocks. Women were stratified by age (<50, 50-69, 70+) and previous experience of yoga (yes, no) and randomised in a ratio of 1:1. Randomisation was undertaken by an independent researcher (IST). Participants were asked not to reveal their group allocation to the physiotherapists.

#### Outcome Measures

The primary study endpoint was the efficacy of the intervention to reduce self-reported arm and shoulder morbidity post-surgery and whether the effect was maintained over a period of 6 months. This was assessed using the Trial Outcome Index (TOI) score of the Functional Assessment of Cancer Therapy-Breast+4 (FACT-B+4) [23-25]. The FACT-B+4 is a 41-item questionnaire with four primary subscales: physical well-being (PWB, 7 items), social well-

being (SWB, 7 items), emotional well-being (EWB, 6 items), functional well-being (FWB, 7 items), along with breast cancer additional concerns plus the sum of four questions relating to upper limb swelling and function (arm-specific subscale) (14 items). Responses to each item use a 5-point scale ranging from 0 (not at all) to 4 (very much). High FACT-B+4 scores indicate high-level functioning or better QoL. The TOI is an efficient summary index of physical/functional outcomes, and a common endpoint used in clinical trials because it is responsive to change in physical and functional outcomes. The TOI score is the sum of the scores of the 28 items included in the PWB, FWB and breast cancer concerns subscales (range 0–112). A change of at least 5 points from baseline in TOI score (calculated for each individual participant) is considered to be a clinically relevant minimally important difference and indicative of arm or shoulder morbidity [26, 27].

Secondary endpoints were changes in patient reported outcome measures (PROMs) for global QoL (FACT-B+4 total score), and self-reported pain or disability in upper limb function, and objective changes in shoulder mobility, hand grip strength and arm circumference.

The Oxford Shoulder Score (OSS), a 12 item questionnaire was used to assess the degree of pain (4 items) and disability/impairment to activities of daily living (ADL) (8 items) caused by shoulder surgery [28]. Each item is scored 1 (no pain/no problem with ADL) to 5 (unbearable pain/impossible to do ADL). The maximum score is 60; higher scores represent greater disability.

The QuickDASH was used as a self-report questionnaire to address symptoms and physical function of the upper limb [29]. The questionnaire has 11 items with scores ranging from 1 (no difficulty) to 5 (unable). At least 10 items must be completed to calculate a total score, which is then transformed into a 0-100 scale. Higher scores on the QuickDASH represent greater limitations.

All PRO measures were completed at home and returned by pre-paid post. Home practise (use of the yoga DVD, and practise of the standard hospital exercises) was recorded in a diary which was returned at the end of weeks 5 and 10. Those allocated the yoga DVD rated its usefulness, user-friendliness and satisfaction at the end of the intervention. At 6 months, all participants completed a follow up questionnaire that assessed current levels of physical activity, further treatments since surgery, joint problems and degree of shoulder and/or arm pain.

Post-operative shoulder mobility measurements (extension, flexion and abduction) were conducted by the physiotherapists using a goniometer. Hand grip strength was measured using a hand-held dynamometer; each measurement was taken 3 times and the average was used for analysis. Evidence of lymphoedema was gauged by arm circumference measurements at proximal wrist, 12cm from wrist and 12cm from elbow, and from these measures arm volumes were calculated. The total volume of the arm was determined by the sum of the segment volumes using the following formula for segmental volume (V):  $V = \sum 3C^2/\pi = 3(C_1^2 + C_2^2 + C_3^2)/\pi$ , where C is the measured circumference [30]. All physiotherapy measurements were performed on the operated and non-operated sides for comparison. Each physiotherapist measured the same patient at both time-points. In addition, levels of pain or discomfort with usual activities were assessed by asking participants to rate their pain or discomfort intensity on a 10-point scale (with '0' representing no pain and '10' worst possible pain). Relevant data concerning medical and surgical history and levels of exercise (formal/informal) were also collected by the physiotherapists during the home visit.

