NCI Protocol #: Not applicable

DF/HCC Protocol #: 16-403

TITLE: Reduction of Post Mastectomy Pain with the Jacki® Recovery Jacket: Randomized Trial

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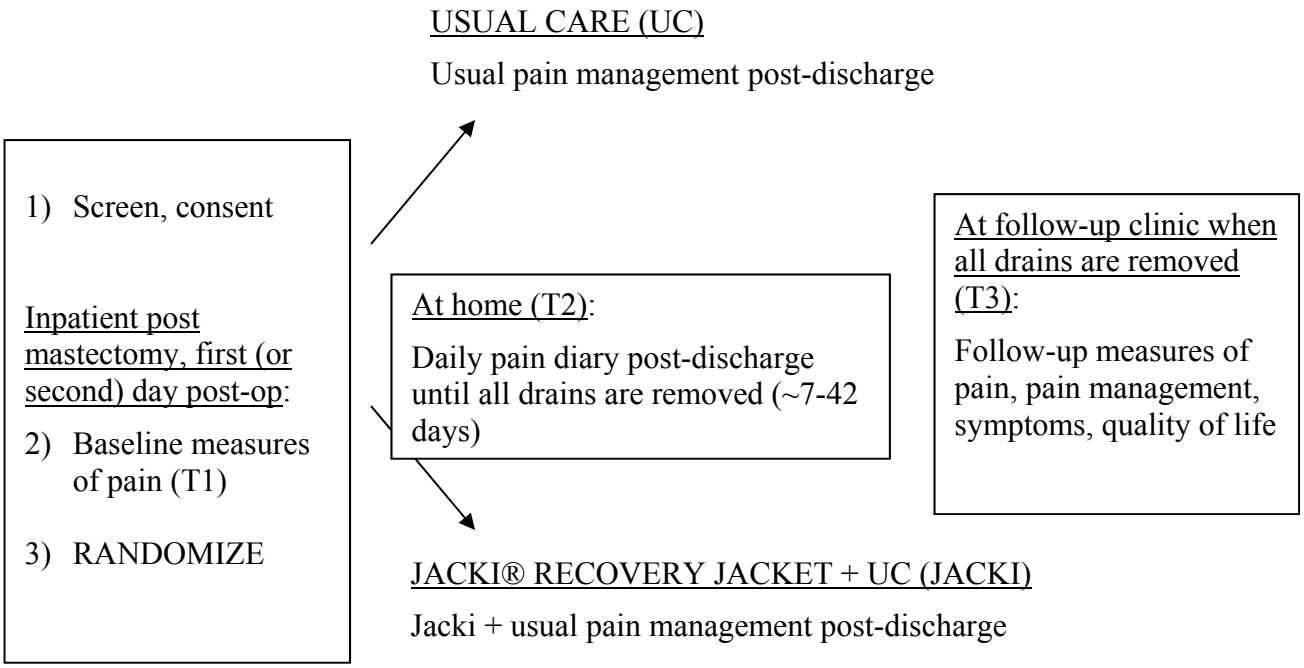
Study Exempt from IND Requirements per 21 CFR 312.2(b).

Protocol Type / Version # / Version Date: Original / Version 8 / 11.13.2017

SCHEMA


USUAL CARE (UC)
Usual pain management post-discharge
1) Screen, consent
Inpatient post mastectomy, first (or second) day post-op:
2) Baseline measures of pain (T1)
3) RANDOMIZE
At home (T2):
Daily pain diary post-discharge until all drains are removed (~7-42 days)
At follow-up clinic when all drains are removed (T3):
Follow-up measures of pain, pain management, symptoms, quality of life
JACKI® RECOVERY JACKET + UC (JACKI)
Jacki + usual pain management post-discharge

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1. OBJECTIVES

1.1 Study Design

The study is a randomized trial of the Jacki® recovery jacket garment versus usual care for post-discharge pain management in patients who had mastectomy and reconstructive surgery in one or both breasts.

1.2 Primary Objectives

1. Compare pain intensity on a 0-10 numeric scale at the post-surgical follow-up clinic when all surgical drains are removed between usual care pain management (UC) and "Jacki" plus usual care (Jacki) groups.

1.3 Secondary Objectives

1. Explore differences in health related quality of life (HRQOL) and breast symptoms between groups at the follow-up clinic.
2. Evaluate at-home (from discharge to follow-up) pain patterns and pain management by group.
3. Evaluate patient-reported Jacki usage frequencies in the intervention group.

2. BACKGROUND

2.1 Study Disease(s) and Health Setting

Patients have mastectomy either in treatment for breast cancer or as prophylaxis, and may have reconstructive surgery at the same time. In 2016, it is estimated that 246,660 new cases of invasive breast cancer will be diagnosed in women in the U.S. along with 60,290 cases of in situ breast cancer.[1] Treatment options for early-stage breast cancer are generally breast conserving surgery with adjuvant radiation or mastectomy. An analysis of the National Cancer Database published in 2015[2] found that national rates of mastectomy for early-stage breast cancer rose from 34.3% in 1998, the first year in the study, to 37.8% in 2011, the last year, with much of the increase in the last eight years. Rates of reconstructive surgery in patients having 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%,[2] a trend that will likely continue[3] despite lack of evidence favoring CPM outside a high risk setting.[4] 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.[5,6]and expected to increase with increased awareness of genetic breast cancer and increased uptake of genetic testing.[6]

2.2 IND Agent(s)

Not applicable.

2.3 *Other Agent(s)*

Not applicable.

