The Jacki Jacket after Mastectomy with Reconstruction: A Randomized Pilot Study

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Abstract

Background. Breast cancer patients undergoing mastectomy with reconstruction (TM+R) often experience post-operative discomfort from surgical drains. Despite a variety of garment options for use in the post-operative period, high quality data assessing the impact of specific garments on post-operative pain are lacking. We report results of a prospective randomized trial assessing the impact of the Jacki Jacket (JJ), a long-sleeve jacket with inner drain receptacle pockets, on post-discharge pain and quality of life (QOL) after TM+R.

Methods. Breast cancer patients undergoing TM+R at a single institution were randomized post-operatively to receive a JJ or usual care (UC). Participant-reported demographics, pain intensity and QOL were collected on post-operative day 1(T1). Following discharge, participants completed a daily pain and medication dairy(T2); on day of drain(s) removal(T3), participants again completed pain and QOL questionnaires. Linear models were used to evaluate associations between JJ use, post-operative pain and QOL.

Results. From 3/8/17 to 12/20/17, 139 women were randomized. All participants completed T1 measures, 102 returned the T2 diary and 118 (84.9%) completed T3 questionnaires. There was no significant difference in pain scores between JJ and UC arms at any timepoint. Adjusting for surgery type, age, marital status, depression, and obesity, participants randomized to JJ reported significantly better body image scores (estimate=12.94, p=0.009). There were no adverse events.

Conclusions. Although JJ garment use did not impact post-operative pain intensity scores; the significant impact of JJ use on body image supports consideration for inclusion of such garments in postoperative care for patients undergoing TM+R.

Key words: Breast cancer; Mastectomy, Reconstruction, Pain, Body Image

Introduction

Treatment options for early-stage breast cancer are generally breast conserving surgery with adjuvant radiation or mastectomy. An analysis of the 2015 National Cancer Database [1] found that national rates of mastectomy for early-stage breast cancer rose from 34.3% in 1998 to 37.8% in 2011, with much of the increase in the last eight years. Rates of reconstruction with mastectomy rose from 11.6% in 1998 to 36.4% in 2011. During the same period, the rate of patients with unilateral breast cancer who elected contralateral prophylactic mastectomy (CPM) rose from 1.9% to 11.2%,[1] a trend that will likely continue [2] despite lack of evidence favoring CPM for survival outside a high risk setting [3]. Rates of bilateral prophylactic mastectomy (BPM) for those with no cancer diagnosis but genetic and/or family risk are more difficult to estimate due to lack of cancer diagnosis and registry, but studies have estimated these surgeries may be in the hundreds to thousands per year in the U.S. [4, 5] and may increase with rising awareness of genetic breast cancer risk and increased uptake of genetic testing [5].

Post-operative care after reconstruction involves drain, incision and pain management. The production of fluid that accumulates under the mastectomy flaps is an expected consequence and drains are placed intraoperatively to manage fluid accumulation and prevent the development of a seroma. The number of drains placed depends on the type of surgery and the preference of the surgeon; ranging from one to two for unilateral and from two for four for bilateral mastectomy [6, 7]. After mastectomy and breast reconstruction, patients may experience soreness in the chest, underarm and shoulder, as well as numbness at the drainage

site. Moreover, post-operative pain can contribute to limited range of motion in the upper body, resulting in worsening stiffness and edema that has a negative impact on quality of life (QOL) and activities of daily living. Patients have reported the greatest discomfort at the drain insertion sites and the number of drains after mastectomy has been associated with increased pain [6, 8]. Studies also have demonstrated that inadequately managed pain in the acute post-operative period is one of the greatest predictors of chronic pain syndromes in breast surgery patients [9-14]. Further, surgical drains often are difficult to manage when patients are discharged from the hospital and begin wearing typical clothing, returning to regular daily activities [15].

Despite a variety of retail undergarment options such as mastectomy bras and camisoles to secure drains, none has been tested to ascertain efficacy in reducing discomfort of drains. We hypothesized that by providing secure pockets to hold drains the Jacki Jacket may not only reduce discomfort, but also enable the woman to wear the garment in public. The purpose of this randomized pilot trial was to compare postoperative pain intensity, over the weeks that participants had surgical drains, between those receiving the Jacki Jacket plus usual care (Jacki+UC) vs UC alone. Secondary outcomes included pain interference, functional status, self-administered pain medication, time to opioid cessation, quality of life, and related breast cancer symptoms.

Methods

Sample and Setting

Breast cancer patients undergoing unilateral or bilateral mastectomy with implant based reconstruction at a single institution from March 8 through December 20th, 2017 and were approached for participation on postoperative day 1 by staff nurses. Eligible patients were 18 years or older, spoke and read English, had a unilateral or bilateral mastectomy with reconstructive surgery, and agreed to be randomized prior to discharge. Co-morbid delirium, dementia, mental illness or neurocognitive deficit prohibiting informed consent and completing study procedures were exclusions. Staff nurses provided standardized teaching on managing pain and drains to all participants, including suggestions on wearing of undergarments, such as a mastectomy bra. Participants assigned to the JJ group also received teaching on how to wear and use the JJ. A study coordinator explained study procedures, obtained written informed consent, and collected baseline data on that same first post-operative day.

