

**THE EXPERIENCE OF EVERYDAY CANCER-RELATED EVENTS AS A
PREDICTOR OF FEAR OF RECURRENCE IN WOMEN WITH EARLY-
STAGE BREAST CANCER**

Elizabeth C. Pasipanodya

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Psychology

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PREDICTOR OF FEAR OF RECURRENCE IN WOMEN WITH EARLY-
STAGE BREAST CANCER**

by

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ABSTRACT

Fear of recurrence (FOR) is a common survivorship concern, even years after initial breast cancer diagnosis. Although past research has identified predictors of FOR, these predictors have largely been immutable demographic or disease/treatment-related factors examined almost exclusively in cross-sectional studies. However, cognitive formulations of FOR hold that cancer-related stimuli (both external and internal) exhibit day-to-day variability and induce coping responses that in turn explain within-person variability in FOR. Consequently, the aim of this study was to investigate predictors of daily variability in FOR, focusing on patients' daily experiences of both internal (e.g., the experience of physical symptoms) and external (e.g., receiving communications related to cancer treatment) cancer-related stimuli and their coping responses. Seventy-two women with recent diagnoses of breast cancer completed an initial cross-sectional questionnaire soon after surgery, as well as an online diary for 21 consecutive days at the completion of adjuvant treatment. Multilevel modeling suggested that the daily experience of cancer-related events influenced their experience of FOR, primarily through intrusive thoughts. These findings help to expand our knowledge of predictors of FOR in the everyday lives of cancer survivors.

Chapter 1

INTRODUCTION

Recent estimates indicate that about 29% of new cancer diagnoses are of breast cancer (American Cancer Society, 2013). Fortunately, through better treatment and early detection, the U.S. has experienced steady declines in mortality and higher survival rates since 1989 such that most women diagnosed with breast cancer successfully complete treatment and transition to becoming survivors of cancer (American Cancer Society, 2013). However, despite the increasingly favorable prognoses for women diagnosed with breast cancer, one of the most frequently cited ongoing survivorship concerns is a fear of the cancer's recurrence (e.g., Schlairet, Heddon, & Griffis, 2010).

While the core of fear of recurrence (FOR) is a worry that the malignancy will return in the same organ or in another part of the body, FOR is construed to be multi-dimensional with cognitive and emotional components encapsulating concerns about health, role changes, treatment, and death (Park, Cho, Blank, & Wortman, 2013; Simard & Savard, 2009; Vickberg, 2003). It has been suggested that the distress associated with FOR may have negative effects on long-term quality of life (Lee-Jones et al., 1997). Indeed, FOR has been linked consistently to maladjustment in cross-sectional research with findings indicating that higher FOR in breast cancer survivors is associated with significantly higher emotional distress (Stanton, Danoff-burg, & Huggins, 2002), lower well-being (Vickberg, 2003), and interpersonal problems (Stefanek, Shaw, DeGeorge, & Tsottles, 1989).

Reviews of the empirical literature show that the most consistent and robust predictors of FOR have tended to be those that are relatively immutable, including variables such as younger age, female gender, and cancer severity (Davis-Ali, Chesler, & Chesney, 1993; Kim, Carver, Spiller, Love-Ghaffari, & Kaw, 2012; Vickberg, 2003). Studies of the course of FOR over time have generally found that it is common, stable, and persists for a long time after initial diagnosis (Deimling, Bowman, Sterns, Wagner, & Kahana, 2006; Hodgkinson et al., 2007). However, despite the ubiquity of FOR, research shows that not all individuals with cancer experience FOR to the same extent. Some experience FOR minimally, or as a normal reaction to a stressful and potentially life-threatening event, while others experience FOR to a clinically significant degree (Simard, Savard, & Ivers, 2010). Indeed, as substantial individual variability exists in FOR as a reaction to cancer diagnosis, it is imperative to identify factors and mechanisms that can contribute to adaptive survivorship versus long-term maladjustment for women with breast cancer.

1.1 Understanding FOR Using the Common Sense Model (CSM) of Illness

Some of the sources of individual variability in FOR after a cancer diagnosis may lie in each individual's understanding of their disease (i.e., in how they perceive and interpret their cancer experience). Leventhal's Common Sense Model of Illness (CSM; Brownlee, Leventhal, & Leventhal, 2000; Leventhal, Meyer & Nerenz, 1980) provides a framework to describe how, when activated, an individual's representation of an illness influences coping behaviors and it has been utilized to explain variability in an individual's responses and outcomes following a health threat. The central tenet of Leventhal's model (1980) is that individuals hold distinct and idiosyncratic beliefs,

or representations, of their illnesses that influence coping responses and, in turn, influence emotional or behavioral outcomes. Indeed, patients may have quite different understandings of the nature of their breast cancer, its characteristic symptoms, time course with regards to acuity or chronicity, consequences, causes, and potential for cure. Beliefs pertaining to these factors can then influence patients' perceptual experiences following a health threat. Additionally, these illness representations, recruited coping responses, and outcomes are not static features; rather, they can change dynamically over the course of illness (e.g., Kaptein et al., 2010).

Delving into the CSM, Leventhal et al. (1980) postulate that illness representations are derived from various abstract and concrete sources of information. The first two sources of information--a previously incorporated general pool of 'lay' information and a pool derived from friends, family, media, and authoritative resources--are externally-derived sources of information. The third source of information, however, is derived from one's own current experience of the illness, such as the experience of somatic sensations and physical symptoms. Taken together, the main premise of the CSM is that illness representations and their indicators (e.g., experience and interpretation of physical symptoms) are related to coping efforts, and via these coping efforts, have an influence on outcomes (e.g., emotional states, mental expectations, and specific actions).

Consistent with the CSM, Lee-Jones and colleagues (1997) proposed a cognitive formulation of FOR in which stimuli (both external and internal) function as indicators of illness representations and play a role in activating processes and coping responses associated with FOR. They suggested that the experience of somatic sensations and physical symptoms may serve to remind patients of their cancer, or be

interpreted as signs of the cancer's impending return. Likewise, common reminders associated with the cancer, such as medical appointments, conversations with others, or everyday chance exposures to reports of cancer in the media may serve to increase worry and thoughts about possible recurrence (Easterling & Leventhal, 1989; Lee-Jones et al., 1997; Northouse, 1981). As such, inherent to the CSM is that current lived experience influences illness representations and, subsequently, emotional and behavioral outcomes.

Although there is good extant evidence (for a review, see Simard et al., 2013) linking the experience of physical symptoms with levels of FOR (consistent with Lee-Jones' formulation and the CSM) this evidence has been derived almost exclusively from cross-sectional studies that do not capture the intra-individual variability that likely exists when FOR is examined over time within a person. Separating between-person and within-person effects is conceptually important because relations between mean levels, or between individuals, do not necessarily generalize to the relations found in fluctuations within-person that may occur on a daily basis. An example of differential patterns of findings within- and between-person can be illustrated by physiological responses such as changes to blood pressure (BP). When examined between-person, individuals who exercise are also those most likely to have lower BP. However, within each individual, fluctuations in BP around the mean level occur in response to environmental factors, including exercise (Ryu, West, & Sousa, 2012). Assuming between and within-person effects to be the same risks committing an ecological fallacy (Robinson, 1950), where the link between two variables at a group level (mistakenly) is assumed to be the same at the individual level.

Although frequently evaluated using cross-sectional methods, the CSM is a model that is implicitly within-person as is-- reflected in its assertion that an individual's illness representations affect that same individual's well-being and behavior. Nevertheless, there is a need to examine predictions from the model focusing on within-person effects explicitly. As such, it is an as yet unexamined question how day-to-day levels of FOR fluctuate around a person's mean level in response to illness stimuli that are part and parcel of the vicissitudes of everyday life. Beyond conceptual value, focusing on within-person effects has greater clinical implications, as within-person linkages are more amenable to translation into the level of analysis needed for strong interventions. Therefore, one of the aims of this study was to investigate predictors of daily within-person variability in FOR, focusing on patients' daily experiences of internal and external cancer stimuli (i.e., the experience of physical symptoms and cancer-related events).

1.2 Mediating Processes in the CSM

As outlined previously, one of the tenets of the CSM is that the causal relationship between illness stimuli and distal outcomes is mediated by coping processes. Evidence from a meta-analysis of empirical studies adopting the CSM supports this supposition, as significant relations have been found between aspects of illness identity and the use of coping strategies such as avoidance, emotion expression, and problem-focused coping (Hagger & Orbell, 2003). Additionally, features of illness perceptions were also found to be related to social functioning and psychological distress (although none of the reviewed studies directly tested the mediation process of illness perceptions → coping → outcomes). Moreover, it should also be noted that

previous examinations of the mediating processes in the CSM have largely focused on cross-sectional associations.

Of particular interest in the present study were the possible roles that both interpersonal and intrapersonal coping variables would play as putative mediators of the relationship between daily cancer-related stimuli and FOR. One intrapersonal mediating factor we considered was engagement in emotional approach coping. The adaptive nature of emotional processing and expression is widely accepted and has received much empirical support (for a review, see Smyth & Pennebaker, 1999). A number of extant studies have examined how emotional approach coping, which involves coping through actively processing and expressing emotions, can influence adjustment to health adversities. For instance, in a cross-sectional study of patients with myofascial pain, Smith et al. (2002) found fewer reports of sensory and affective pain to be related to greater emotional approach coping. They also found higher reports of emotional approach coping to be related to lower levels of distress. In the area of breast cancer research, Stanton and colleagues (2000) found that women reporting greater emotional expressivity at one time-point reported experiencing fewer cancer-related symptoms later on than women who endorsed less emotional receptivity at the first assessment. Additionally, emotional expressivity interacted with the extent of social receptivity of their environments such that women who reported greater emotional expression in social environments that were more encouraging of disclosures about breast cancer derived the most adjustment-related benefit. As such, coping via emotional approach may be more beneficial when it occurs in a receptive social environment.