2.4 Rationale

Patients who have mastectomy and reconstructive surgery often experience discomfort from not only the surgical incisions, but also from the drainage tubes inserted at the incision sites. The tubes and drainage receptacles are often difficult to manage when patients are discharged from the hospital, wearing typical clothing and returning to regular daily activities.

Most women are able, at the time of mastectomy, to have breast reconstruction surgery to rebuild and contour breast shape. Post-operative care is more complex than mastectomy alone and requires an inpatient stay of two to four nights. The accumulation of fluid – a *seroma* – is a frequent complication following breast surgery and warrants the insertion of drainage tubes for prevention. In a review investigating techniques in the prevention and management of seromas after breast surgery, drains produced a significant reduction in seroma incidence.[7] The number of drains depends on the type of surgery and preference of the surgeon and ranges from 2 for unilateral and from 4 for bilateral mastectomy.[8,9] Patients after mastectomy and breast reconstruction experience soreness in the chest, underarm and shoulder, as well as numbness at the drainage site. Patients have reported the greatest discomfort at the drain insertion sites. The number of drains after mastectomy has also been associated with increased pain in the post mastectomy patient, although the number of drains was not associated with the rate or number of seromas.[8,10] If axillary lymph nodes are removed, patients may experience some numbness in the arm and also are at risk for *lymphedema*,[11] a build-up of lymph that causes swelling in the arm, hand, breast, underarm, chest, trunk and/or back.

Post-operative pain experienced by women undergoing mastectomy and breast reconstruction can contribute to limited range of motion in the upper body, resulting in worsening stiffness and edema that have a negative impact on quality of life (QOL) and activities of daily living (ADL). It is vital that early upper body exercise and movement is performed to prevent lymphedema or swelling.[12] Increased activity can reduce the side effects of surgery, shorten recovery time, and ultimately improve long-term outcomes.[13,14] This was demonstrated in a study of 35 post-operative mastectomy patients randomized to participate in an early physical rehabilitation program: participants in the program reported significant improvement in pain reduction and QOL.[15] Consequently, studies 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.[16-21]

Traditional clothing options for women post mastectomy are undergarments such as post mastectomy camisoles, tank tops, and customized mastectomy bras. Camisoles are usually worn as nightwear or under loose fitting clothing until surgical drains are removed. The Jacki is a post mastectomy garment that was developed by a breast cancer survivor as a means to manage and hold the drainage system. The jacket is professionally manufactured, made with high quality material (cotton and Polartec® microfleece), and is suitable for business casual attire. Anecdotally-reported patient experiences suggest that use of the Jacki immediately after surgery is an early intervention that may reduce pain and prevent activity limitations over time.[22,23] The Jacki is unique as outer apparel that can be worn in the workplace, at social events, and during usual activity, and that allows full range of motion. The Jacki allows the patient to discreetly place drainage tubes in hidden and secure inside pockets that reduce the possibility of dislodgement and pulling. Velcro sleeves allow for easy access when patients return for follow-up appointments that require taking blood pressure, IV access, injections and medical exams. In particular, women have described[24] how the Jacki has put them at ease when in public venues that otherwise would have created feelings of vulnerability and self-consciousness because of body changes and functional limitations from surgery.

2.5 Preliminary Data

A preliminary survey study was conducted to explore self-reported pain intensity levels (just before discharge to ambulatory care) in patients post mastectomy in the Boston area. The sample (n=88) had a nearly equal distribution of age above and below 50 years; most were college educated and married/partnered. Of the 88 participants, 39% reported moderate to severe pain intensity, 53% reported pain several times a week to constantly, and 34% reported pain intensity as fair to almost unbearable soon after surgery. Sixty percent of participants had received a bilateral mastectomy, and 43% of these had bilateral implant reconstruction. Mean scores on the 0-10 pain intensity scale were 5.26 (SD=2.28) for those who had bilateral mastectomy and 2.5 (SD=2.13) for those having single mastectomy; participants who had reconstruction at the time of surgery pain averaged 4.98 (SD=2.18).

3. PARTICIPANT SELECTION

3.1 Eligibility Criteria

1. Patients who are ≥ 18 years old.
2. Patients who speak and understand English.
3. Patients who have had mastectomy with reconstructive surgery in one or both breasts.

3.2 Exclusion Criteria

1. Co-morbid delirium, dementia, mental illness, or neurocognitive deficit prohibiting informed consent and/or ability to complete study procedures.

3.3 Inclusion of Women and Minorities

The sample will be entirely women (although men are at risk for, or diagnosed with, breast cancer, they do not have reconstructive surgery post mastectomy). English-speaking women of all races and ethnic groups are eligible and will be recruited for this trial.

4. REGISTRATION PROCEDURES

4.1 General Guidelines for DF/HCC Institutions

Institutions will register eligible participants in the Clinical Trials Management System (CTMS) OnCore. Registrations must occur prior to the initiation of protocol therapy (i.e., discharge from the hospital). Any participant not registered to the protocol within this timeframe will be considered ineligible and registration will be denied.

A member of the study team will complete the protocol-specific eligibility checklist.

4.2 Registration Process for DF/HCC Institutions

DF/HCC Standard Operating Procedure for Human Subject Research Titled *Subject Protocol Registration* (SOP #: REGIST-101A for Centralized Registration) must be followed. Research staff at enrolling institutions will fax the signed informed consent form and eligibility checklist to the protocol registrar at the Office of Data Quality (ODQ) at 617-632-2295, who will confirm eligibility and complete centralized registration of the participant in OnCore.

4.3 General Guidelines for Other Investigative Sites

Not applicable.