Intervention

The Jacki Jacket (Figure 1) is unique as outer apparel that can be worn at home as well as in the workplace, at social events, and allows full range of motion. The jacket is a long sleeve, soft, cotton and Polartec® high performance wicking fabric. The jacket allows the patient to discreetly place drainage tubes in hidden and secure inner pockets to reduce the possibility of dislodgement and pulling. Arm-length Velcro openings in the sleeves allow for easy access when patients return for follow-up appointments that require blood pressure measurement, intravenous access, injections and/or physical exams.

Design and procedures

Participants were randomized 1:1 to UC or Jacki+UC groups in blocks with permuted size, stratified by unilateral vs bilateral mastectomy. The study was reviewed and approved by the Dana-Farber Cancer Institute Institutional Review Board.

On the first post-operative day (T1), participants self-reported demographic characteristics (age, ethnicity, race, languages spoken at home, marital status, education and work status) and pain measures: 0-10 pain intensity (PINS), the pain frequency and intensity distress items from the Symptom Distress Scale [16], and the 3-item PROMIS Pain Intensity short form measure [17] following discharge (typically 1-2 days after surgery). Participants completed a paper daily diary for reporting pain intensity (T2 PINS), self-administered pain medications, and frequency and duration of wearing the Jacki+UC and/or mastectomy bras or other undergarments intended to support drains. Following drain removal, (T3 PINS) participants repeated the baseline pain measures along with the 8-item PROMIS Pain Interference short form scale [18], the 30-item European Organization for Research and Treatment of Cancer (EORTC) QLC-C30 [19] symptom, quality of life, and functional status measure, and the 23-item EORTC QLQ-BR23 Breast Cancer Module [20] measuring side effects of surgery, arm and breast symptoms, body image, sexual functioning, and future perspective.

Data abstracted from the medical record included clinical, demographic and psychosocial information: diagnosis, use of neoadjuvant chemotherapy, prior breast surgery, body mass index (BMI), baseline depression and anxiety, number of children (<18 years) in the household, type of surgery and reconstruction, sentinel lymph node biopsy, axillary lymph node dissection, in-patient peri- and post-operative pain medications, post-discharge complications, other symptoms and quality of life. Data were abstracted by two trained registered nurses on the

study team; 15% of clinical case report forms were coded independently and compared with >99% agreement.

Analyses

The primary objective of this study was to compare pain intensity measured on a 0-10 pain intensity numerical scale (PINS) between those randomized to UC or Jacki+UC groups at the T3 timepoint. With a sample size of 130, we projected 80% power to detect a 1-point difference in PINS at T3 between groups using a Wilcoxon rank sum test at the 2-sided, 0.1 significance level assuming a standard deviation of 2.2 (based on prior clinical pain data). Study group was assigned following a 1:1 randomization, stratified by type of surgery (unilateral or bilateral). The statistical plan allowed for parametric procedures (e.g. t-test, ANCOVA, modeling), assuming assumptions were not violated. Other secondary endpoints included additional pain measures, breast cancer symptoms, and health-related QOL measured by EORTC QLQ-C30 and QLQ-BR23.

Descriptive statistics were used to compare study groups at T1 as well as evaluate patterns of T3 missing data. Fisher's exact test and the t-test/Wilcoxon rank sum test were used to compare proportions and means/medians, respectively. Initial group comparisons of outcome measures (primary and secondary endpoints) were evaluated with univariate analysis-linear models, adjusting for the type of surgery. A sensitivity analysis with a Tobit model [21] was conducted between groups for T3 PINS score, due to an observed floor effect (19% participants reported T3PINS=0).

Multivariable models included race (white vs. others), ethnicity (Hispanic/Latino vs. others), marital status (married/partnered vs. others), education (college or more vs no college), work

status, age, BMI group, pre-surgery depression, the receipt of either paravertebral nerve block or gabapentin during surgery, sentinel lymph node biopsy (yes vs. no), axillary lymph node dissection (yes vs. no), time from discharge to T3, all adjusted for surgery type and T1 PINS. A step-wise model selection was used to select the final multivariable model that required study group and surgery type be retained in the model.

Diary data were collected during the time from discharge to the final drain removal. The first 7 days post-discharge pain intensity scores (T2) and morphine equivalent doses (MED) were calculated [22] and plotted. T2PINS was calculated as the average score for those participants who reported PINS score for at least 5 days

All analyses were performed in R, version 3.5.1. [23] All p-values were two-sided and considered significant at the 0.10 level based on the design of this signal-finding study.