Relatedly, an aspect of the interpersonal environment that may have relevance as a feature of coping is the presence and extent of social constraints on disclosure of cancer-related thoughts and feelings. Social constraints are defined as objective or perceived interpersonal factors, such as withdrawal, criticizing, or silencing from the social environment, that limit a person's disclosure of thoughts and feelings related to a stressor (Lepore & Revenson, 2007). The Social Cognitive Model of Processing (Lepore, 2001) predicts that the presence of social constraints interferes with adjustment to cancer and increases the experience of FOR because social constraints are believed to interrupt cognitive processing by inhibiting personal disclosure and preventing integration of the stressful event. As social constraints on disclosure can deter discussion and inhibit subsequent cognitive processing, this can lead to negative changes in how individuals think and talk about cancer as well as to negative changes in how they cope with their illness (Lepore & Revenson, 2007). Conversely, the facilitation of exposure and processing, in an accommodating social environment, can shape thoughts or help find meaning following stressful events (Clark, 1993).

Indeed, evidence points to the necessity of open disclosure of thoughts and feelings to significant others when coping with the diagnosis and treatment of cancer. For instance, social constraints have been associated with lower relationship satisfaction, greater depression, and lower emotional well-being among women with breast cancer (Cordova, Cunningham, Carlson, & Andrykowski, 2001; Donovan-Kicken, & Caughlin, 2010) as well as their spouses/partners (Pasipanodya et al., 2012). Social constraints have also been associated with increases in avoidance of negative thoughts about illness (Schnur et al., 2004; Zakowski, Ramati, Morton, Johnson, & Flanigan, 2004) and greater levels of general and disease-related distress (Schnur et

al., 2004). Consequently, social constraints were hypothesized to be a relevant variable in a CSM of illness stimuli and FOR.

While not a coping action taken per se, an important factor we also considered was the presence of intrusive thoughts, defined as unwanted and unpleasant thoughts, images, memories, or dreams of a stressful event (Horowitz, 1986) as intrusive thoughts may be an intermediary in the relationship between activating stimuli and subsequent FOR. Intrusive thoughts are frequent complaints among cancer patients, particularly in the early-stages of cancer diagnosis and treatment, and they have been associated with the experience of FOR (Mehnert, Berg, Henrich, & Herschbach, 2009; Simard, Savard, & Ivers, 2010).

Intrusive thoughts are presumed to be aspects of coping arising from the cognitive processing of stressful experiences (Horowitz, 1986). According to cognitive processing models of adjustment, distress arises after difficult events because they challenge preexisting views of the self and the world. Adaptation to such events requires incorporation of the experiences either by changing one's view of the world or by changing one's view of the events to maintain congruence with existing mental models (Horowitz, 1986). The process of incorporation is believed to involve alternating cycles of intrusions and avoidance, which gradually subside with assimilation. In the early stages of a stressor, intrusive thoughts may be adaptive as they bring aspects of the stressor to awareness, facilitating processing, emotional expression, and eventual integration of the experience; however, if intrusive thoughts become prolonged because of avoidance, they become indicators of incomplete processing and are linked to maladjustment (Lepore, Silver, Wortman, & Wayment, 1996).

Regarding intrusive thoughts and the CSM, Jim et al. (2007) found greater reports of physical symptoms/side effects experienced during cancer treatment (radiation and/ chemotherapy) were associated with higher levels of intrusive thoughts months later. They additionally found the relationship between physical symptoms/side effects and general distress to be mediated by intrusive thoughts. As such, intrusive thoughts were a plausible mediator to include in the relationship between cancer-related stimuli and FOR. Figure 1.1 depicts a conceptual CSM model of daily FOR with proposed mediators.

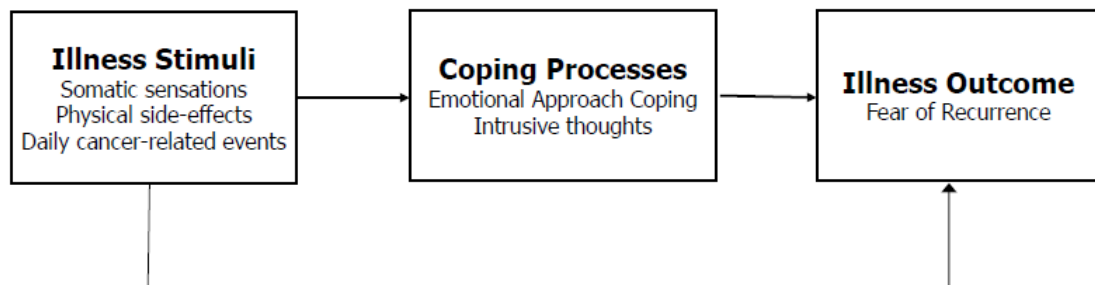


Figure 1.1. Conceptual model of study variables drawn from the Common Sense Model (adapted from Hagger & Orbell, 2010).

1.3 Between-Person Relationships in the CSM of FOR

Our within-person model was separate from the examination of between-person effects in its motivation to examine how changes in individuals' daily perceptual experiences would relate to their daily FOR. However, it was also of some interest to examine how average daily predictors in our model would influence average daily FOR (i.e., replicate cross-sectional findings linking illness stimuli and

coping responses to FOR). Furthermore, as the CSM acknowledges that previously incorporated information and held beliefs (which may be trait-like features of the individual) are also relevant to the interpretation of on-going experiences (Leventhal et al., 1980), a more complete model may be one that additionally examines how between-person variables may moderate the relationship between illness stimuli and downstream FOR. In order for a variable to be a moderator of effects, it should ideally be a baseline characteristic that has an interactive effect with a predictor on an outcome and, as such, help explain individual differences in the effect of the predictor (Kraemer, Wilson, Fairburn, & Agras, 2002).

Cross-sectional research has robustly found younger age at diagnosis to be associated with greater FOR and maladjustment (Simard, 2013; Vinokur, Threatt, Vinokur-Kaplan, & Satariano 1990). This is likely because, from a life-stage perspective, younger women experience greater challenges in adapting to the unexpectedness of a cancer diagnosis or the developmental prematurity of a chronic illness (Mor, Malin, & Allen, 1994). Other factors that have consistently been associated with FOR are illness intrusiveness (defined as the extent to which a disease and/or its treatment interfere with activities in important life domains), beliefs regarding perceived risk of future cancer recurrence, and trait anxiety (Devins, 2010; Simard, 2013; Lebel, Beattie, Ares, & Bielajaw, 2013). As age, beliefs with regards to degree of illness intrusiveness in daily life, trait worry, and risk perception can be considered baseline characteristics (when measured early during cancer treatment), and it was of interest to examine them as moderators of the relationship between illness stimuli and subsequent FOR. We hypothesized that it would be the case that older women who experienced less functional impairment after surgery, were less

anxious on average, and held less inflated perceptions of personal risk of future cancer would interpret internal and external illness stimuli less threateningly and be subsequently less affected by cancer-related stimuli.

1.4 The Present Study

Despite the known variability in individuals' experiences of FOR and the dynamic processes that likely underlie coping with an ongoing health concern, few studies have assessed the role of daily-experienced events that would purportedly act as triggers of FOR. Consequently, this study sought to examine the effects of perceived somatic experiences and cancer-related events as daily influences on FOR as well as probe for theoretically-motivated mechanisms through which daily-experienced somatic and cancer-related events exert their influence on concerns about cancer recurrence.

Both empirical (King, Kenny, Schiel, Hall, & Boyages, 2000) and anecdotal (McKinley, 2000) evidence suggest that FOR emerges soon after the end of acute and adjuvant therapy when patients, accustomed to regular care from nurses and physicians, transition to the uncertainty of survivorship. Therefore, we recruited women coping with early-stage breast cancer soon after surgery and began assessing their daily FOR immediately after the end of adjuvant therapy, reasoning this to be an appropriate interval of time to assess symptoms of incipient FOR.

We utilized an intensive longitudinal methodology (Bolger, Davis, & Rafaeli, 2003; Bolger & Laurenceau, 2013) where patients at the end of each day provided reports of their extent of fear of recurrence, social constraints on disclosure of cancer-related thoughts, intrusive thoughts, as well as the occurrence of cancer-related

negative events and physical symptoms. The daily diary methodology allowed us to obtain more reliable (due to repeated assessments) and less biased (due to minimizing retrospective recall) indices of FOR and its predictors (Bolger et al., 2003; Laurenceau & Bolger, 2005; Shiffman, Stone, & Hufford, 2008). A daily diary study also allowed us to examine the day-to-day links between cancer stimuli (i.e., the experience of physical symptoms and cancer-related events), coping processes, and FOR as well as the between- and within-subject variables that potentially moderated relationships in the proposed model. Additionally, we used an electronic daily diary survey as, unlike paper and pencil measures, electronic diaries provide date/time stamps and enable researchers to assess compliance with study procedures.

This study examined: (1) the extent to which patient's reports of experiencing cancer-related stimuli (i.e., their reports of physical symptoms and negative cancer-related events) predicted their daily FOR, independently of their experience of daily negative affect; (2) whether the relationship between cancer-related stimuli and FOR was mediated by coping processes; and (3) whether the link between cancer-related stimuli and FOR was moderated by demographic and baseline disease-/treatment-related variables assessed earlier on in the cancer-treatment phase.

The specific hypotheses tested in this study, and summarized in Figure 1.2, were:

A. Patient daily reports of experiencing cancer-related stimuli were expected to be positively associated with daily FOR, even after controlling for the experience of daily negative affect.

B. i) The occurrence of daily cancer stimuli was expected to be associated with increased emotional approach coping. However, emotional approach coping would be

negatively associated with daily FOR. Additionally, emotional approach coping would mediate the within-person relationship between daily cancer-related stimuli and daily FOR.

ii) Daily intrusive thoughts would be positively associated within-person with both cancer stimuli and daily FOR. Additionally, intrusive thoughts would mediate the within-person relationship between daily cancer-related stimuli and daily FOR.