4.4 Registration Process for Other Investigative Sites

Not applicable.

5. TREATMENT AND/OR IMAGING PLAN

5.1 Treatment Regimen

5.1.1 Enrolling Sites and Study Entry

A sample of 130 women who have had or will have mastectomy with reconstruction will be recruited.

Screening will be conducted by a research team member using the clinical surgery and post-op schedule to identify eligible patients. A clinical care nurse or clinical research associate who is a member of the research study team will invite the participant to hear about the study, and if the patient agrees to participate, will consent the participant. The research team member will complete the eligibility checklist.

The research team member will fax the consent form and eligibility checklist to the Office of Data Quality to register the participant and will receive the participant's randomized study group assignment. Participants will be randomly assigned in blocks of random permuted size, stratified by site and unilateral vs bilateral mastectomy, to the usual care pain management (UC) or "Jacki" plus usual care (Jacki) groups.

The research team member will meet the participant in the hospital on the first day post-surgery (or second day, if the patient is too sick, has a surgical complication, or is in too much pain or distress to be approached the first day) to collect the baseline (T1) questionnaire and will provide the post-discharge daily diary questionnaires (T2) to the participant, answer questions, and make arrangements for collection of the follow-up questionnaire (T3) with the participant at the clinic visit when all the post-surgical drains are removed. The research team member will telephone or email the participant at home the first or second day after discharge to remind her to fill out the T2 daily questionnaire; if the participant has multiple follow-up visits before all drains are removed, the research team member may also telephone, email or meet the participant at follow-up visits to remind her to continue filling out the T2 daily questionnaire until all drains are removed.

5.1.2 Treatment Regimen

A clinical care nurse will provide instruction to participants allocated to the Jacki arm on safe and appropriate use of the Jacki (for example, how to put on the jacket and tuck drainage tubes into jacket pockets, and the need to remove drainage tubes from jacket pockets prior to removing the jacket). Participants in the Jacki arm will be encouraged to use the jacket at home between discharge and their follow-up clinic appointment; no minimum amount of use is required.

Participants in both groups will receive all usual pain management including prescription of pain medications and instructions on pain management post-discharge as standard of care.

The treatment period for participants in both arms is from discharge from the hospital post mastectomy until the follow-up clinic appointment at which all drains are removed, usually in 7-14 days, sometimes as long as 28 or (rarely) 42 days.

5.1.3 Instruments Measuring Study Outcomes

Participants will complete study questionnaires self-reporting pain, pain management, breast symptoms and health related quality of life at three time points (see section 10, Study Calendar). Questionnaires will be answered using pen and paper in the hospital on the first (or second) day post-surgery (T1), at home (T2), or in follow-up clinic after all drains are removed (T3). If participants cannot answer the T3 questionnaire in clinic, a research coordinator will contact the participant to administer the questionnaire within 24 hours of the follow-up appointment via telephone interview or secure file exchange (using the Partners Biscom Delivery Server). Instruments are the following:

Demographic questionnaire (T1)
The questionnaire includes age, language spoken at home, ethnicity, race, marital status, education, and occupational status.

Pain Intensity Numeric Scale (PINS) (T1, T2, T3)
The PINS measures pain intensity with a single item, on a 0-10 scale and is in common clinical use.

Pain Frequency and Pain Intensity Distress (Symptom Distress Scale) (T1, T3)
Two items from the Symptom Distress Scale[25,26] measure pain frequency and pain intensity in the past week, on a 5-point scale.

Patient-Reported Outcomes Measurement Information System (PROMIS®) Pain Intensity (T1, T3)
This 3-item instrument from the PROMIS item bank[27] measures pain intensity over the past week and right now, on a 5-point scale (PROMIS Item Bank v.1.0 – Pain Intensity – Short Form 3a).

Patient-Reported Outcomes Measurement Information System (PROMIS®) Pain Interference (T3)
This 8-item instrument from the PROMIS item bank[27] measures the interference of pain with daily activities and social relations, on a 5-point scale (PROMIS Item Bank v.1.0 – Pain Interference – Short Form 8a).

Pain Management (T2)
Participants will keep a daily pain diary between hospital discharge and follow-up clinic appointment (the T2 period) to document pain intensity, use of pain medications, and whether and how long they wear post mastectomy garments each day.

EORTC QLC-C30 (T3)

The EORTC QLQ- C30[28] is a 30-item questionnaire with 5 functional subscales, global health status quality of life subscale, and 9 symptom subscales/items. The time it takes to complete the questionnaire is approximately 11 minutes. The C30 has been used in over 3000 clinical trials and in 81 languages.[29] Authors of a recent meta-analysis[30] of the C30 performance concluded that all subscales perform reliably except cognitive function, a 2-item subscale assessing memory and concentration. Raw scores for the QLQ-C30 range from 0 to 100 and can be transformed and compared to reference values published in the EORTC QLQ-C30 manual.

EORTC QLQ-BR23 (T3)
The QLQ-BR23 supplementary Breast Cancer Module is comprised of 23 questions in five multi-item scales to assess side effects of surgery, arm and breast symptoms, body image, sexual functioning and future perspective. Cronbach's alpha coefficient results for QLQ-BR23 have been reported at 0.873.[29]

Medical Record Review (T1 and T3)
A member of the study team will record clinical data, such as cancer diagnosis (if any) and surgery details at T1 prior to the participant's hospital discharge, and documentation from the medical record of pain and pain management post-discharge within 1 week after the T3 visit.

5.2 Pre-Treatment Criteria

Not applicable.

5.3 Agent Administration

Not applicable.