Results

One hundred sixty-six eligible patients were approached during the study period and 139 (84%) were enrolled and randomized (67 UC and 72 Jacki+UC) after completing baseline measures (Figure 2). Most participants were enrolled the first day after surgery; 4 were enrolled the second day due to first-day complications or high pain levels. Sample characteristics are reported in Table 1. Tissue expanders were placed in all but two, one in each study group. Baseline PINS scores were balanced between the two groups, with an overall mean of 4.7 (SD=2.1) indicating moderate pain (Table 2). Participants with bilateral mastectomy reported significantly higher baseline pain compared with those with unilateral mastectomy (PINS score: 5.3 vs. 4.1, p=0.001).

The T2 diary was returned by 102 participants. Participants who were not working (p=0.007) or older (p=0.043) were significantly more likely to submit a diary. Averages for the first 7 days could be calculated (at least 5 of 7 days reported) for pain intensity in 98 participants and morphine equivalent dose (MED) in 94 participants. There were no apparent differences in pain intensity or MED by treatment group for those submitting drug diaries; a substantial amount of variability was seen for these outcomes in both groups. (Figures, Supplemental Digital Content 2, 3)

Of the participants randomized to receive Jacki+UC, 52 of the 53 participants returning a diary reported wearing the Jacki Jacket at least once. Of the 49 participants who reported wearing the JJ at least five of the first seven days in the diary, the JJ was worn a median 6.3 (range 0-7) days. Participants in both groups also reported using mastectomy bras: 39 (75%) of 52 Jacki+UC participants and 27 (67%) of 41 UC participants reported wearing a bra at least once.

A total of 118 participants (85%) completed the T3 questionnaire on the day of the last drain pull. The median time from discharge to the T3 questionnaire was 17.5 (actual range 5-45) days. A higher proportion of those with a T3 questionnaire were married/partnered (p=0.05), and/or had a unilateral mastectomy (p=0.10) (Table, Supplemental Digital Content 1). Among these, 2 participants did not provide an answer for the primary pain intensity measure. Six participants did not answer T3 questionnaire but provided a pain intensity score in their T2 diary for the same day as the final drain removal, resulting in an analytic sample for the T3PINS endpoint of 122. In the univariate analysis, there was no statistically significant difference between Jacki+UC and UC with respect to pain intensity at the time (T3) of the final drain removal

(p=0.41) (Table 2). The result remained the same with Tobit model. No other statistically significant differences were detected between treatment groups and the other pain measures.

In univariate analyses of the BR23 measure collected at T3, the body image score of the QLQ-BR23 was marginally higher (better body image) for those randomized to Jacki+UC vs UC (p=0.11) (Table 3). No other Br23 or C30 subscales were significantly different between study groups (data not shown). The number of drains was significantly correlated with surgery type and was not included in the multivariable model. A moderate correlation between T1 and T3PINS (Pearson r = 0.4) was observed, thus T1PINS was adjusted in multivariate model for the T3PINS (outcome ANCOVA model). Treatment group, age, marital status, pre-surgery depression, and being overweight/obese were retained in a multivariable model at significance levels $p<0.10$; no significant difference in surgery type was noted (p=0.55) (Table 4). Those randomized to UC (estimate=-12.94, p=0.009), those with a history of depression (estimate=-11.82, p=0.025), and those who were overweight/obese (estimate=-10.83, p=0.032) had significantly lower body image scores. Participants who were older (estimate=0.63, p=0.006) and married/partnered (estimate=11.34, p=0.079) reported significantly better body image scores. No other statistically significant associations between treatment group and QOL outcome measures were detected.

Discussion

In this randomized pilot, findings did not suggest a pain intensity benefit for the Jacki Jacket as hypothesized. Other pain outcomes were not different between groups between discharge from the hospital and the day of the last drain removal. One quality of life aspect, body image,

was found to favor the Jacki+UC group, along with older age and being married/partnered. History of depression, bilateral mastectomies and overweight/obesity predicted worse body image.

Pain management typically has been focused on pharmacological agents including both opioids and non-opioids [24]. Analgesics such as oral gabapentin during the perioperative period [25] paravertebral [26] or pectoral nerve blocks [27], have been found to reduce use of intra- and post-operative opioid pain medications. To our knowledge, non-pharmacological interventions specifically directed toward pain caused by surgical drains have not been tested.

The JJ may well have provided a means for women to return to “normal” dress and appear as before. As no other group of investigators has evaluated an intervention such as the JJ, we cannot find direct confirmation or rebuttal of our findings in prior research. However, other investigators have explored the impact of co-variates we studied and only one study was conducted with measures in the first few weeks after surgery. Zimmerman et al. [28] evaluated body image within eight weeks of diagnosis in women with a variety of breast cancer surgeries and, similar to our findings, reported that body image and self-acceptance were lower in women with depressive symptoms. Paterson and colleagues [29] systematically reviewed 11 studies which included a body image variable in women with breast cancer and found that the majority confirmed our finding that body image was worse in younger women. These reviewers reported evidence that poorer body image was associated with psychological distress. In contrast to our finding that married/partnered women had better body image scores, King et al. [30] reported that single women in Australia with early stage breast cancer scored significantly higher than partnered women on a body image measure three months after surgery. Additional

disruption in body image of having both breasts removed vs just one removed is understandable and supported by a review of issues related to prophylactic bilateral mastectomy [31]. The relationship between body image and being overweight and/or obese is established in breast cancer survivors [32], as well as for women in general [33].