#### Data Analyses

The aim of the statistical analysis was to assess changes in TOI, FACT B+4, QuickDASH and Oxford shoulder scores at 10 weeks and 6 months, contrasting between the yoga DVD and SC groups. An estimated sample size of 47 participants per arm provided 80% power with significance level set at 5% to detect a clinically significant difference of 5 units in mean change scores of the FACT B+4 TOI between the yoga DVD and SC groups [27].

Changes in scores were assessed using random effects regression models which extend standard regression analyses to account for the correlation amongst responses for each individual to yield valid inferences on the size of the regression coefficients.

Changes in the single items of the FACT B+4 arm subscale were assessed using logistic regression models for the probability of reporting symptoms (i.e. the proportion of participants who reported 'somewhat', 'quite a bit' and 'very much' for the items) using a generalised estimating equations approach to account for the correlation amongst repeated observations. Standard linear regression models for the differences at 10 weeks in the secondary outcomes were used. In all the analysis, difference in response by participants characteristics were explored by adding age, adjuvant chemo (yes/no), previous yoga experience (yes/no), mastectomy (yes/no) and axillary surgery (axillary lymph node dissection or axillary clearance) as explanatory variables in the regression models. All analyses were conducted using the statistical software R [31].



## Results

### Accrual and participant characteristics

Figure 1 displays recruitment, randomisation, and participant flow by group. 145 eligible women were approached about the study between April 2011 and May 2013. A total of 103 women expressed interest in the study; 92 (89%) were randomised.

Table 1 shows the characteristics of the study sample. Groups were balanced on demographic and disease-related characteristics, and there were no differences between groups on type of axillary surgery, yoga experience, and levels of formal and informal exercise.

### Protocol adherence and weekly practise

Seventy-eight (85%) participants completed the study (39 in each group). Most study withdrawals (12/14) were during the intervention period, predominantly because of illness (9/14, including 5 who started chemotherapy). There were no differences between women who completed the study and those with baseline data only.

The practise diary was returned by 35 participants in the yoga DVD group and 38 participants in the SC group. The proportion of women reporting to practise the standard post-operative hospital based exercises  $\geq 5$  times per week at week 1-5 was 75% in the SC group and 50% in the yoga DVD group ( $P=0.055$ ). During week 6-10 this was 68% in the SC group and 32% in the yoga DVD group ( $P=0.011$ ). However, 59% of yoga participants also reported following the DVD at least 3 times per week in the first half of the study; during weeks 6-10 this was 42%. No adverse effects (exercise/yoga related) were reported.

### Primary outcome TOI

Table 2 provides an exploratory analysis of score changes. In the yoga DVD group, 62% improved from baseline (post-surgery) to 10 weeks and 81% from baseline to 6 months, compared with 69% in the SC group at both time-points. The mixed-effects model showed no significant between-group differences for mean change from baseline TOI score at 10 weeks or 6 months (see also Figure 2a). The estimated differences in mean changes between SC plus yoga DVD and SC alone were -0.57 (95% confidence interval (CI): -7.2, 6) and 1.72 (95% CI: -8.5, 5.1) at 10 weeks and 6 months respectively.

Overall, there were clinically significant improvement in symptoms, the estimated mean changes in TOI score were 11.3 (95% CI: 7.4, 15.1) and 14.9 (95% CI: 10.9, 18.9) at 10 weeks and 6 months respectively,  $P<0.001$ . Significant effects over the 2 time-points were observed for

women who had adjuvant chemotherapy. The estimated mean TOI score for these patients ( $b = -8.9$  95% CI: -13.9, -3.9;  $P < 0.001$ ) was lower than the mean score for patients who did not have chemotherapy.

#### Intervention effects on secondary outcome measures

There were no significant group differences for the physiotherapist assessments (shoulder extension, flexion and abduction, hand grip strength of the operated and non-operated side, ratio of arm volume). Self-reported pain/discomfort intensity scores decreased for both groups at 10 weeks however, at 6 months the mean pain score was higher in the SC group (2.8 v 1.5;  $P = 0.015$ ).