5.4 Definition of Dose-Limiting Toxicity (DLT)

Not applicable.

5.5 General Concomitant Medication and Supportive Care Guidelines

Not applicable.

5.6 Criteria for Taking a Participant Off Protocol Therapy

Not applicable.

5.7 Duration of Follow Up

Not applicable.

5.8 Criteria for Taking a Participant Off Study

Participants will be removed from study when any of the following criteria apply:

- Lost to follow-up
- Withdrawal of consent for data submission
- Death
- It is considered to be in the participant's best interest
- The study device or procedures are found to be unsafe or ineffective
- There is any problem with using the study device or following study procedures
- The participant's condition worsens
- A decision is made to close the study
- Or for any other unforeseen reasons that make it necessary to stop the participant's participation in the research study

The reason for taking a participant off study, and the date the participant was removed, must be documented in the case report form (CRF).

For Centralized Subject Registrations, the research team submits a completed Off Treatment/Off Study form to ODQ when a participant comes off study. This form can be found on the ODQ website or obtained from the ODQ registration staff.

6. DOSING DELAYS/DOSE MODIFICATIONS

Not applicable.

7. ADVERSE EVENTS: LIST AND REPORTING REQUIREMENTS

7.1 Adverse Events

7.1.1.1 Adverse Event List for the Jacki Recovery Jacket

The Jacki has not previously been studied, and no adverse events or serious adverse events have been reported to A Little Easier Recovery® or at the enrolling study sites, which have previously provided jackets to some post-operative patients.

Potential adverse events include the following:

1.) A participant wearing the jacket may remove the jacket without first removing the drains from the pockets. This may cause pain and/or the drains to be dislodged, which would require a trip to the hospital to have them re-inserted. It could also lead to a greater risk of infection at the site of the drains.
2.) A participant wearing the jacket may become too warm in warm weather or may develop a skin reaction to the jacket, which is made of 50% cotton and 50% polyester.

7.2 Adverse Event Characteristics

Adverse events are not graded.

7.3 Expedited Adverse Event Reporting

7.3.1 Investigators **must** report to the Overall PI any adverse event that occurs while the subject is on study. The event must be reported to the Overall PI within 24 hours.

7.4 Routine Adverse Event Reporting

All Adverse Events **must** be reported in routine study data submissions to the Overall PI on the clinical data forms. **AEs reported through expedited processes must <u>also</u> be reported in routine study data submissions.**

8. PHARMACEUTICAL AND/OR IMAGING AGENT INFORMATION

Not applicable.

9. BIOMARKER, CORRELATIVE, AND SPECIAL STUDIES

Not applicable.

10. STUDY CALENDAR

Measure	Inpatient Post Mastectomy (T1)	At Home Post-Discharge (T2)	Follow-up Clinic Appointment (T3)
Participant Demographics	X		
Pain Intensity Numeric Scale (0-10)	X	X	X
Pain Frequency and Intensity Symptom Distress Scores	X		X
Health Related Quality of Life			X
Breast Symptoms			X
Pain Management		X	
Post-Discharge Pain, Pain Management, Complications (Documented in Electronic Medical Record)			X
Participant Clinical Characteristics (Diagnosis, Treatment Regimen			

Documented in the Medical Record)			

T1: First (or second) day post mastectomy, during inpatient stay
T2: Exclusive of day discharged and day of follow-up when all drains are removed, daily for 7-42 days
T3: Day of follow-up clinic appointment when all drains are removed

11. MEASUREMENT OF EFFECT

11.1 Antitumor Effect – Solid Tumors

Not applicable.

11.2 Antitumor Effect – Hematologic Tumors

Not applicable.

11.3 Other Response Parameters

Other endpoints include pain, breast cancer symptoms, and health related quality of life and are measured as described in section 5.

12. DATA REPORTING / REGULATORY REQUIREMENTS

Adverse event lists, guidelines, and instructions for AE reporting can be found in Section 7.0 (Adverse Events: List and Reporting Requirements).

12.1 Data Reporting

12.1.1 Method

The Dana-Farber research study team will collect, manage, and perform quality checks on the data for this study.

12.1.2 Responsibility for Data Submission

Investigative sites within DF/HCC or DF/PCC are responsible for submitting data and/or data forms to the Dana-Farber research study team according to the schedule set by the Dana-Farber research study team. All data will be submitted within 10 days of the participant's T3 appointment.

12.2 Data Safety Monitoring

The PI will monitor the study, including review of study conduct, enrollment, adverse events with prompt reporting of AEs and other study-related information to the IRB, sponsor, and other agencies as appropriate. Good Clinical Practice (GCP) will be followed for conduct of the study and modifications; deviations will be reported to the IRB, along with an annual status report as per IRB guidelines.

12.3 Multicenter Guidelines

Not applicable.

12.4 Collaborative Agreements Language

Not applicable.

13. STATISTICAL CONSIDERATIONS

13.1 Study Design/Endpoints

The study is a randomized trial of the Jacki recover jacket versus usual care for post-discharge pain management in patients who received mastectomy with reconstructive surgery in one or both breasts. All participants will complete questionnaires measuring pain, pain management, breast symptoms, and health-related quality of life (Appendix A). Questionnaires will be completed at three time points: pre-discharge (T1), at home over approximately 7-14 (up to 42) days (T2), and at follow-up clinic when all drains are removed (T3). Participants will receive usual pain management or the Jacki plus usual pain management post-discharge. Clinical data will be collected by a member of the research study team using a clinical data form.