Schreiber et al. [34] published a 2018 analysis of pain outcomes reported by women after three types of cancer-related breast surgery and reported that axillary node dissection predicted pain 14 days after surgery. This differed from our results of women exclusively receiving mastectomies with reconstruction in which lymph node dissection did not predict pain outcomes. Schreiber and colleagues also reported post-operative day 14 PINS scores averaging about 2.0 (reported "at rest") and the scores varied substantially in women receiving mastectomies with reconstruction, both at post-operative day 1 and 14, all similar to our findings.

Adherence to suggested frequency of jacket use as documented within the first week post-discharge indicated the acceptability of the intervention. The significantly higher response rate at T3 in the Jacki+UC participants could be explained with the fact that these women were more engaged in the study due to receiving a material benefit versus usual care education. Post-mastectomy bras were worn in both groups, suggesting the combination of the bra and JJ may have made a difference in body image

Limitations

The patient population at the hospital from which we recruited was predominantly, non-Hispanic white women. Lack of diversity in our sample precludes any generalization to other

races or ethnicities. The median age at diagnosis in our study was 48 years, substantially lower than that of the average breast cancer patient in the US (62 years) [35] and also lower than the mean 52 years for women receiving reconstruction in Jonczyk and colleagues' analysis of breast cancer treatment trends from 2005-2016 in the American College of Surgeon's National Surgical Quality Improvement Program [36].

T3 data collection occurred just after final drain removal at the conclusion of the clinic visit. The PINS reported by participants may have reflected the discomfort experienced at drain removal versus discomfort associated with the drains intact. This may have limited our ability to observe a difference between groups for our primary outcome measure. The high variability in pain scores and MED may have precluded finding a difference for T2 diary analyses as well as for the T3 primary outcome of pain intensity.

While we utilized two measures of pain (PINS and pain interference) and we sized the study on the PINS. This single item may not have been robust-enough for the context of post-operative pain related to drain discomfort.

Anecdotal accounts [37] have praised the Jacki Jacket for comfort and appropriateness when returning to settings outside home after surgery. While the great majority of the women on our trial were employed, we did not follow women long enough to assess the jacket's potential impact on return to the workplace.

Future research

As our study was likely underpowered to detect a significant difference in pain scores given the high variability in PINS scores and the variability of self-administered opioid doses, a larger trial

is clearly indicated. An additional study group receiving a jacket without drain pockets would help define the impact of simply being given a new jacket. Further, pain outcome assessments with any intervention may be best collected on consistent duration of time from surgery and not immediately after a painful procedure.

Clinical implications

The Jacki Jacket has been delivered to thousands of women to date with support from philanthropic sources. However, the future availability likely depends on an individual's ability to purchase the jacket or third-party payer coverage. This low-risk intervention could be helpful to women, particularly with regard to self-image.

Conclusion

While our findings suggested no significant impact of the Jacki Jacket on pain intensity at the time of drain removal, the positive impact on body image is encouraging, as women are vulnerable during this post-operative period to body image changes. As a low risk intervention, the jacket may be a valuable addition to post-operative discharge instructions.

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Compliance with Ethical Standards:

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Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This protocol was reviewed and approved by the Dana-Farber Cancer Institute (DFCI) IRB, in accordance with the applicable Federal regulations set forth at 45 CFR Part 46, and 21 CFR Parts 50 and 56, if applicable.

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Figure 1. The Jacki Jacket prototype. Photo used with permission.