C. At the between-person level, younger age, greater average daily illness stimuli, greater baseline illness intrusiveness, greater trait anxiety, and greater perceived risk of future cancers, would be associated with greater average daily FOR. Furthermore, the link between daily cancer-related stimuli and coping responses would be moderated by demographic and baseline disease-/treatment-related variables assessed earlier on in the cancer-treatment phase such that individuals of younger age, with greater perceptions of personal risk of cancer recurrence, greater trait anxiety, and greater illness intrusiveness at baseline would report greater recruitment of coping responses and, subsequently, greater daily FOR.

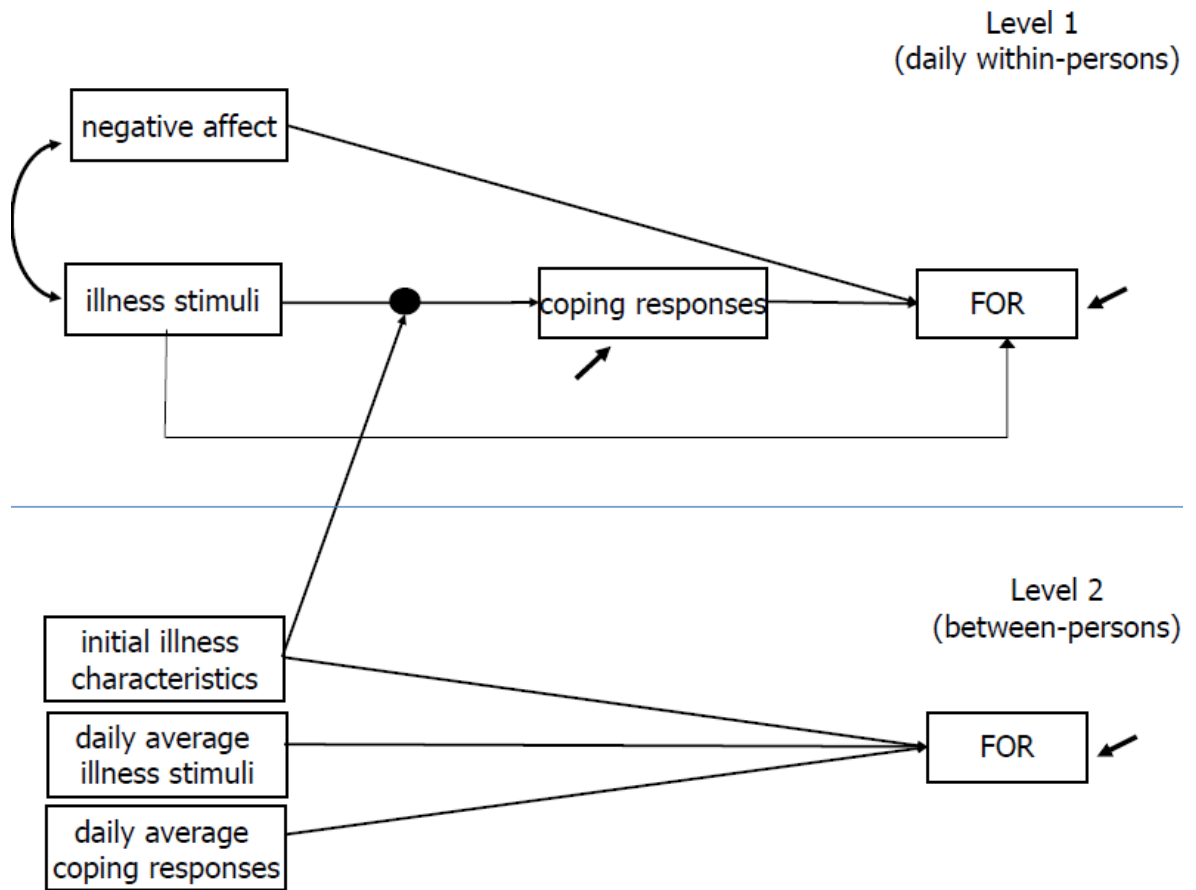


Figure 1.2. Multilevel path diagram depicting the proposed statistical model. The closed black circle indicates a random slope, while the arrow pointing towards it indicates a cross-level interaction.

D. Following these hypotheses, exploratory analyses were carried out to further elucidate the role of emotional approach and social constraints in the relationship between stimuli and FOR. While it had been initially hypothesized that social constraints on disclosure would mediate the within-person relationship between daily cancer-related stimuli and daily FOR, this hypothesis was modified to consider social constraints as a possible moderator of the link between cancer-related stimuli and FOR. Furthermore, other secondary analyses were carried out to examine carry-over effects of study variables on FOR in order to bolster claims of causality

Chapter 2

METHOD

2.1 Participants and Procedure

Participants in this study were women diagnosed with early-stage breast cancer recruited as part of a larger R21 study funded by the National Cancer Institute (NCI). Potential participants were first identified through a review of the Helen F. Graham Cancer Center and Research Institute's (HFGCCRI) tumor registry of patients with a recent positive breast biopsy. Identified individuals were subsequently mailed an informational flyer with details of the study before they were telephoned for invitation into the study, whereupon further screening along several inclusion criteria was carried out.

Inclusion criteria were a recent first diagnosis of early-stage breast cancer (i.e., Stage I, II, IIIa, or Ductal Carcinoma In-Situ (DCIS)), being English-speaking and above the age of 18, and being partnered in a cohabiting/committed relationship. While not relevant to this study, being partnered was an inclusion criterion as the larger R21 study consisted of a year-long study of women with breast cancer and their partners. In the larger study, participants were assessed across multiple cross-sectional time points and two 21-day diary bursts (the first at the end of adjuvant treatment and the second spanning the women's follow-up mammogram approximately a year after cancer diagnosis). This study, however, utilized data from only some of the measurement periods; specifically, the first cross-sectional measurement and the first

daily-diary period. Figure 2.1 depicts the temporal placement of data collected for the present study in relation to other assessment periods that were part of the larger study.

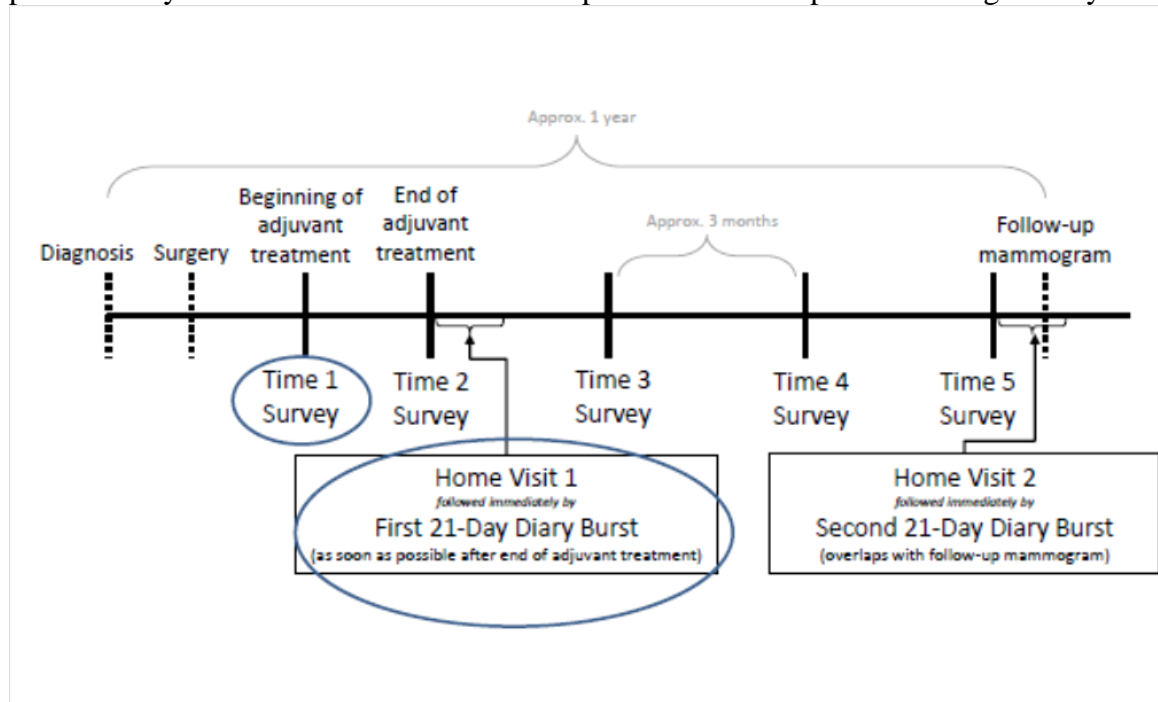


Figure 2.1. Timeline of the present study in relation to the larger study. The blue ovals highlight the measurement periods used in this study.

A total of 1161 patients with positive biopsies were screened for eligibility and, of these patients, 698 were ineligible after initial review (see Figure 2.2). Of the remaining women, 463 were contacted to participate via a mailed study announcement and a follow-up phone call; 346 women were excluded following further review of eligibility and 236 declined to participate through either active (154) or passive refusal (82). This left a sample of 117 women who initially agreed to participate by telephone; however, only 83 returned the study packet and signed consent forms. Of this subset of women, 77 continued on to participate in the study by completing at least one study survey; however, only 72 provided enough information to be included in analyses.