13.2 Sample Size, Accrual Rate and Study Duration

The primary objective of this study will be to compare pain intensity (measured on the 0-10 scale, PINS) at the follow-up clinic appointment when all drains are removed (T3) between those randomized to UC or Jacki groups. A reduction of 1.0 on the PINS is thought to be clinically significant. With a sample size of 130 there is 80% power to detect a 1-point difference in PINS between UC and Jacki groups using a Wilcoxon rank sum test at the 2-sided 0.1 significance level assuming a standard deviation of 2.2 from

the preliminary study. The following table depicts the impact on power if the standard deviation at the follow-up visits is smaller or larger than estimated.

Standard Deviation	Power
1.8	91%
2.0	86%
2.2	80%
2.4	74%
2.6	68%

With a projected 13% rate of attrition, a total of 149 participants enrolled will yield an analytic sample of 130 evaluable participants. This number of participants will be accrued and will complete data collection within 10 months, based on clinical volume .

Accrual Targets					
Ethnic Category	**Sex/Gender**				
	Females		**Males**		**Total**
Hispanic or Latino	39	+	0	=	39
Not Hispanic or Latino	91	+	0	=	91
Ethnic Category: Total of all subjects	130	+	0	=	130
Racial Category					
American Indian or Alaskan Native	0	+	0	=	0
Asian	6	+	0	=	6
Black or African American	13	+	0	=	13
Native Hawaiian or other Pacific Islander	0	+	0	=	0
White	111	+	0	=	111
Racial Category: Total of all subjects	130	+	0	=	130

No interim analyses are planned due to the short duration, minimal risk, and minimal burden of the study. There are no early stopping rules.

13.3 Stratification Factors

Randomization will be stratified by enrolling hospital and unilateral vs bilateral mastectomy following a permuted block randomization supplied by the statistician.

13.4 Interim Monitoring Plan

Data and safety monitoring is described in section 12.

13.5 Analysis of Primary Endpoints

All randomized patients will be included in all analyses. Minimal missing data is expected; therefore, in the event of missing data, no imputation will be performed. The analyzable sample for the primary endpoint includes participants who are randomized and have reported a pain score at T3 regardless of intervention use. The primary endpoint is pain intensity measured on the 0-10 scale at the follow-up clinic appointment (T3). The pain score will be summarized at each time point and plotted. The T3 pain score will be compared between UC and Jacki groups using a Wilcoxon rank sum test. Due to the nature of the pain measure (i.e., integers on a 0-10 scale), there will be ties in pain score, and the number of ties could affect the performance of the non-parametric test. Depending on the structure of the data, a t-test may be considered with a possible transformation. Assumptions will be examined and a method selected prior to testing.

Additionally an analysis of covariance (ANCOVA) approach may be considered. Factors that may be associated with the T3 pain score (baseline score, time since discharge, unilateral vs bilateral mastectomy, number of post-surgical drains, neoadjuvant chemotherapy, axillary lymph node dissection, pain management at home with pain medication, and post mastectomy clothing) will be assessed univariately and then adjusted in a multivariable model. The change in pain over time will also be evaluated using linear mixed models.

13.6 Analysis of Secondary Endpoints

Other secondary endpoints include other pain measures, breast cancer symptoms, and HRQOL which will be measured as described in sections 5 and 10. Scoring and handling of missing data will follow the user manual for the EORTC QLQ-C30 and QLQ-BR23. Analyses conducted at the final time point will be consistent with the analyses described in section 13.5. The change from discharge (T1) to follow-up (T3) will also be evaluated for all secondary measures that are measured at both timepoints.

13.7 Reporting and Exclusions

13.7.1 Evaluation of Toxicity

Not applicable.

13.7.2 Evaluation of the Primary Efficacy Endpoint

Efficacy will be established if a statistically significant difference of 1.0 or greater on the PINS is detected.

14. PUBLICATION PLAN

The results should be made public within 24 months of reaching the end of the study. The end of the study is the time point at which the last data items are to be reported, or after the outcome data are sufficiently mature for analysis, as defined in the section on Sample Size, Accrual Rate and Study Duration. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. A full report of the outcomes should be made public no later than three (3) years after the end of the study.

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APPENDIX A PARTICIPANT QUESTIONNAIRES

Participant Information Form

For each of the following questions, please write your answer in the space provided or **circle the number** for the appropriate response.

Age: _____ (on your last birthday)

Ethnicity:
1 = Hispanic/Latino
2 = Not Hispanic/Latino
3 = Prefer not to answer

Race:
(Circle 1 or more)
1 = White/Caucasian
2 = Black/African American
3 = Native American/Alaska Native
4 = Native Hawaiian/Pacific Islander
5 = Asian
6 = Prefer not to answer

Language you speak at home:
(Circle 1 or more)
1=English
2=Spanish
3=Other: _____

Marital status:
1 = Single, never married
2 = Married/partnered
3 = Separated, divorced, or widowed

Education:
(Highest level)
1 = Grade school
2 = Some high school
3 = High school graduate or G.E.D
4 = Some college, business or technical school
5 = College graduate
6 = Post-graduate degree
7 = Prefer not to answer

Work status:
1 = Retired
2 = Working part-time
3 = Working full-time
4 = Unemployed
5 = Homemaker
6 = Student
7 = Disability
8 = Other: _____

Reduction of Post Mastectomy Pain with the Jacki® Recovery Jacket: Randomized Trial