No significant group differences at any time-point were found for FACT-B+4, QuickDASH and OSS (Table 3). Compared to baseline, the average total scores on the FACT-B+4 increased significantly and decreased on the QuickDASH and OSS in both groups, indicating that patients reported improved functioning. Total FACT-B+4 scores were significantly lower in patients who had adjuvant chemotherapy compared with those who did not receive chemotherapy,  $b = -11.3$  (95% CI: -17.5, -5.1;  $P < 0.001$ ).

Arm function improved significantly over time for both groups (Figure 2b). There were no significant effects of mastectomy or previous yoga experience on the arm function items. A significant effect of age showed that older patients were less likely to report stiffness and pain when moving the operated arm compared to younger patients, the odds ratio of reporting symptoms comparing 2 patients with a difference of 1 year in age was OR = 0.96 (95% CI: 0.93, 0.99),  $P = 0.015$ .

Patients in the SC alone group (OR = 2.5, 95% CI: 1.1, 5.6;  $P = 0.033$ ), and patients receiving chemotherapy reported more symptoms (OR = 2.17, 95% CI: 1, 4.6;  $P = 0.045$ ), of numbness in the operated arm. Patients who had axillary lymph node dissection or axillary clearance were more likely to report greater limitations (i.e. higher scores on QuickDASH,  $b = 7$ , 95% CI: 0.4, 13.7;  $P = 0.039$ ), and stiffness in the operated arm (OR = 4.4, 95% CI: 2, 9.8;  $P < 0.001$ ).

#### Yoga programme evaluation

Most women in the yoga DVD group that completed the study (78%; 25/32) followed the yoga class on the DVD and found it useful during their post-operative recovery. The majority (81%) watched the introduction and 69% rated it very useful, including the explanation about breast cancer and lymph glands. Some women commented on the physical and emotional benefits of the programme and cited the gentle exercises and relaxation as positive elements of the study.

One woman said: *'It certainly taught me how to relax and breathe whilst doing exercises'*. Negative experiences were related to technical problems with the DVD, the demonstration of the postures (i.e. having to select the levels), and preference for group-based yoga. One participant reported: *'It would be much more useful to undertake the yoga in a class with other women, using the DVD was a bit tiresome'*. However, 74% (23/31) stated that they would definitely recommend the DVD to other women with breast cancer.

## **Discussion**

This study is the first RCT in which yoga was used as an intervention for arm and shoulder morbidity in women with breast cancer. Previous observational studies in women following breast cancer surgery with or without lymphoedema demonstrated some preliminary effects in favour of the yoga intervention, but studies were not representative due to small sample sizes [19-21,32,33].

The results from our RCT showed no significant differences in favour of the yoga DVD group in arm morbidity compared with standard post-operative exercises. Regular practice of either standard care alone or in combination with yoga improved arm and shoulder function and QoL significantly at 10 weeks post-surgery, and this effect was maintained at 6 months for both study groups. As reported in previous studies [34-37], improvement was greater in women who did not have axillary clearance or chemotherapy. In addition, older women (>65yrs) were less likely to complain about stiffness and pain in the operated arm and also reported higher QoL than younger women (<50yrs). The finding of better QoL in older women was noted in the ALMANAC study; a prospective RCT of sentinel node biopsy (SNB) compared with standard axillary treatment. Researchers noted for the first 6 months post-surgery younger patients reported less favourable QOL scores, and suggested that younger women may have different expectations from their surgery and be more sensitive to the discomfort resulting from axillary surgery [27].

The current study is one of the few to include an objective assessment of arm and shoulder function by physiotherapists, as most RCTs use only self-reported outcome measures [11]. There were no objective differences noted between groups. Being assessed twice by physiotherapists however, may have influenced women in the SC group to perform their hospital based exercises regularly and more often than women in the yoga DVD group, as they had no additional exercise to follow. Importantly the results from the objective assessments showed that there were no

adverse effects during study participation, suggesting that it is safe for women with breast cancer to perform gentle yoga postures post-operatively in addition to standard care.

Physical function and QoL of women in both study groups improved significantly over time, but our study failed to demonstrate that this was related to self-guided additional yoga practise. A possible explanation for an improvement in physical functioning is that many of the women were keen exercisers prior to surgery which may reflect in exercise compliance. In addition, women were not barred from accessing yoga, Pilates or other exercise classes during their time in the study, which may have positively influenced performance in both groups.