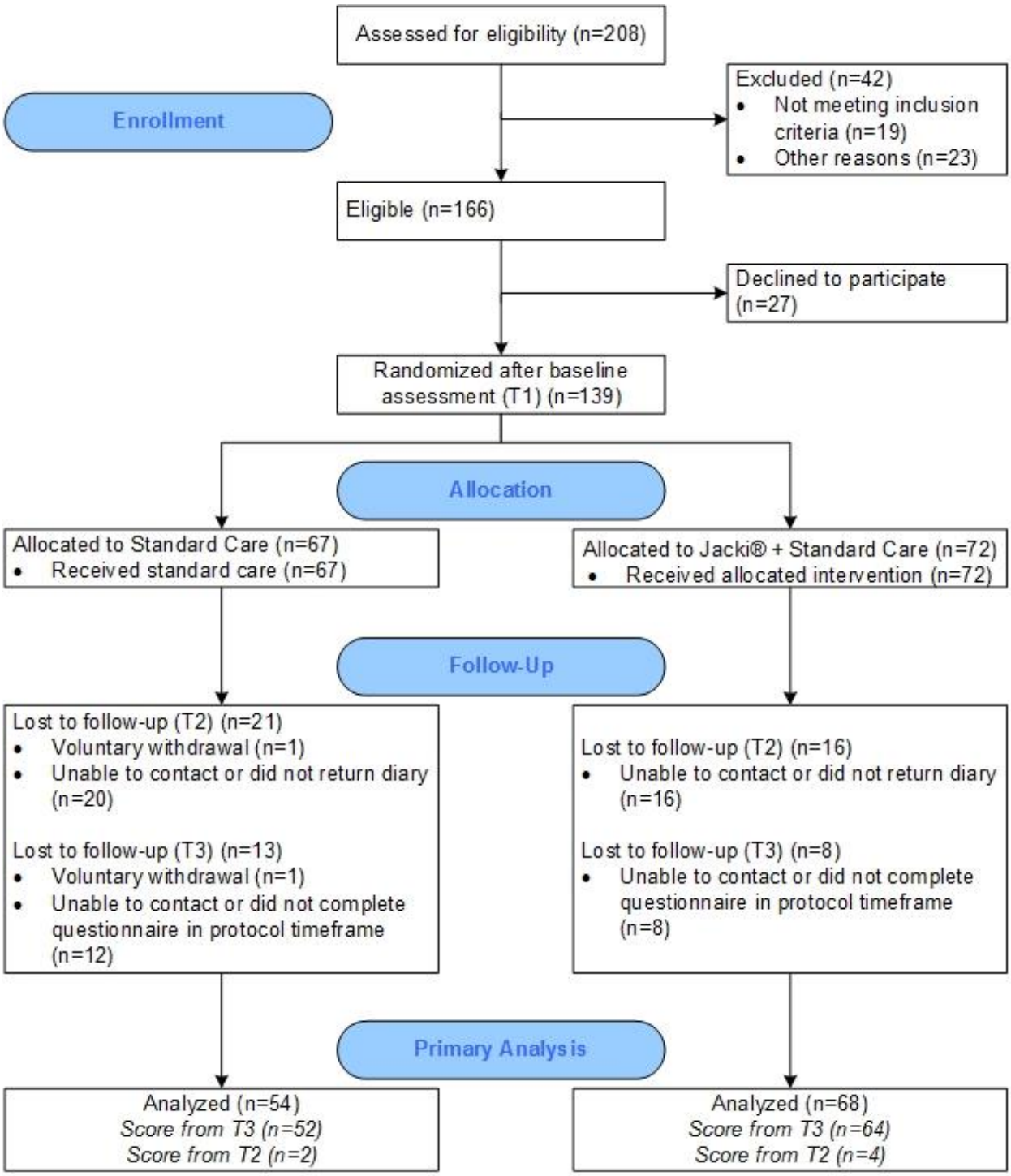


Figure 2. Consort diagram

Table 1. Participant demographic and clinical data

	Total	Study Group		P-value
		JJ	UC	
Race				
White/Caucasian	122 (87.8%)	62 (86.1%)	60 (89.6%)	0.83
Black/African American	9 (6.5%)	5 (6.9%)	4 (6.0%)	
Asian	4 (2.9%)	3 (4.2%)	1 (1.5%)	
Multiple	1 (0.7%)	1 (1.4%)	0 (0.0%)	
Missing	3 (2.2%)	1 (1.4%)	2 (3.0%)	
Ethnicity				
Hispanic/Latino	10 (7.2%)	5 (6.9%)	5 (7.5%)	0.75
Not Hispanic/Latino	127 (91.4%)	67 (93.1%)	60 (89.6%)	
Prefer not to answer	1 (0.7%)	0 (0.0%)	1 (1.5%)	
Missing	1 (0.7%)	0 (0.0%)	1 (1.5%)	
Language				
English	130 (93.5%)	64 (88.9%)	66 (98.5%)	0.14
Spanish	4 (2.9%)	3 (4.2%)	1 (1.5%)	
Other	2 (1.4%)	2 (2.8%)	0 (0.0%)	
Multiple	3 (2.2%)	3 (4.2%)	0 (0.0%)	
Marital Status				
Single/never married	12 (8.6%)	7 (9.7%)	5 (7.5%)	0.48
Married/partnered	110 (79.1%)	54 (75.0%)	56 (83.6%)	
Separated/divorced/widowed	17 (12.2%)	11 (15.3%)	6 (9.0%)	
Education				
High school	8 (5.8%)	4 (5.6%)	4 (6.0%)	0.65
Some college	22 (15.8%)	13 (18.1%)	9 (13.4%)	
College graduate	55 (39.6%)	25 (34.7%)	30 (44.8%)	
Post graduate	54 (38.8%)	30 (41.7%)	24 (35.8%)	
Work Status				
Working	115 (82.7%)	61 (84.7%)	54 (80.6%)	0.65
Not working	24 (17.3%)	11 (15.3%)	13 (19.4%)	
Age				
Median (range)	48.0 (23.0 - 75.0)	47.0 (25.0 - 66.0)	49.0 (23.0 - 75.0)	0.58
Body Mass Index				
Median (range)	24.8 [16.0, 38.1]	25.6 [19.2, 38.1]	24.5 [16.0, 34.3]	0.03
History of depression				
No	95 (68.3%)	46 (63.9%)	49 (73.1%)	0.32
Yes	44 (31.7%)	26 (36.1%)	18 (26.9%)	
Surgery Type				
Bilateral	67 (48.2%)	32 (44.4%)	35 (52.2%)	0.40
Unilateral	72 (51.8%)	40 (55.6%)	32 (47.8%)	