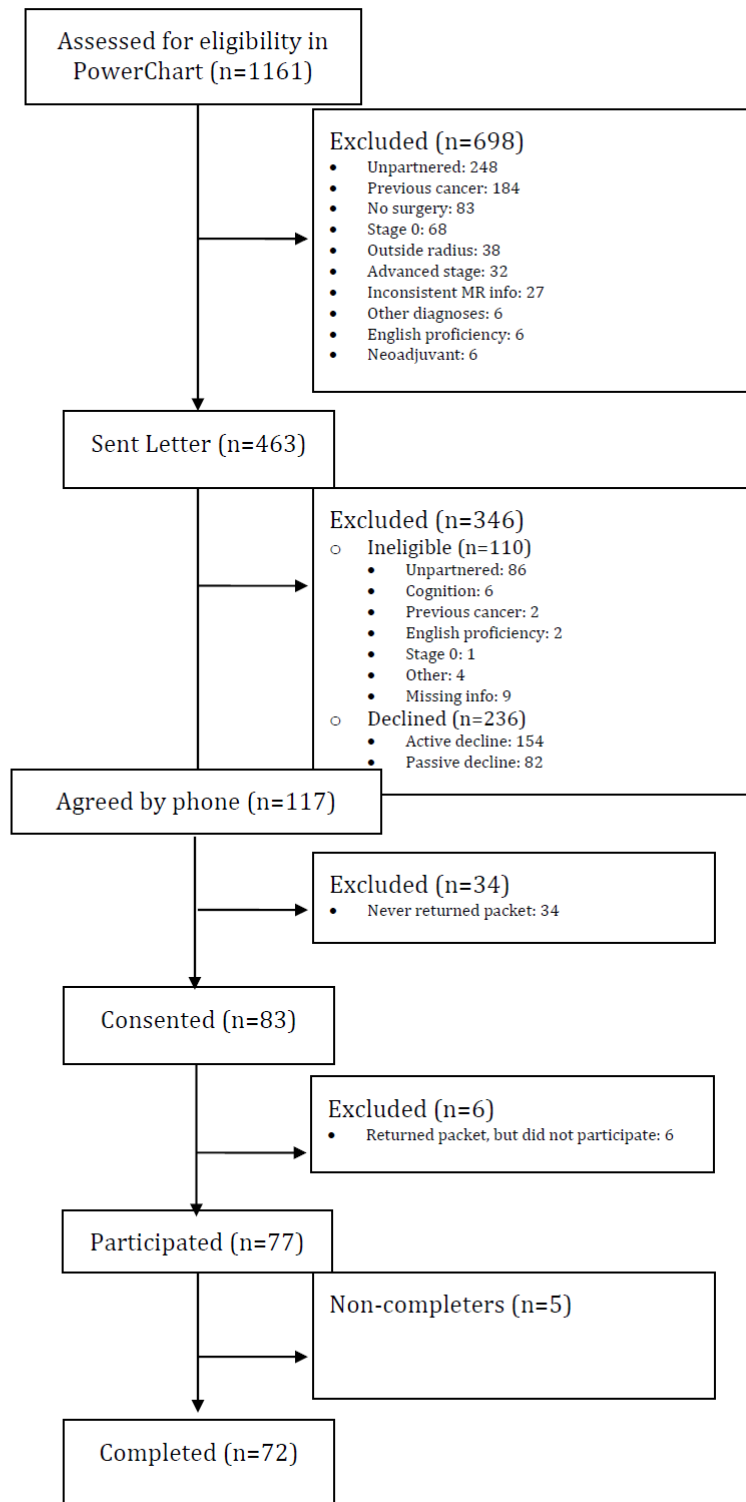


Figure 2.2. Participant flowchart diagram for recruitment.

Consenting participants completed the first cross-sectional measures soon after surgery via an initial set of online questionnaires accessed through an email link that led to Qualtrics, a secure survey server site. Approximately 3 months later, at the end of adjuvant therapy (i.e., post-surgery radiation or chemotherapy), participants subsequently completed a daily diary for 21 consecutive evenings approximately an hour prior to bedtime. The daily diaries were similarly accessed through a link to the secure survey server site. The average length of time to complete the diaries each night was about 13 minutes ($M = 12.73$, $SD = 7.23$) and participant compliance with the diary procedure was monitored with a time–date stamp to ensure completion within valid time periods. Only daily entries that fell within valid evening time intervals (i.e., completed between 6p and 3a) were used in this study. Patients averaged just over 17 diary entries out of the 21 instructed and all available valid data were used in analyses. Regarding missing data, the percentage of missing variables on daily items ranged from 3.9% to 22%.

Participant demographic information for the 72 participants is described below. The average age for participants was 57.99 years ($SD = 9.51$ years) and the majority of women (86.1%) were Caucasian. Most women were married (90.3%; $M = 29.57$ years, $SD = 13.90$ years) with the remainder (5.6%; $M = 6.00$ years, $SD = 5.29$ years) in committed relationships. Additionally, 37.5% of them worked full-time, 18.1% worked part-time, and 40.3% were not working. Furthermore, 69% of women reported earning a combined income of greater than \$60,000 along with their partners. 5.6% of women reported having had a previous cancer diagnosis and 26.4% reported having at least one other concurrent illness. Additionally, 76.4% of women reported seeing/knowing someone close to them go through a cancer experience.

2.2 Cross-sectional Measures

In addition to basic demographic and disease-/treatment-related information (such as age, type of treatment received, and ethnicity), patients completed the following measures (see Appendices A - I for the specific wording of all measures):

Risk Perception. Patients' perception of risk of cancer recurrence was assessed using two items, "What do you think your chance is of developing cancer again within the next 5 years?" and "What do you think your chance is of developing cancer again at any point in your lifetime?", see Appendix A. Both items were scored on a scale ranging from 0% ("no chance of getting cancer again") to 100% ("definitely will get cancer again"). These questions were devised for this study to capture the face valid content of cancer patients' perceptions of risk of cancer recurrence. The correlation of these two items across study participants was .73 indicating good inter-item reliability.

Illness Intrusiveness. Patient perceptions of the degree to which their cancer interfered with various aspects of their quality of life, including disrupting lifestyle, activities, and interests, was assessed using the 13-item *Illness Intrusiveness Rating Scale (IIRS)*; Devins, 2010), listed in Appendix B. Participants rated the extent to which they perceived their cancer as intrusive on a 7-point Likert scale with responses ranging from 0 ("not very much") to 6 ("very much"). The IIRS has demonstrated good reliability (i.e., internal consistency and test-retest), validity (i.e., construct, criterion-related, and discriminant), and factorial invariance across numerous chronic-disease groups (Devins, 2010). The reliability of this measure, as used, in our study was $\alpha = .93$

Trait Worry. The tendency to experience worry was assessed using the 16-item *Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990)*, shown in Appendix C. Participants responded to questions such as “I am always worrying about something” or “I find it easy to dismiss worrisome thoughts” on a scale from 1 (“Not at all typical of me”) to 5 (“Very typical of me”). Positively-worded items were recoded to be consistent with low scores on the scale corresponding to low levels of worry and high scores indicating greater trait worry. The PSWQ has been found to have high internal consistency and good test-retest reliability during validation studies (Meyer, 1990). In this study, Cronbach’s α was .95 indicating good reliability of scale items.

2.3 Daily Diary Measures

Patients also completed daily diary measures for 21 consecutive days following the end of adjuvant treatment. The types of daily items are presented below (see Appendix for specific wording):

Daily Negative Cancer-Related Events. Patients reported daily on whether or not a number of cancer-related negative events occurred that day. For instance, the patients reported whether they had a billing/insurance issue or whether they experienced any of a number of cancer-related somatic symptoms that included nausea or vomiting, fatigue, or a skin irritation. As cognitive-behavioral models of health anxiety often describe two processes - information-processing biases (like selective attention) and physiological reactions (for example, heightened experience of bodily sensations) - that contribute to the experience of health anxiety (Salkovskis, Warwick, & Deale, 2003), we parsed cancer-related negative stimuli into internal and external

stimuli to correspond to heightened reactivity to bodily sensations and selective attention/biases towards monitoring for negative environmental cues respectively. Consequently, the measure of internal/physical stimuli was a checklist of items that included whether or not women experienced pain, tingling, fatigue, or cognitive difficulties while the measure of external stimuli included whether they received bad news, had a frustrating interaction with a medical professional, or had a long wait at a doctor's office.

Participants additionally provided a rating of their level of pain on an 11-point scale with anchors ranging from 0 ("not at all") to 10 ("worst pain imaginable"); however, because the distribution of daily momentary evening pain was positively-skewed and more than half of daily responses were zeroes (Figure 2.3), these ratings were dichotomized and the pain item collapsed into two categories that captured whether or not women experienced evening pain. This new variable was then included as an item on the internal cancer-related events checklist. Study items assessing both internal and external stimuli are shown in Appendix D.