Our RCT had several limitations. Unfortunately the study was underpowered with 92 women randomised and data available only for 82 women at all time-points. The lack of a pre-surgery baseline assessment of arm and shoulder function was restrictive; potential group differences in function before randomisation may have been overlooked because of this. Also, the post-operative hospital based exercises were less time consuming than familiarising oneself to the poses in the yoga DVD, which may have been an incentive for women in the SC group. It is also possible that the intervention group performed more exercise (both standard care and yoga) than the SC group. A recently published review of the effectiveness of postoperative physical therapy for arm and shoulder morbidity after breast cancer showed that active exercise is found to be more effective compared to no physical therapy following breast cancer treatment or compared to information on the treatment of impairments of upper limb [38]. Differences in outcome may therefore be attributed to exercise frequency rather than specifically to the yoga component. In addition to this, many women were already active and motivated to exercise and therefore may not be representative of the general public. Finally, the design of the study did not allow us to measure the effect of yoga practise alone because it was combined with the routine post-operative exercises.

## **Conclusions**

Regular practise of both standard hospital exercises plus or minus general yoga appears to improve arm and shoulder function and general well-being in patients who had breast cancer surgery. The results of this study do suggest that gentle yoga exercises following breast cancer surgery are acceptable to women and can be safely used during the early post-operative recovery period, and it can therefore be considered as a potential therapeutic intervention for breast cancer patients.

An interesting angle for future research is to evaluate the use of behavioural change techniques such as prompts to encourage women to do their post-operative exercises or any other exercise-based intervention [39, 40]. This could take the form of either telephone calls from a physiotherapist or allied health care worker, or text alert on a mobile or smartphone.

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Figure 1. CONSORT flow diagram.