Table 1. Participant demographic and clinical data

	Total	Study Group		P-value
		JJ	UC	
Sentinel lymph node biopsy				
No	34 (24.5%)	16 (22.2%)	18 (26.9%)	0.56
Yes	105 (75.5%)	56 (77.8%)	49 (73.1%)	
Axillary lymph node dissection				
No	106 (76.3%)	58 (80.6%)	48 (71.6%)	0.24
Yes	33 (23.7%)	14 (19.4%)	19 (28.4%)	

Table 2: Baseline (Time 1) and Time 3 PINS score summary by treatment group and stratum used for randomization.

	Time 1 PINS (n=139)			Time 3 PINS (n=122)		
	n	**Mean (±SD)**	**P**	**n**	**Mean (±SD)**	**P**
Treatment Group			0.98			0.41
Jacki Jacket	72	4.7 (±2.0)		68	2.1 (±1.9)	
Usual Care	67	4.7 (±2.2)		54	1.9 (±1.7)	
Stratum			0.001			0.48
Bilateral	67	5.3 (±2.1)		55	2.1 (±1.9)	
Unilateral	72	4.1 (±1.9)		67	1.9 (±1.8)	

Notes: PINS=pain intensity numerical scale; SD=standard deviation

Table 3: Univariate comparison of secondary outcomes at Time 3.

	n*	Jacki Jacket (n=68)	n*	Usual care (n=54)
PROMIS® Pain Intensity				
T-score	64	46.1 (±5.3)	54	46.8 (±7.0)
PROMIS® Pain Interference				
T-score	62	59.1 (±7.5)	54	58.9 (±8.4)
		Mean (±SD)		**Mean (±SD)**
SDS Pain Items				
Frequency	64	2.9 (±1.1)	54	2.9 (±1.2)
Intensity	64	2.1 (±0.9)	53	2.0 (±0.9)
QLQ-C30				
Global QOL	64	64.1 (±16.7)	54	66.0 (±17.2)
Physical Function	62	71.7 (±20.0)	53	76.3 (±23.9)
Role Function	62	40.3 (±24.6)	54	36.1 (±27.2)
Emotional Function	64	73.3 (±21.7)	54	72.8 (±20.1)
Cognitive Function	64	81.0 (±21.6)	54	84.0 (±22.9)
Social Function	64	56.5 (±26.7)	54	59.0 (±28.7)
Symptom Pain	64	46.1 (±24.3)	54	44.8 (±25.7)
QLQ-BR32 Breast Cancer Module				
Body Image	64	64.8 (±25.0)	53	56.6 (±29.8)
Sexual functioning	57	15.8 (±19.0)	49	18.0 (±18.3)
Sexual enjoyment	22	57.6 (±29.4)	17	54.9 (±35.2)
Future perspective	64	53.1 (±30.1)	54	49.4 (±30.2)
Side effects	64	15.4 (±12.8)	54	13.4 (±12.6)
Breast symptoms	64	31.4 (±21.7)	54	32.8 (±21.9)
Arm symptoms	64	30.9 (±19.8)	54	30.9 (±20.2)
Upset by hair loss	11	22.4 (±27.9)	8	19.1 (±25.6)

Notes: *Number participants responding; SD=standard deviation; SDS=Symptom Distress Scale; PROMIS®=®Patient-Reported Outcomes Measurement Information System; QLQ=Quality of Life Questionnaire; BR=Breast

Table 4. Multivariable linear model of body image

			90% CI	
	Estimate	**P**	**LB**	**UB**
Usual care vs Jacki Jacket	-12.94	0.009	-21.02	-4.85
Unilateral vs Bilateral	-2.95	0.55	-11.11	5.20
Age	0.63	0.006	0.26	1.00
Married/partnered vs not	11.34	0.079	0.73	21.96
Hx Depression vs none	-11.82	0.025	-20.45	-3.20
Overweight/obese vs not	-10.83	0.032	-19.11	-2.54

Notes: CI=Confidence interval; LB=lower bound; UB=upper bound;

Hx=history

Supplemental Digital Content 1. Comparison of baseline demographics of Time 3 respondents and non-respondents.