QUESTIONNAIRE 1

Thank you

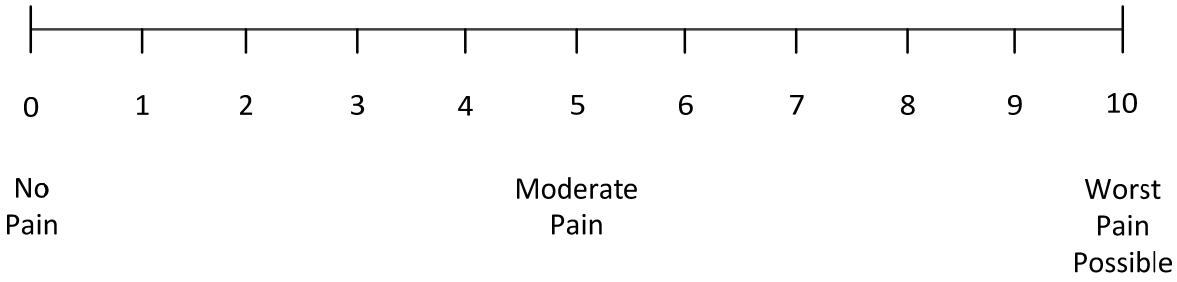
Thank you in advance for filling out this questionnaire, which asks about your pain level after your recent surgery.

All of your answers will be kept private, and you can skip any questions that you do not feel comfortable answering. Skipping questions will not affect your treatment in any way.

We hope to learn more about patient's experiences and how better to manage pain in patients after surgery.

When you are finished, please give the questionnaire to the research study coordinator.

Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



Think about what each statement says, then choose the one statement that most closely indicates how you have been feeling during the past week including today.

Pain Frequency

1. I almost never have pain
2. I have pain once in a while
3. I have pain several times a week
4. I am usually in some degree of pain
5. I am in some degree of pain almost constantly

Pain Intensity

(If you had no pain during the past week, please choose the first answer.)

1. When I have pain, it is very mild
2. When I do have pain, it is mildly distressing
3. When I do have pain, it is fairly intense
4. The pain I have is very intense
5. The pain I have is almost unbearable

Please respond to each item by marking one answer per row.

In the past 7 days...	Had no pain	Mild	Moderate	Severe	Very severe
How intense was your pain at its worst?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How intense was your average pain?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	No pain	**Mild**	**Moderate**	**Severe**	**Very severe**
What is your level of pain right now?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Reduction of Post Mastectomy Pain with the Jacki® Recovery Jacket: Randomized Trial

QUESTIONNAIRE 3

Thank you

Thank you in advance for filling out this questionnaire, which asks about your pain level after your recent surgery, other side effects, and how you feel about your body and appearance.

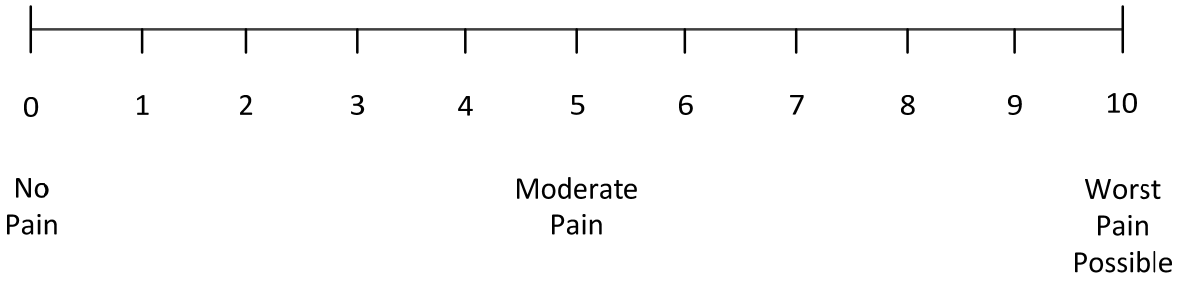
For questions that ask about the "past week" or "past 7 days," please think about the time since you left the hospital after your surgery, even if it has been slightly more or less than one week.

All of your answers will be kept private, and you can skip any questions that you do not feel comfortable answering. Skipping questions will not affect your treatment in any way.

We hope to learn more about patient's experiences and how better to manage pain in patients after surgery.

When you are finished, please give the questionnaire to the research study coordinator.

Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



Think about what each statement says, then choose the one statement that most closely indicates how you have been feeling during the past week including today.

Pain Frequency

6. I almost never have pain
7. I have pain once in a while
8. I have pain several times a week
9. I am usually in some degree of pain
10. I am in some degree of pain almost constantly

Pain Intensity

(If you had no pain during the past week, please choose the first answer.)

6. When I have pain, it is very mild
7. When I do have pain, it is mildly distressing
8. When I do have pain, it is fairly intense
9. The pain I have is very intense
10. The pain I have is almost unbearable

Please respond to each item by marking one answer per row.

In the past 7 days...	Had no pain	Mild	Moderate	Severe	Very severe
How intense was your pain at its worst?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How intense was your average pain?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	No pain	**Mild**	**Moderate**	**Severe**	**Very severe**
What is your level of pain right now?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with work around the home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your ability to participate in social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your household chores?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with things you usually do for fun?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your enjoyment of social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your enjoyment of life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your family life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

If there is anything else you would like to tell us about your pain and pain relief since you left the hospital, please write your comments here: _____

_____

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall <u>health</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall <u>quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
31. Did you have a dry mouth?	1	2	3	4
32. Did food and drink taste different than usual?	1	2	3	4
33. Were your eyes painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	1	2	3	4
36. Did you feel ill or unwell?	1	2	3	4
37. Did you have hot flushes?	1	2	3	4
38. Did you have headaches?	1	2	3	4
39. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
40. Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
41. Did you find it difficult to look at yourself naked?	1	2	3	4
42. Have you been dissatisfied with your body?	1	2	3	4
43. Were you worried about your health in the future?	1	2	3	4