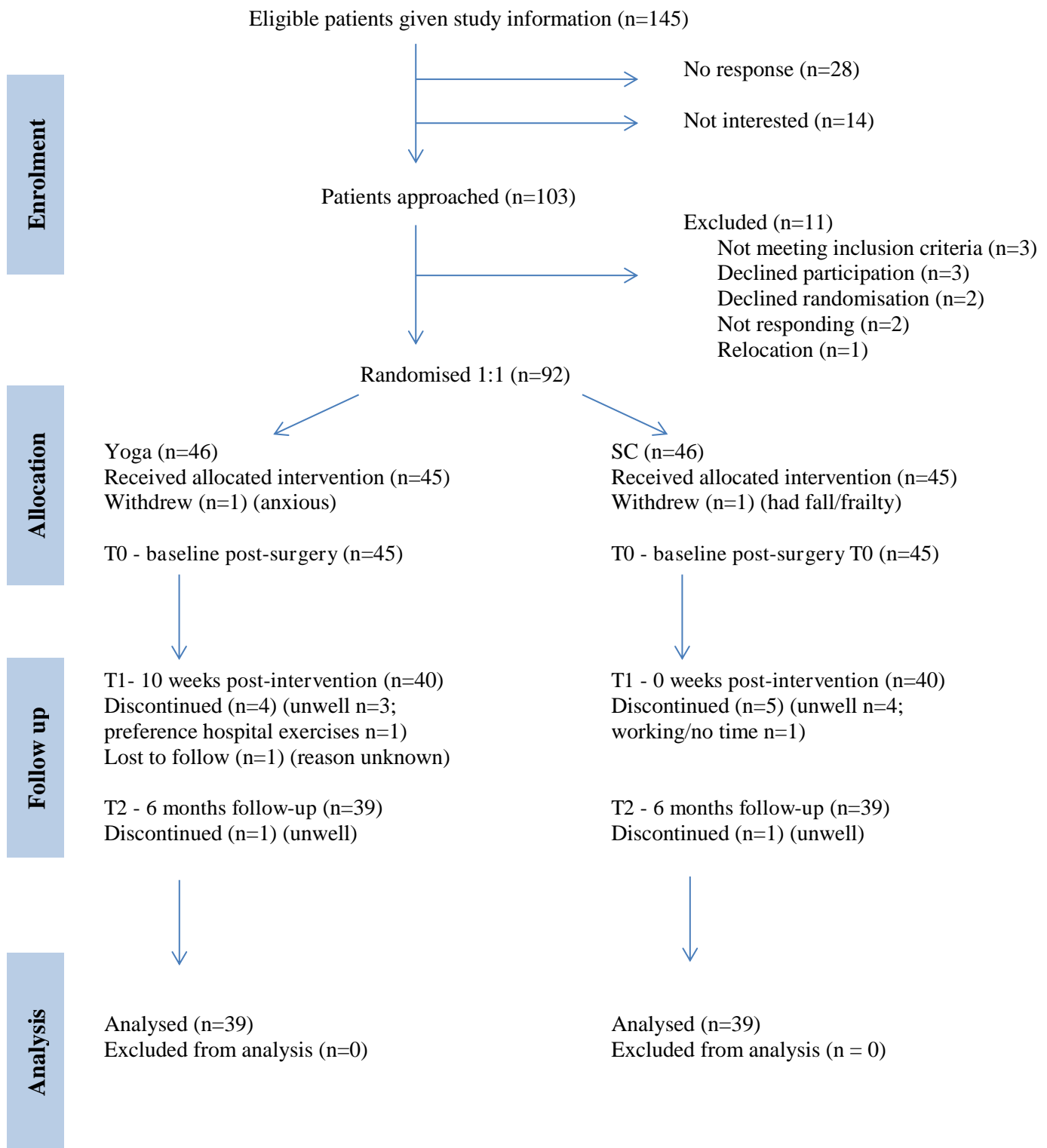
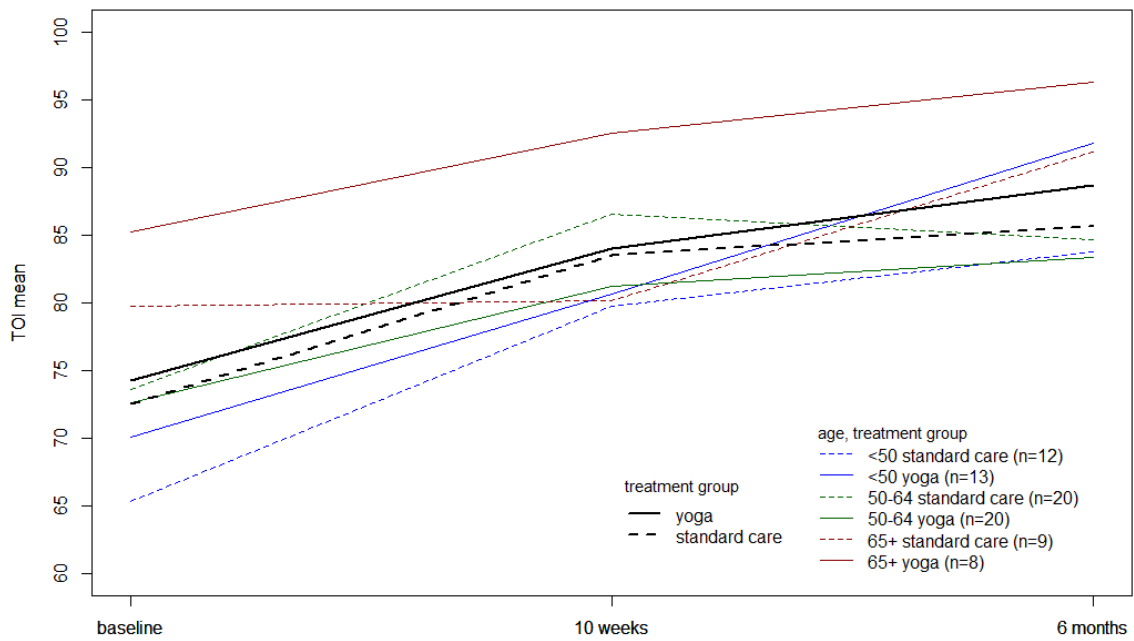
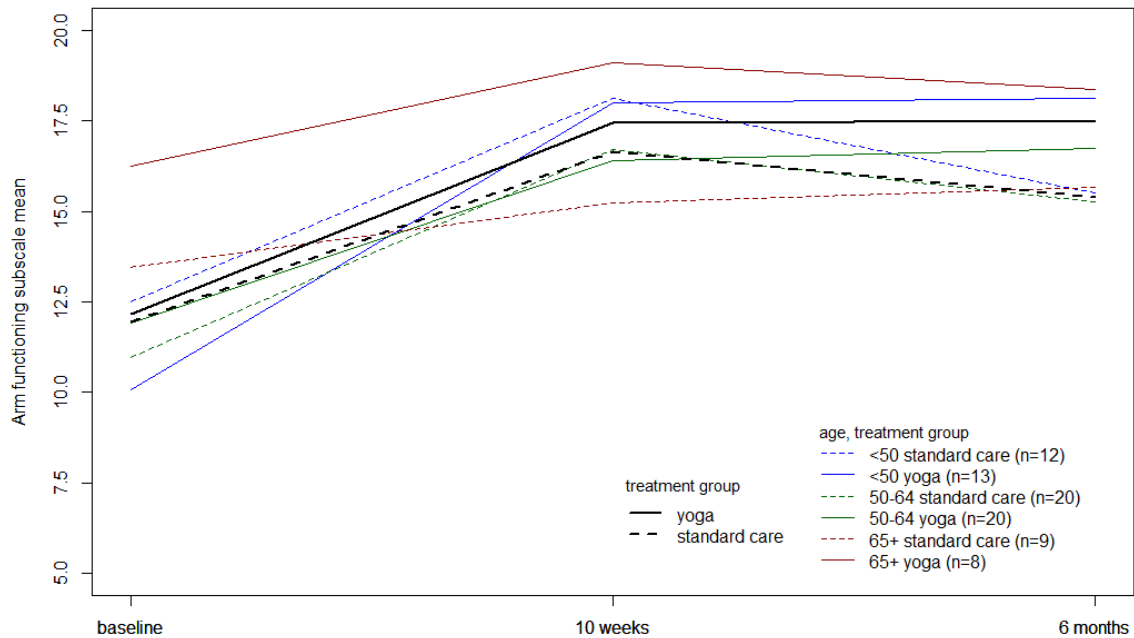