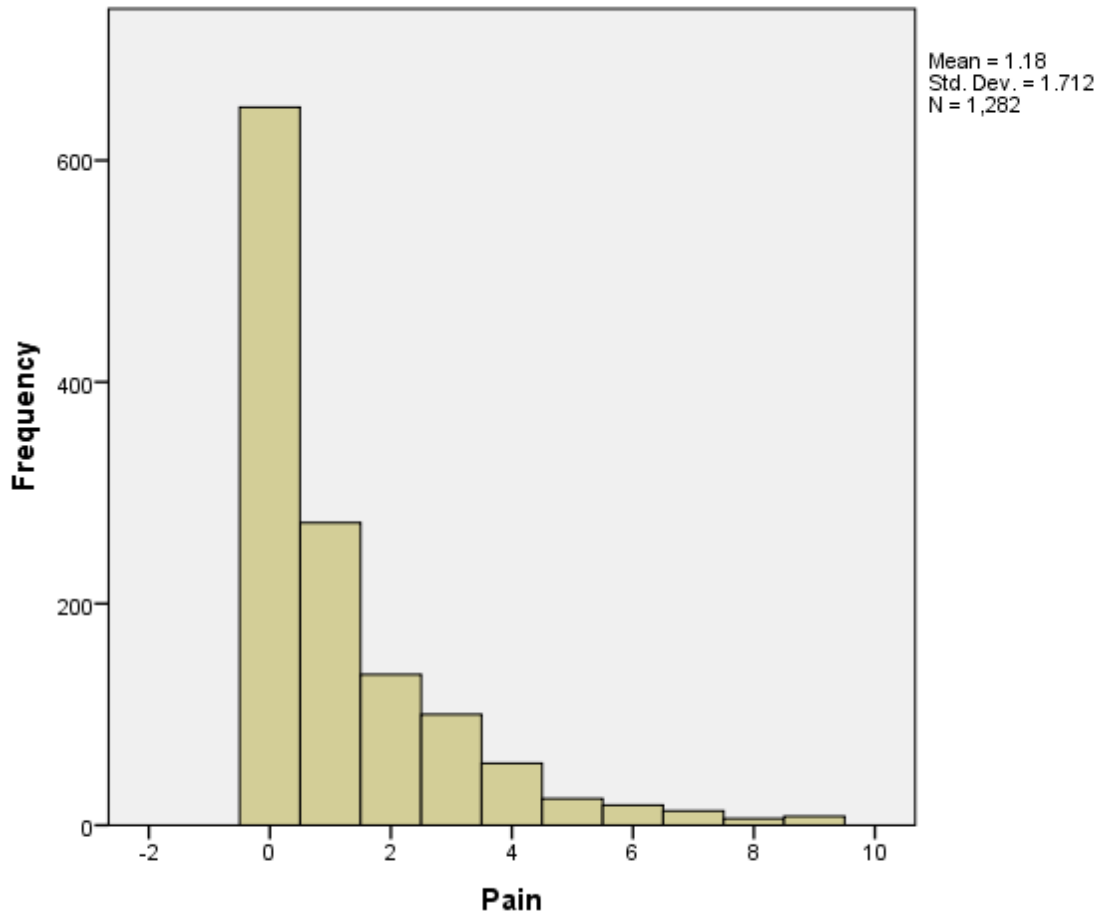


Figure 2.3 Histogram of the distribution of momentary evening pain.

Intrusive Thoughts. Firstly, patients reported whether they experienced any cancer-related thoughts and, if they did, they were asked whether these thoughts were intrusive using two additional questions taken from Horowitz and colleagues’ Impact of Events Scale (IES, 1979). These items, “*Were the thoughts you had today about cancer unwanted?*” and “*Were the thoughts that you had today about cancer upsetting?*”, were assessed on a 5-point Likert scale ranging from 0 (“not at all”) to 4

(“extremely”); see Appendix E. The within-person correlation for the two intrusive thought items was strong ($r = .86$).

Emotional Approach Coping. We also assessed patients’ coping via emotional approach and expression to the worst cancer-related event of the day using 3 questions culled from the *Emotional Approach Scale* (EAS; Stanton, Kirk, & Cameron, 2000), listed in Appendix F. An example of a question participants responded to is “*I took time to figure out what I was really feeling.*” Participants rated the extent to which they engaged in emotional approach coping on a 5-point Likert scale ranging from 0 (“not at all”) to 4 (“extremely”). The EAS is a measure that has demonstrated good high internal consistency and good convergent and discriminant validity in undergraduate samples (Stanton et al., 2000). Within-person reliability of the 3 items was calculated using McDonald’s (1999) omega, ω , which is calculated from factor loadings that take into account the within-subjects variation in items that have been repeatedly measured (Bolger & Laurenceau, 2013). Reliability of emotional approach items was $\omega = .93$.

Social Constraints. Patient perceptions of daily social constraints on disclosure to cancer-related thoughts and feelings were assessed using items that were taken from the *Social Constraints Scale* (Lepore & Ituarte, 1999) and listed in Appendix G. The items selected for use in this study were chosen based on their high loadings onto a latent within-person social constraints factor modeled on previously collected pilot data. Patients rated the extent to which they experienced social constraints from their significant other using a 5-point scale from 0 (“not at all”) to 4 (“extremely”). The reliability index showed good reliability of items in this study across patients and days ($\omega = .85$).

Fear of Recurrence. Patient fear of cancer recurrence was assessed using items culled from the Fear of Cancer Inventory (*FCRI*; Simard & Savard, 2009) that tap into the emotional response of FOR (e.g., “*I was worried, afraid, or anxious about the possibility of a cancer recurrence*”). Study items are listed in Appendix H and these questions from the psychological distress factor of the FCRI were measured on a 5-point Likert scale ranging from 0 (“not at all”) to 4 (“extremely”). The FCRI has been found to have good internal consistency as well as good construct validity when evaluated against other self-report scales assessing fear of cancer recurrence (Simard & Savard, 2009). The estimated within-person variability for this scale was $\omega = .91$.

Negative Affect. Patient momentary negative affect was assessed using 8 items culled from the *Positive and Negative Affect Scale (PANAS-X)*; Watson & Clark, 1994); see Appendix I. Patients were asked, “*Tell us how much you feel this way at this moment, right now*” on a 5-point scale ranging from 0 (“not at all”) to 4 (“extremely”). The PANAS has been found to have good temporal stability and consistency in samples of healthy adults as well as breast cancer survivors (Ganz et al., 2002; Watson & Clark, 1994). The estimated within-person variability for this scale was $\omega = .82$.

2.4 Data Analytic Plan

Overview of Data Analytic Strategy. Data in the study consisted of consecutive daily observations from each of the breast cancer patients, conforming to a multilevel data structure where persons and days were treated as non-independent observations. Accordingly, a multilevel modeling framework was used in which diary

data were modeled as multivariate outcomes (Bolger & Laurenceau, 2013; Laurenceau & Bolger, 2005).

Analyses were carried out in Mplus v7.4 (Muthén & Muthén, 1998-2010) using robust maximum likelihood estimation (MLR) which provides standard errors for parameters that are robust to non-normality (Yuan & Bentler, 2000). MLR is also able to handle the interdependencies inherent in repeatedly measured data as well as produce valid statistical inferences in the presence of data that are missing at random.

As FOR and intrusive thoughts demonstrated a Poisson distribution, with variances significantly greater than their means and an over-representation of zeros (see Figures 2.4 and 2.5 for histograms of their distributions), zero-inflated Poisson (ZIP) regression was used to model count data when these two variables were examined as outcomes.

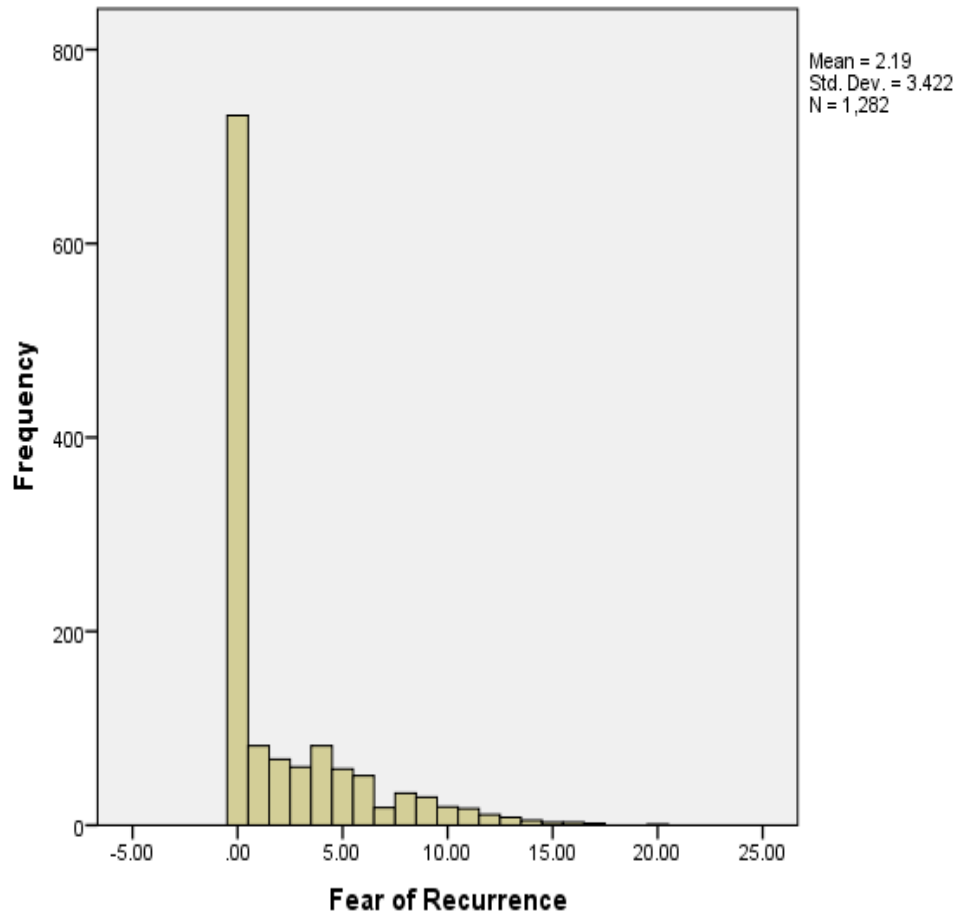


Figure 2.4. Histogram of the distribution of daily FOR.