Du ring the past <u>four</u> weeks:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
44. To what extent were you interested in sex?	1	2	3	4
45. To what extent were you sexually active? (with or without intercourse)	1	2	3	4
46. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	1	2	3	4

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
47. Did you have any pain in your arm or shoulder?	1	2	3	4
48. Did you have a swollen arm or hand?	1	2	3	4
49. Was it difficult to raise your arm or to move it sideways?	1	2	3	4
50. Have you had any pain in the area of your affected breast?	1	2	3	4
51. Was the area of your affected breast swollen?	1	2	3	4
52. Was the area of your affected breast oversensitive?	1	2	3	4
53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	1	2	3	4

Reduction of Post Mastectomy Pain with the Jacki® Recovery Jacket: Randomized Trial

QUESTIONNAIRE 2

Thank you

Thank you in advance for filling out this daily diary questionnaire, which asks about your pain, medications for pain, and clothing you wear each day at home after your surgery until you return for your follow-up appointment. Please answer the daily diary questionnaire **at the end of each day**.

All of your answers will be kept private, and you can skip any questions that you do not feel comfortable answering. Skipping questions will not affect your treatment in any way.

We hope to learn more about patient's experiences and how better to manage pain in patients after surgery.

Please bring the daily diary questionnaire to your follow-up appointment and give the questionnaire to the research study coordinator.

DAY 1 *(The day AFTER you leave the hospital)* Day of the Week _____

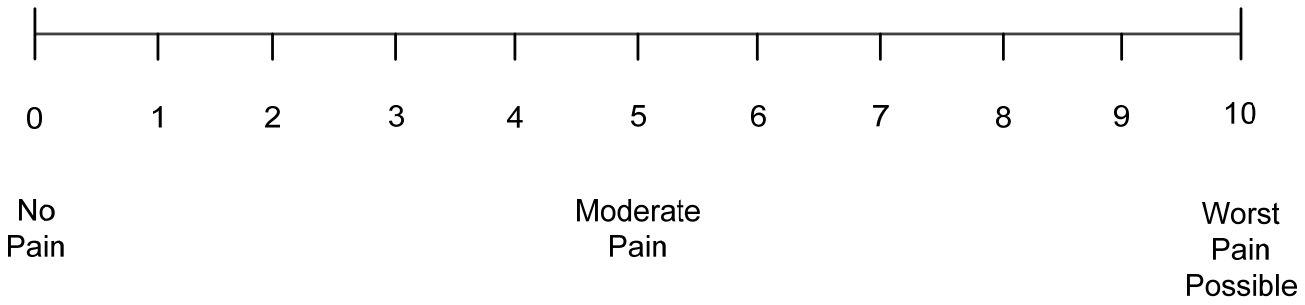
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 2 Day of the Week_____

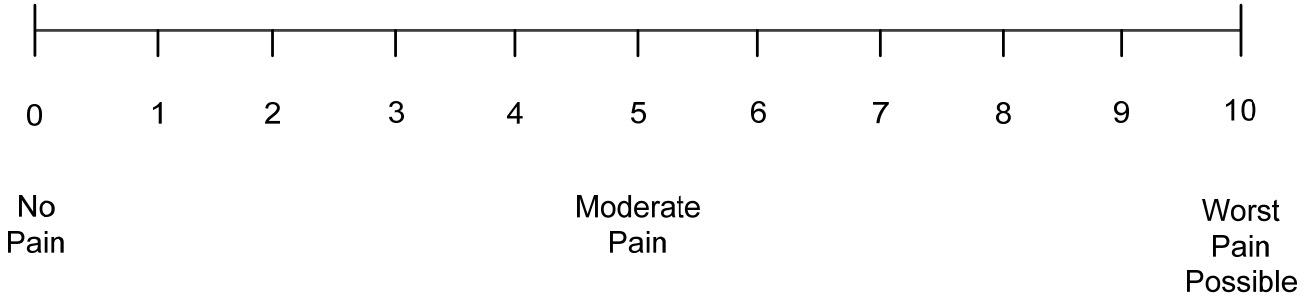
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 3 Day of the Week _____

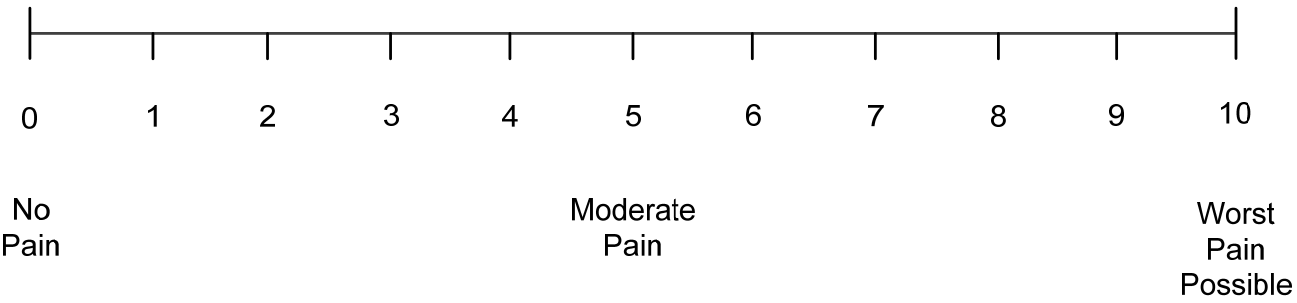
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 4 Day of the Week_____