Figure 2. Mean changes in FACT-B+4 scores (2a TOI; 2b arm functioning)



2a. TOI by intervention and age group



2b. Arm functioning by intervention and age group

**Table 1. Demographic and clinical characteristics by group (n, %)**

	Yoga (n = 46)	Standard care (n = 46)
Age		
Mean (SD)	54.6 (10.9)	55.8 (11.6)
Range, years	33-77	31-77
Previous yoga experience <sup>a</sup>	25 (54.4)	27 (58.7)
Surgery		
Wide local excision	32 (69.6)	29 (63)
Mastectomy (no reconstruction)	11 (23.9)	15 (32.6)
Mastectomy (with reconstruction)	3 (6.5)	2 (4.4)
Axillary surgery		
Sentinel lymph node biopsy	36 (78.3)	35 (76.1)
Axillary lymph node clearance	10 (21.7)	11 (23.9)
Surgery on side of dominant hand		
Yes	23 (50)	25 (54.4)
No	20 (43.5)	19 (41.3)
Unknown	3 (6.5)	2 (4.4)
Received post-operative exercises	43 (93.5)	39 (84.8)
Medical history		
Arthritis	7 (15.2)	9 (19.6)
Trauma to shoulder/arm <sup>b</sup>	7 (15.2)	10 (21.7)
Joint replacements	0	2 (4.4)
No medical history	32 (69.6)	25 (54.3)
Adjuvant treatment <sup>c</sup>		
Chemotherapy	24 (54.5)	19 (43.2)
Radiotherapy	29 (67.4) <sup>d</sup>	29 (65.9) <sup>e</sup>
No chemo/radiotherapy	6 (13.0)	7 (15.2)
Hormone therapy at 6 months	17 (53.1)	17 (51.5)
Unknown	2 (4.3)	2 (4.3)
Previous level formal exercise		
Daily	7 (6.5)	4 (8.7)
Weekly	13 (28.3)	11 (23.9)
Rarely	3 (15.2)	4 (8.7)
None	21 (45.7)	24 (52.2)
Unknown	2 (4.3)	3 (6.5)
Previous level informal exercise		
Daily	22 (47.8)	19 (41.3)
Weekly	6 (13.0)	10 (21.7)
Rarely	4 (8.7)	5 (10.9)
None	4 (8.7)	4 (8.7)
Unknown	10 (21.7)	8 (17.4)