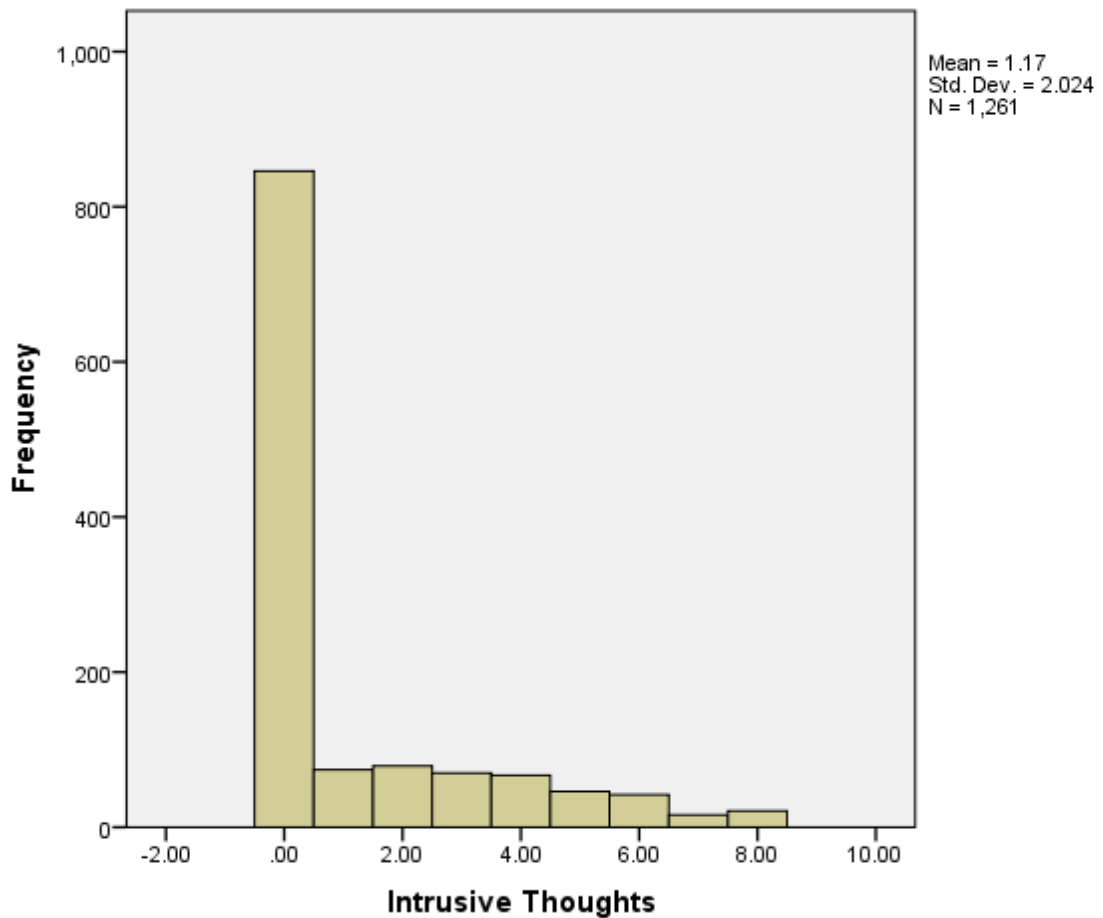


Figure 2.5. Histogram of the distribution of daily intrusive thoughts.

When data are zero-inflated, zero values may arise because of dual processes; on the one hand, the first type of zeroes, “structural zeros”, likely occurred because some of the women did not have any FOR or intrusive thoughts across the diary period and were likely not at risk of experiencing these phenomena. On the other hand, the other type of zeros were random zeros, i.e., they could take on other values, but were observed to be zero on some days due to sampling variability (He, Tang, Wang, & Crits-Christoph, 2014). Thus, in the within-person analyses, ZIP models allowed for over-dispersion and excess zeroes by assuming that there were two different types of

days represented by the data: 1) those that were zero on the outcome, following a logistic process, and 2) those that could have count values, following standard Poisson distributions (Lambert, 1992). Following this, the first component of a ZIP model was a binary variable that predicted being a “zero-day” on which women did not experience either FOR or intrusive thoughts (depending on the outcome of interest) using logistic regression, while the second part modeled the extent of FOR or intrusive thoughts as count values. A multilevel ZIP regression model can be represented as below:

$$Y_{i,j} \sim \begin{cases} 0 & \text{with probability } p_{i,j}, \\ \text{Poisson}(\lambda_{i,j}) & \text{with probability } 1 - p_{i,j}. \end{cases} \quad (1)$$

Each observation, $Y_{i,j}$, is an independent random variable that follows a Bernoulli distribution, with $Y_{i,j} \sim \text{Bern}(p_{i,j})$ for the i th day and the j th participant. As mentioned previously, ZIP models produce outcomes following two processes, the first (which only generates zero counts) with probability $p_{i,j}$ and the second, with probability $1 - p_{i,j}$, which generates values following a Poisson distribution (Hall, 2000). In addition to more accurately modeling the non-normal distribution present in zero-inflated outcomes, this modeling approach also allowed for potentially different predictors to be regressed on the two components of the outcome simultaneously.

Attempts at estimating random slopes for all within-person predictors in all models, consistent with a maximal approach, were made as it has been argued that including all possible random effects and examining how sampling units may vary allows for greater generalizability of analyses and more accurate inferences (Barr,

Levy, Scheepers, & Tily, 2013). However, due to problems with non-convergence of models, particularly when model complexity increased and in the context of our relatively small sample size and modeling at two-levels, random slopes were generally not included. All models were estimated with random intercepts.

Chapter 3

RESULTS

The inter-correlations and intra-class correlations of daily study variables are presented in Table 3.1 while the means, standard deviations, and inter-correlations of daily and cross-sectional study variables are presented in Table 3.2.

Table 3.1
Within-Person Correlations and Intraclass Correlations (ICCs) of Daily Study Variables

Measure	1	2	3	4	5	6	7	ICC
1. FOR	1							0.46
2. Internal Stimuli	.18***	1						0.80
3. External Stimuli	.19***	.16**	1					0.60
4. Emotional Approach	.17**	.10**	.16**	1				0.44
5. Social Constraints	.26**	.06*	.07	.01	1			0.57
6. Intrusive Thoughts	.73***	.18**	.16**	.19***	.23***	1		0.32
7. Negative Affect	.25**	.12**	.08 [†]	.03	.21***	.22***	1	0.51

Note: [†] $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Table 3.2

Between-Person Correlations, Means, and Standard Deviations of Cross-Sectional and Daily Study Variables

Measure	1	2	3	4	5	6	7	8	9	10	11	M	SD
1. Age	1											57.67	9.76
2. Worry	.06	1										1.76	0.91
3. Illness Intrusiveness	-.47	.08	1									1.51	1.72
4. Risk	-.21	.17	.00	1								29.77	26.24
5. FOR	-.14	.29 [†]	-.04	.47***	1							2.17	2.31
6. Internal Stimuli	-.19	.17	.68***	.02	.59***	1						2.11	1.61
7. External Stimuli	-.26	-.20	.74	-.37	.30**	.62***	1					0.15	0.47
8. Emotional Approach	.01	.16	.47**	-.07	.47***	.59***	.41**	1				0.57	0.66
9. Social Constraints	-.05	.04	.37*	.01	.53***	.49***	.38 [†]	.37**	1			0.43	1.14
10. Intrusive Thoughts	-.15	.43*	.43*	.12	.80***	.53***	.18	.43*	.54***	1		1.18	1.14
11. Negative Affect	-.19	.30	.51**	-.06	.76***	.54***	.48**	.39*	.31*	.63***	1	0.18	0.07

Note: [†] $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

3.1 Study Hypotheses

A: Relationship between cancer-related stimuli and FOR. The first set of hypotheses tested were those regarding the concurrent relationship between FOR and daily cancer-related stimuli. As mentioned previously, because FOR was a count variable with an excess of zeroes, it was modeled as a zero-inflated outcome with two sets of coefficients. At the within-person level, the first group of coefficients were those related to the binomial/logit part of the model (predicting whether or not FOR was experienced on a typical day) and the second were related to the count portion of the model (predicting the extent of FOR, when on days in which FOR was experienced). Thus, the coefficients in the “Logit” panels of Table 3 are those predicting the odds of a “zero FOR day” for a typical patient, while the count coefficients are related to prediction of the extent of FOR on days in which women did report having some fears of recurrence. It should be noted that the link between internal stimuli and FOR was examined at both the within-person and between-person levels and between-person coefficients (indicating the prediction of being in the class of women that did not experience FOR and prediction of women’s levels of FOR in the “logit” and “count” columns respectively) are also reported in Table 3.3.

Table 3.3
Multilevel ZIP Results for Models Regressing FOR on Negative Events

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standar rd Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
Model 1										
(within-person) Daily FOR on										
Internal stimuli	0.087**	0.029	1.091	0.030	0.146	-0.320**	0.106	0.726	-0.528	-0.112
Negative Affect	0.269**	0.060	1.301	0.156	0.390	-0.800 [†]	0.471	0.449	-1.723	0.124
Diary Day	0.000	0.006	1.000	-0.011	0.011	0.048**	0.016	1.049	0.017	0.078
(between-person) Average Daily FOR on										
Average Daily	0.044	0.059	1.045	-0.072	0.161	-0.649***	0.145	0.523	-0.932	-0.365
Internal Stimuli										
Average Daily	1.249 [†]	0.752	3.487	-0.224	2.723	-3.087*	1.328	0.046	-5.690	-0.485
Negative Affect										
Model 2										
(within-person) Daily FOR on										
External stimuli	0.159***	0.045	1.172	0.070	0.248	-0.675*	0.283	0.509	-1.229	-0.120
Negative Affect	0.269***	0.063	1.309	0.146	0.393	-0.921 [†]	0.503	0.398	-1.907	0.064
Diary Day	0.001	0.006	1.002	-0.010	0.012	0.048**	0.015	1.049	0.018	0.078
(between-person) Average Daily FOR on										
Average Daily	-0.155***	0.030	0.856	-0.214	-0.096	-0.597	0.774	0.550	-2.115	0.920
External Stimuli										
Average Daily	1.536***	0.177	4.646	1.188	1.884	-4.963***	1.383	6.99x10 ³	-7.673	-2.252
Negative Affect										

Note. [†] $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

The experience of daily internal stimuli was found to be a within-person predictor of daily FOR in both the logistic ($B = -0.320$, $Odds Ratio = 0.726$, $p = .003$) and count ($B = 0.087$, $Rate Ratio = 1.091$, $p = .003$) parts of the FOR model, controlling for patient negative affect. This indicated that on days on which a participant reported experiencing an additional physical symptom above her average daily level, she would be about 28% more likely to report having any FOR that same day. Additionally, when a woman did report experiencing FOR, she reported a 9% greater level of concern of recurrence for each additional physical symptom reported that day. As such, at the within-person level, the experience of internal symptoms was found to be associated with increased likelihood of having FOR, as well as with greater levels of FOR on days on which FOR was encountered.