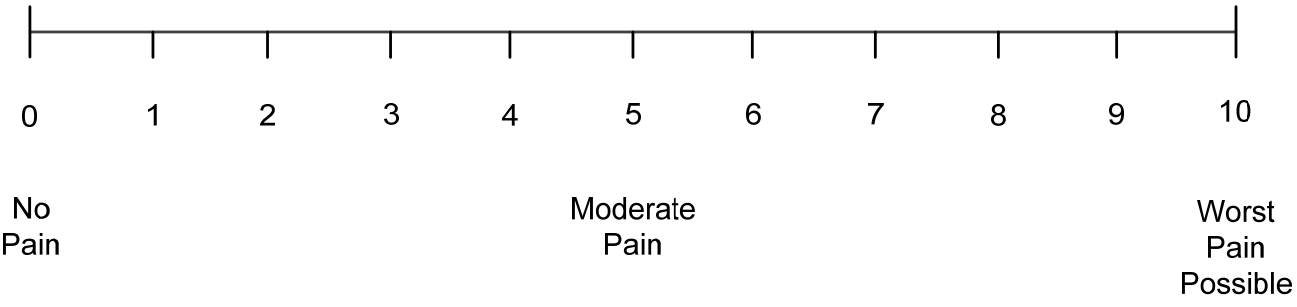
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 5 Day of the Week _____

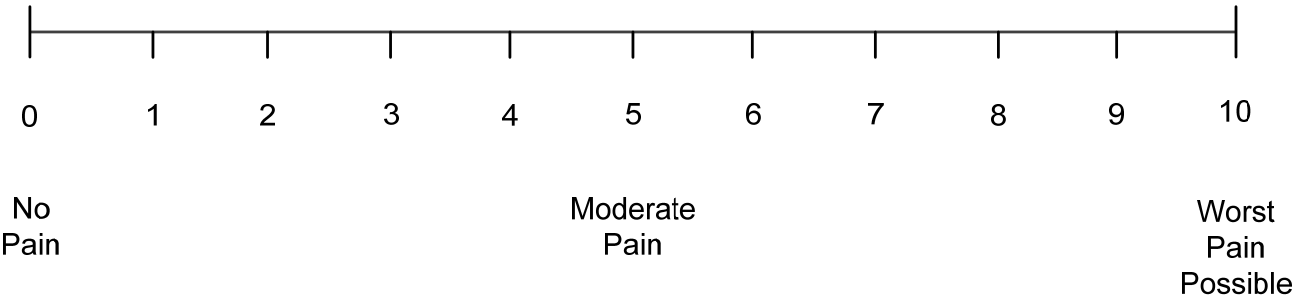
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 6 Day of the Week _____

1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.

No Pain — Moderate Pain — Worst Pain Possible

DAY 7 Day of the Week _____

1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Moderate Pain — Worst Pain Possible

DAY 8 Day of the Week _____

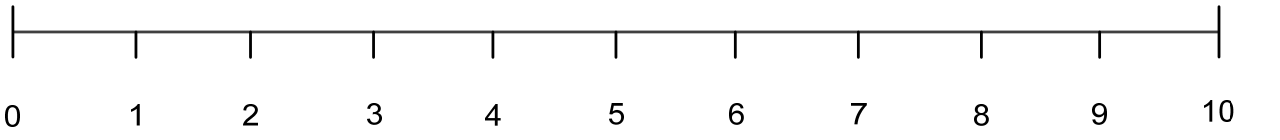
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 9 Day of the Week _____

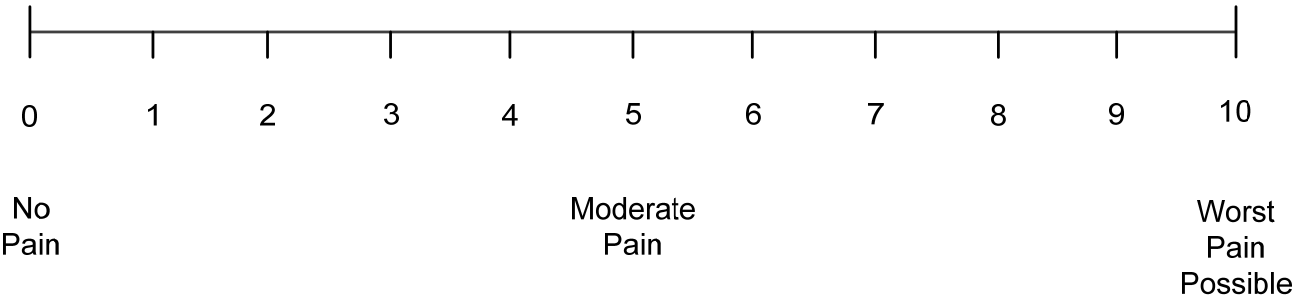
1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.



DAY 10 Day of the Week _____

1. Please enter each **pain medication** you take throughout the day. If you don't recall the time or number of pills/ tablets for any time you took a pain medication, please enter "unsure".

Time of Day	Name of Pain Medication	Number of Pills/ Tablets	Dose per Pill/Tablet*
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg
AM/PM			mg

2. *Answer at the end of the day:* Did you wear any of the following **clothing** today?

Clothing Type	Worn? (circle your answer)	If Yes, Number of Hours Worn
Jacki® recovery jacket	Yes No	
Mastectomy bra	Yes No	
Mastectomy camisole or tank top	Yes No	

3. *Answer at the end of the day:* Please rate **today's pain or discomfort** on a scale of 0-10 by circling one of the numbers below, where 0 means no pain or discomfort and 10 is the worst you could imagine.