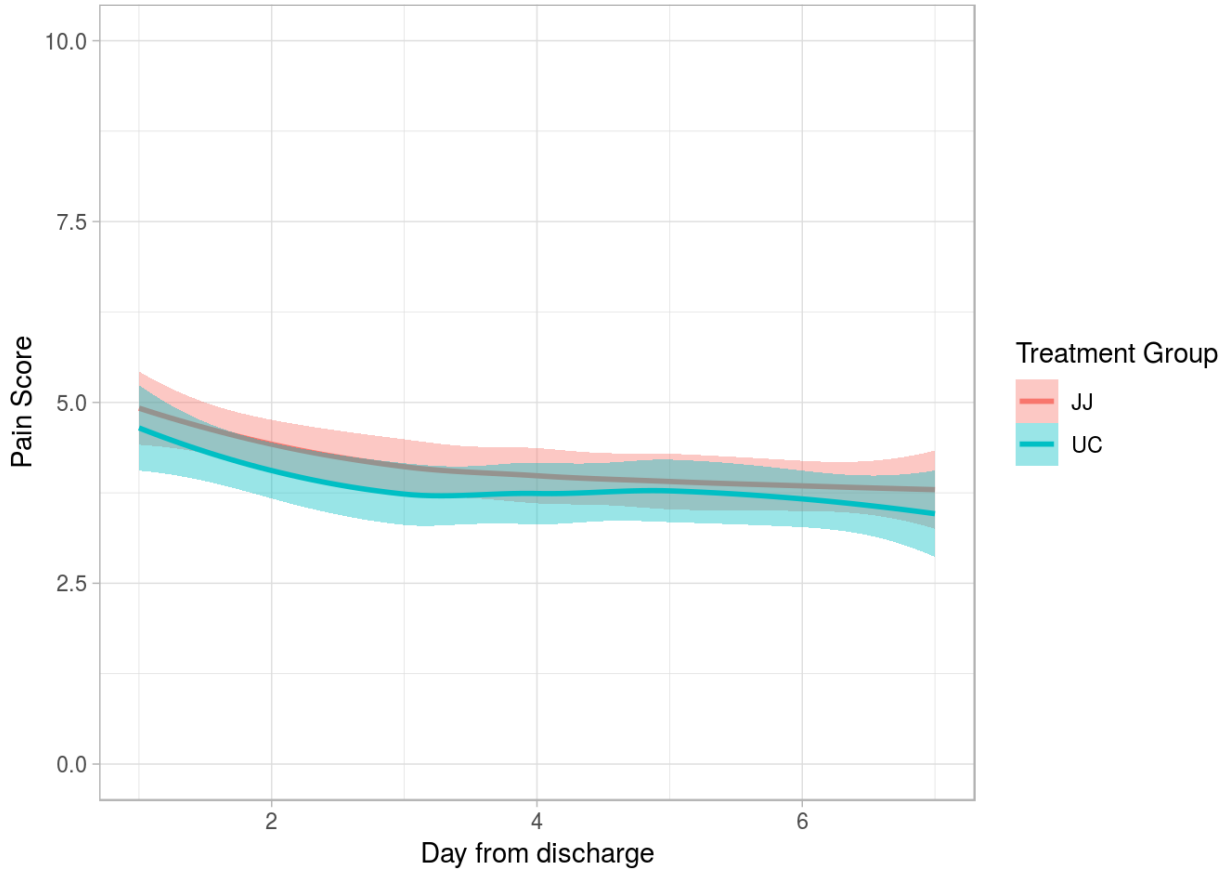
	Time 3 Questionnaire		
	Non-respondent	Respondent	P-value
Study group			
Jacki Jacket	8 (38.1%)	64 (54.2%)	0.24
Usual care	13 (61.9%)	54 (45.8%)	
Race			
White/Caucasian	20 (95.2%)	102 (86.4%)	1.0
Black/African American	1 (4.8%)	8 (6.8%)	
Asian	0 (0.0%)	4 (3.4%)	
Multiple	0 (0.0%)	1 (0.8%)	
Missing	0 (0.0%)	3 (2.5%)	
Ethnicity			
Hispanic/Latino	0 (0.0%)	10 (8.5%)	0.54
Not Hispanic/Latino	21 (100.0%)	106 (89.8%)	
Prefer not to answer	0 (0.0%)	1 (0.8%)	
Missing	0 (0.0%)	1 (0.8%)	
Other	1 (4.8%)	1 (0.8%)	
Multiple	0 (0.0%)	3 (2.5%)	
Marital status			
Single/never married	2 (9.5%)	10 (8.5%)	0.048
Married/partnered	13 (61.9%)	97 (82.2%)	
Separated/divorced/widowed	6 (28.6%)	11 (9.3%)	
Education			
High school	0 (0.0%)	8 (6.8%)	0.80
Some college	4 (19.0%)	18 (15.3%)	
College graduate	9 (42.9%)	46 (39.0%)	
Post graduate	8 (38.1%)	46 (39.0%)	
Work			
Working	19 (90.5%)	96 (81.4%)	0.53
Not working	2 (9.5%)	22 (18.6%)	
Age			
Median (range)	45.0 (27.0 - 62.0)	49.5 (23.0 - 75.0)	0.23
T1 PINS			
Median (range)	4.0 (2.0 - 8.0)	5.0 (0.0 - 10.0)	0.78
Stratum for randomization			
Bilateral	14 (66.7%)	53 (44.9%)	0.096
Unilateral	7 (33.3%)	65 (55.1%)	
BMI			

Supplemental Digital Content 1. Comparison of baseline demographics of Time 3 respondents and non-respondents.