At the between-person level, the relationship between internal negative events and FOR across women roughly mirrored the within-person findings. Controlling for average daily negative affect, average daily internal stimuli predicted average daily FOR in the logistic ($B = -0.649$, $Odds Ratio = 0.523$, $p < .001$) but not the count part of the model ($B = 0.044$, *ns*). This suggested that, across individuals, an increase in the experience of physical stimuli was associated with a 47.7% unit increase in the odds of belonging to the group of women that did not experience any FOR over the diary study.

Similarly, the effect of daily external stimuli on daily FOR, controlling for evening negative affect, was examined. Daily external stimuli were associated with increased odds of FOR that same day ($B = -0.675$, $Odds Ratio = 0.509$, $p = .017$). This indicated that women were 49% more likely to report being FOR when they experienced an additional negative external stimulus. Furthermore, external stimuli

events were associated with greater FOR on days in which women reported having fears of cancer recurrence ($B = 0.159$, $Rate\ Ratio = 1.172$, $p < .001$) such that women reported a 17% increase in their levels of same-day FOR when they experienced a one-unit increase in external cancer-related events.

At the between-person level, controlling for average negative affect over the diary period, average daily FOR was significantly associated with average daily external stimuli in the count part of the model ($B = -0.155$, $Rate\ Ratio = 0.856$, $p < .001$) but not in the logistic part of the model ($B = -0.597$, ns). Unlike the relationship at the within-person level, the between-person results suggested that, across individuals, women that experienced greater average daily levels of negative external events were those that had less FOR.

B: i) Relationship between daily emotional approach, cancer-related events, and FOR. Detailed results of the analyses examining links, at the within and between-person level, between emotional approach and both internal and external stimuli are summarized in Table 3.4. The concurrent association between daily internal stimuli and daily emotional approach was significant ($B = 0.092$, $p = .002$) indicating that on a day which patients reported experiencing a one-unit increase in physical symptoms above their average daily levels, they also reported greater engagement in emotional approach coping. At the between-person level, average daily internal stimuli and average daily emotional approach were similarly positively associated such that women who reported more internal negative stimuli also reported greater average daily emotional approach ($B = 0.206$, $p < .001$).

Table 3.4
Multilevel Regression Results for Models Examining the Relationship Between Negative Events and Emotional Approach

	Estimate	Standard Error	95% CI	
			Lower	Upper
Model 1				
(within-person) Daily Emotional Approach on				
Internal stimuli	0.092**	0.029	0.044	0.168
Negative Affect	0.040	0.162	-0.277	0.457
Diary Day	0.001	0.004	-0.007	0.012
(between-person) Average Daily Emotional Approach on				
Internal stimuli	0.206***	0.046	0.116	0.297
Negative Affect	0.280	0.342	-0.389	0.949
Model 2				
(within-person) Daily Emotional Approach on				
External stimuli	0.297*	0.120	0.063	0.532
Negative Affect	0.051	0.162	-0.266	0.368
Diary Day	0.002	0.004	-0.006	0.010
(between-person) Average Daily Emotional Approach on				
Average Daily External Stimuli	0.453**	0.143	0.173	0.732
Average Daily Negative Affect	0.556	0.318	-0.067	1.178

Note. † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Similarly, at the within-person level, the slope for the concurrent association between daily external stimuli and daily emotional approach was significant ($B = 0.297$, $p = .013$), indicating that, when patients reported experiencing additional external cancer-related events above their average daily levels, they were more likely to report that they engaged more in emotional approach coping that same day. At the between-person level, this relationship was also significant and positive ($B = 0.453$, $p = .002$), such that women who reported more external stimuli than other women also reported greater average daily emotional approach.

Table 3.5 summarizes similar analyses examining the link between emotional approach coping and FOR. Regarding the daily within-person relationship between emotional approach coping and FOR, an increase in emotional approach coping above

a typical woman's average levels was associated with increased odds of having FOR that same day ($B = -0.597$, *Odds Ratio* = 0.550, $p = .001$); this suggested that, on days that women as engaged in more emotional approach coping, they were 45% more likely to report that day as a day one with FOR. Additionally, a one-unit increase in emotional approach was associated with a 7.5% greater chance of increased same-day FOR ($B = 0.072$, *Rate Ratio* = 1.075, $p = .001$). At the between-person level, greater emotional approach was only associated with greater average daily FOR in the logistic ($B = -1.205$, *Odds Ratio* = 0.300, $p < .001$), and not the count part of the model ($B = -0.002$, ns), indicating that women with greater average levels of emotional approach were 70% more likely to report that they had any days with FOR. These effects, showing greater concurrent FOR with increases in emotional approach, were in the opposite direction of hypothesized linkages, suggesting that, when examined concurrently and across individuals, emotional approach does not immediately manifest as an adaptive way of coping to illness triggers. Proposed mediation analyses examining emotional approach as a coping mechanism were subsequently not carried out due to concerns of appropriately interpreting resulting effects.

Table 3.5

Multilevel ZIP Results for the Model Regressing FOR on Emotional Approach

	Count	Standard	Rate	95% CI		Logit	Standard	Odds	95% CI	
	Estimate	Error	Ratio	Lower	Upper	Estimate	Error	Ratio	Lower	Upper
(within-person) FOR on										
Emotional Approach	0.072**	0.028	1.075	0.018	0.126	-0.591**	0.179	0.554	-0.943	-0.240
Negative Affect	0.279***	0.064	1.322	0.153	0.405	-0.834 [†]	0.470	0.434	-1.755	0.087
Diary Day	-0.001	0.006	0.999	-0.013	0.011	0.053**	0.016	1.054	0.021	0.085
(between-person) Average Daily FOR on										
Average Daily	-0.002	0.060	0.998	-0.120	0.115	-1.205***	0.324	0.300	-1.841	-0.569
Emotional Approach										
Average Daily	1.432***	0.174	4.187	1.092	1.773	-4.234***	1.138	0.014	-6.464	-2.004
Negative Affect										

Note. [†] $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

B: ii) Relationships between daily negative events, intrusive thoughts, and FOR. Daily external stimuli were found to be a within-person predictor of daily intrusive thoughts in the logistic part of the model ($B = -0.656$, $Odds Ratio = 0.519$, $p < .001$) and in the count part of as well ($B = 0.129$, $Rate Ratio = 1.138$, $p < .001$) indicating that, on a day on which participants reported experiencing an additional negative external cancer-related event above her average daily level, the odds of that day being one with intrusive thoughts increased by about 48%. Additionally, when the typical woman experienced intrusive thoughts, increases in external cancer-related events that day were associated with a 13% greater likelihood of intrusive thoughts. At the between-person level, the link between external stimuli and intrusive thoughts was not significant in either the logistic ($B = -0.625$, ns) or the count part of the model ($B = -0.564$, ns), indicating no changed likelihood of experiencing intrusive thoughts across women because of greater external stimuli.

Similarly, the effect of daily internal stimuli on daily intrusive thoughts was examined, and the experience of daily internal stimuli on a particular day was associated with the increased odds of having a day with intrusive thoughts ($B = -0.439$, $Odds Ratio = 0.645$, $p < .001$). The link between physical symptoms/internal stimuli and the degree to which intrusive thoughts were experienced was marginally significant ($B = 0.046$, $Rate Ratio = 1.05$, $p = .067$). At the between-person level, the link between internal stimuli and intrusive thoughts was significant in the logistic ($B = -0.445$, $Odds Ratio = 0.641$, $p < .001$) but not the count part of the model ($B = 0.032$, ns), indicating increased odds of being in the class of women who experienced intrusive thoughts when average daily levels of internal stimuli increased. Results for

analyses examining links between intrusive thoughts and cancer-related events are summarized in Table 3.6.

Table 3.6

Multilevel ZIP Results for Models Regressing Intrusive Thoughts on Negative Events

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standard Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
Model 1										
(within-person) Intrusive Thoughts on										
Internal stimuli	0.046 [†]	0.025	1.047	-0.003	0.095	-0.439***	0.110	0.645	-0.653	-0.224
Negative Affect	0.138 [†]	0.076	1.148	-0.011	0.286	-1.212**	0.381	0.298	-1.958	-0.466
Diary Day	-0.002	0.005	0.998	-0.011	0.007	0.045**	0.016	1.046	0.014	0.076
(between-person) Average Daily Intrusive Thoughts on										
Average Daily	0.032	0.044	1.033	-0.055	0.119	-0.445***	0.109	0.641	-0.658	-0.231
Internal Stimuli										
Average Daily	0.683***	0.153	1.980	0.383	0.984	-2.726*	1.267	0.065	-5.209	-0.242
Negative Affect										
Model 2										
(within-person) Intrusive Thoughts on										
External stimuli	0.129**	0.040	1.138	0.051	0.207	-0.656***	0.184	0.519	-1.017	-0.295
Negative Affect	0.136 [†]	0.076	1.146	-0.012	0.284	-1.316**	0.392	0.268	-2.085	-0.547
Diary Day	-0.002	0.004	0.998	-0.011	0.006	0.045**	0.015	1.046	0.015	0.075
(between-person) Average Daily Intrusive Thoughts on										
Average Daily	-0.564	0.866	0.569	-2.262	1.133	-0.625	1.493	0.535	-3.551	2.301
External Stimuli										
Average Daily	0.824***	0.215	2.2796	0.403	1.245	-3.668**	1.395	0.026	-6.402	-0.934
Negative Affect										

Note. [†] $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

As FOR and intrusive thoughts were found to be very significantly correlated and to have a high degree of relatedness in regression analyses, more so than any other pairs of variables in this study, factor analysis was utilized to examine their degree of distinctiveness. In particular, a one factor model (containing all items assessing FOR and intrusive thoughts) and a 2-factor model (with separate correlated factors for the two constructs) were compared. A one factor model yielded adequate fit indices: $\chi^2 = 198.63$ (20, $N = 72$), $p < .001$; CFI = .986 and RMSEA = .083. However, a 2-factor model displayed improved fit, $\chi^2 = 42.97$ (19, $N = 72$), $p = .001$; CFI = .998 and RMSEA = .031, suggesting that items assessing FOR and intrusive thoughts tap separate constructs.