<sup>a</sup> yoga experience varied from 4 months to 10 years

<sup>b</sup> trauma to shoulder/arm: e.g. fractures, sports injuries, dislocation, carpal tunnel syndrome

<sup>c</sup> sums add up to more than 100% or sample size because multiple treatment options are possible

<sup>d</sup> 15/29 received also chemotherapy

<sup>e</sup> 11/29 received also chemotherapy

**Table 2. Changes in TOI scores over time**

	Assessment Interval		
	Baseline to week 10 <sup>a</sup>	Baseline to month 6 <sup>a</sup>	Week 10 to month 6 <sup>a</sup>
<b>Yoga DVD group</b>	<b>n = 34</b>	<b>n = 32</b>	<b>n = 31</b>
Improvement	21 (62%)	26 (81%)	9 (29%)
Deterioration	5 (15%)	2 (6%)	3 (10%)
No change	8 (24%)	4 (12%)	19 (61%)
<b>SC group</b>	<b>n = 36</b>	<b>n = 32</b>	<b>n = 33</b>
Improvement	25 (69%)	22 (69%)	15 (45%)
Deterioration	5 (14 %)	5 (16%)	9 (27%)
No change	6 (17%)	5 (16%)	9 (27%)

<sup>a</sup> in numbers and proportions

**Table 3. Mean baseline and follow-up PROs scores by group (mean, SD)**

Measures	Yoga DVD group						Standard care group					
	post-surgery		10 weeks		6 months		post-surgery		10 weeks		6 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
TOI score	74.3	(16.1)	84.0	(21.1)	88.7	(19.7)	72.5	(13.6)	83.5	(18.0)	85.6	(17.1)
PWB	19.7	(6.0)	20.7	(7.6)	23.6	(5.6)	20.2	(4.0)	21.9	(5.5)	23.2	(5.3)
FWB	18.7	(5.0)	20.7	(6.3)	21.6	(6.1)	17.4	(5.3)	20.0	(6.7)	21.9	(5.5)
EWB	18.3	(3.6)	19.0	(4.4)	18.9	(4.7)	17.5	(4.5)	18.8	(4.7)	19.2	(4.0)
SWB	25.3	(3.5)	25.3	(3.0)	24.1	(5.3)	23.1	(6.8)	24.1	(4.7)	23.3	(5.4)
Arm function (5 item)	12.2	(4.7)	17.5	(3.7)	17.5	(3.1)	12.0	(4.1)	16.7	(4.2)	15.4	(4.3)
QuickDash	41.2	(20.4)	10.8	(15.8)	9.9	(17.2)	43.2	(18.3)	15.2	(19.1)	15.4	(16.3)
OSS	25.7	(9.1)	16.1	(6.8)	15.0	(6.1)	27.0	(8.6)	17.0	(7.7)	17.7	(7.3)
Pain score	3.0	(2.6)	1.0	(2.0)	1.5	(1.7)	2.9	(2.0)	1.4	(2.1)	2.8	(2.5)

Abbreviations: EWB, emotional well-being; FWB, functional well-being; OSS, Oxford Shoulder Score; PRO, patient reported outcome measures; PWB, physical well-being; SD, standard deviation; SWB, social well-being; TOI, trial outcome index.

Range scores: FACT-B+4 0-164, PWB 0-28, FWB 0-28, EWB 0-24, SWB 0-28, TOI 0-112, BCS 0-36, 5-item arm morbidity (items B3, B10, B11, B12, B13) 0-20: higher scores reflect better functioning; QuickDash 0-100 and OSS 0-60: higher scores represent poorer functioning or greater limitations; Pain scores 0-10.