	Time 3 Questionnaire		
	Non-respondent	Respondent	P-value
Median (range)	24.2 (17.5 - 34.3)	25.1 (16.0 - 38.1)	0.33
BMI group			
Under/Normal	14 (66.7%)	58 (49.2%)	0.16
Over/Obese	7 (33.3%)	60 (50.8%)	
History of Depression			
No	14 (66.7%)	81 (68.6%)	1.0
Yes	7 (33.3%)	37 (31.4%)	
Paravertebral Nerve Block			
No	21 (100.0%)	111 (94.1%)	0.59
Yes	0 (0.0%)	7 (5.9%)	
Gabapentin			
No	12 (57.1%)	66 (55.9%)	1.0
Yes	9 (42.9%)	52 (44.1%)	
SLNB			
No	8 (38.1%)	26 (22.0%)	0.17
Yes	13 (61.9%)	92 (78.0%)	
ALND			
No	16 (76.2%)	90 (76.3%)	1.0
Yes	5 (23.8%)	28 (23.7%)	

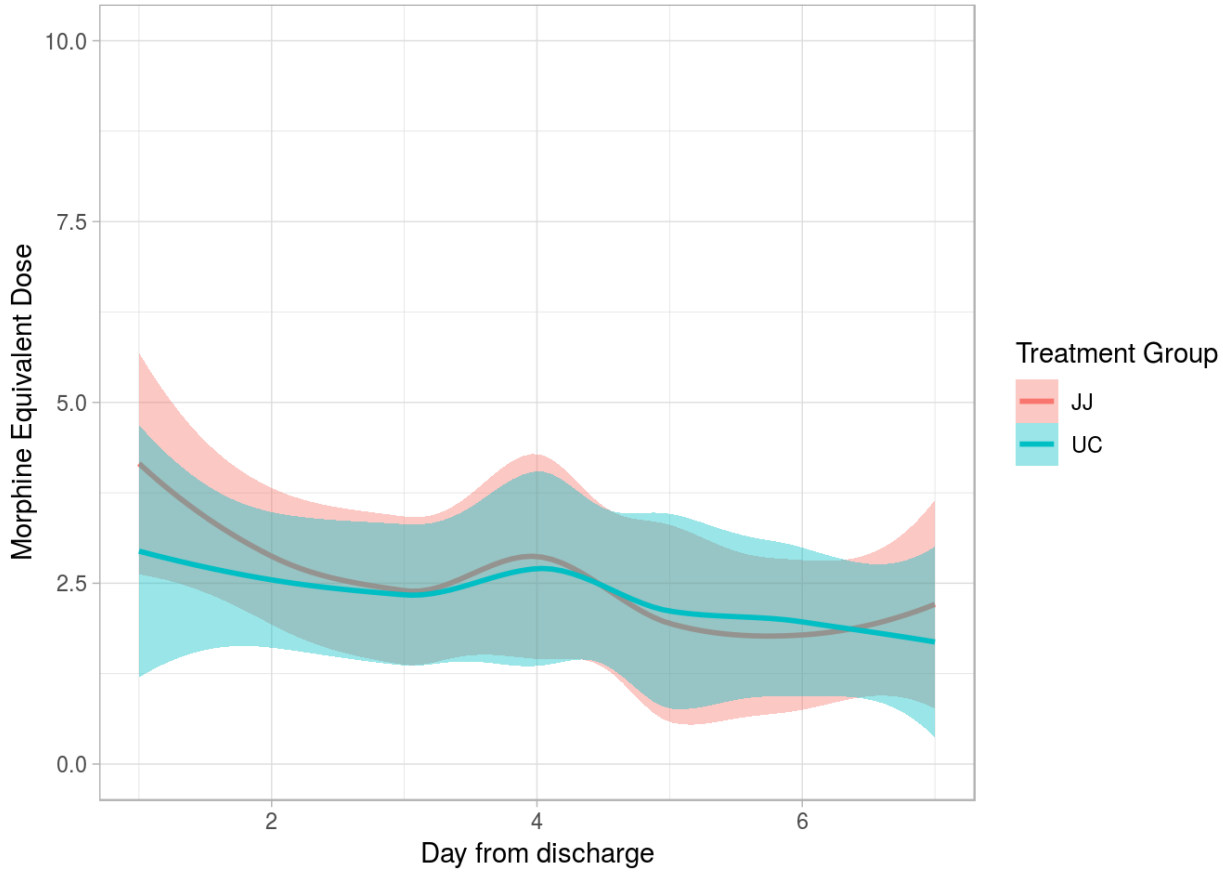
Notes: PINS= pain intensity numerical scale; BMI=Body Mass Index; SLNB=single lymph node biopsy; ALND= Axillary lymph node dissection

Supplemental Digital Content 2. Pain intensity numeric scale (PINS) score daily for first 7 days post-discharge, by group.



Notes: JJ=Jacki Jacket; UC=Usual care

Supplemental Digital Content 2. Morphine equivalent dose (MED) daily for first 7 days post-discharge, by group.



Notes: JJ=Jacki Jacket; UC=Usual care