Regarding the relationship between intrusive thoughts and FOR, daily intrusive thoughts were found to be associated with greater FOR, controlling for negative mood, in both the logistic part of the model ($B = -3.458$, *Odds Ratio* = 0.031, $p < .001$) and in the count portion ($B = 0.149$, *Rate Ratio* = 1.161, $p < .001$). This indicated that, regardless of a patient's negative mood, days on which the average patient reported experiencing intrusive thoughts were those with a increased odds of those being days with FOR. Additionally, when patients reported experiencing FOR, intrusive thoughts were positively associated with the extent of FOR on that day. At the between-person level, average daily intrusive thoughts were significantly associated with average daily reports of FOR in both the logistic and the count part of the model. This was such that women who reported greater average daily intrusive thoughts were likely to be the same women that reported FOR ($B = -3.909$, *Odds Ratio* = 0.020, $p < .001$) and, when they did report experiencing FOR, higher levels of average intrusive thoughts across

days were associated with greater FOR ($B = 0.244$, *Rate Ratio* = 1.276, $p < .001$).

Detailed results for these sets of analyses are presented in Table 3.7.

Table 3.7
Multilevel ZIP Results for the Model Regressing FOR on Intrusive Thoughts

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standard Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
(within-person) FOR on										
Intrusive Thoughts	0.149***	0.022	1.161	0.106	0.192	-3.458***	0.840	0.032	-5.103	-1.812
Negative Affect	0.131*	0.055	1.140	0.022	0.239	0.313	0.721	1.368	-1.101	1.726
Diary Day	0.001	0.004	1.001	-0.008	0.009	0.030	0.026	1.030	-0.020	0.081
(between-person) FOR on										
Intrusive Thoughts	0.244***	0.068	1.276	0.111	0.378	-3.909***	0.845	0.0201	-5.565	-2.253
Negative Affect	1.001***	0.208	2.721	0.593	1.408	-2.473 [†]	1.407	0.084	-5.231	0.285

Note. [†] $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

In order to probe for the presence of mediation, a multilevel structural equation modeling approach (Little, Card, Bovaird, Preacher, & Crandall, 2007) was used to estimate the magnitude and significance of both direct and indirect effects in the same model simultaneously; Table 3.8 reports results of these analyses while Figure 3.1 depicts the path model tested and labels the size and significance of obtained coefficients.

Table 3.8

Multilevel ZIP Results for the Simultaneous SEM Estimation of the Mediation of the Relationship Between FOR and Internal Stimuli by Intrusive Thoughts

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standard Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
FOR on										
Internal Negative Event	0.041 [†]	0.024	1.042	-0.006	0.089	-0.095	0.180	0.909	-0.448	0.259
Intrusive Thoughts	0.142***	0.022	1.153	0.099	0.185	-1.756***	0.372	0.173	-2.485	-1.027
Negative Affect	0.131*	0.057	1.140	0.019	0.244	0.706	0.869	2.026	-0.998	2.410
Diary Day	0.003	0.004	1.003	-0.005	0.011	0.036	0.024	1.037	-0.027	0.083
Intrusive Thoughts on										
Internal Negative Event	0.047 [†]	0.025	1.048	-0.003	0.097	-0.445***	0.112	0.641	0.016	0.077
Negative Affect	0.146 [†]	0.082	1.157	-0.066	0.307	-1.228**	0.430	0.293	-2.335	-0.385
Diary Day	-0.003	0.005	0.997	-0.011	0.006	0.046**	0.016	1.047	0.016	0.077

Note. [†] $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

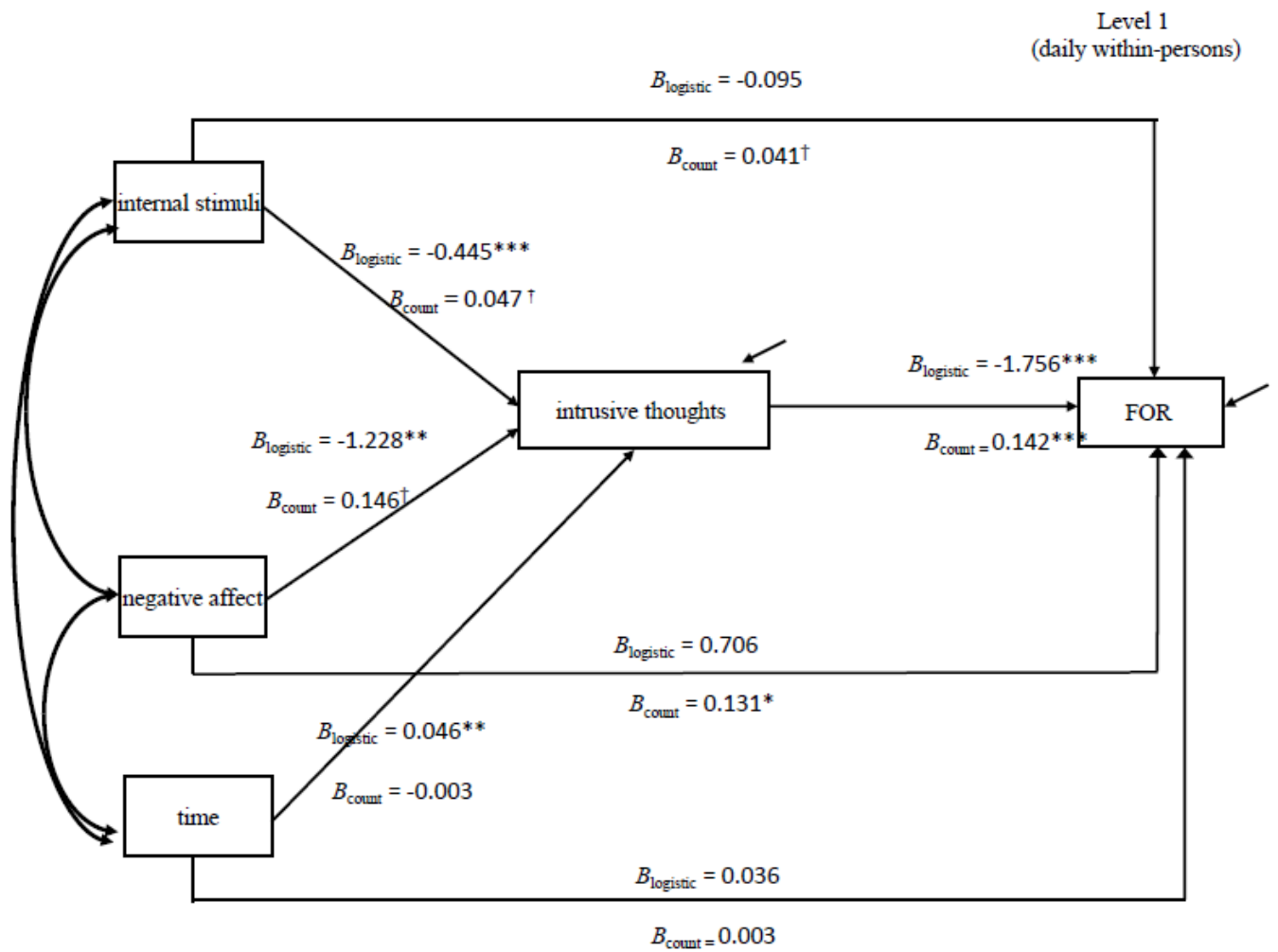


Figure 3.1. SEM estimation of the mediation of the relationship between FOR and internal stimuli by intrusive thoughts.

Accounting for all other paths in the model, the link between the count part of intrusive thoughts and negative internal cancer stimuli was marginally significant ($B = 0.047$, *Rate Ratio* = 1.048, $p = 0.065$) while the link between the logistic part of intrusive thoughts and negative internal cancer stimuli was significant ($B = -0.445$, *Odds Ratio* = 1.560, $p < 0.001$). A significant relationship between intrusive thoughts and count FOR ($B = 0.142$, *Rate Ratio* = 1.153, $p < 0.001$) in was found and, as before, a significant relationship was observed between intrusive thoughts and the 0/1 part of FOR ($B = -1.756$, *Odds Ratio* = 0.173, $p < 0.001$). Particularly relevant for mediation, the direct path, denoting the relationship between internal negative events and FOR, once accounting for the association with the mediator, became marginally significant in the count part of the model ($B = 0.041$, *Rate Ratio* = 1.042, $p = 0.085$) and non-significant in logistic part of the model ($B = -0.095$, *Odds Ratio* = 0.909, $p = 0.599$). This patterns of results, of a weakened direct effect, is strongly suggestive of mediation of the relationship between internal negative events and FOR by intrusive thoughts. Unfortunately, given the combination of ZIP distributions of the mediator and count variables and the multilevel context, no appropriate test of mediation is available in currently available statistical software to carry out to accurate calculation of the size or the significance of the mediated effect.

Similarly, Table 3.9 documents the sizes and confidence intervals of all effects in the path mediation model tested to examine the relationships between external cancer-related events, intrusive thoughts, and FOR while Figure 3.2 diagrammatically depicts them.

Table 3.9
Multilevel ZIP Results for the Simultaneous SEM Estimation of the Mediation of the Relationship Between FOR and External Stimuli by Intrusive Thoughts

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standard Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
FOR on										
External Negative Event	0.090*	0.042	1.094	0.007	0.199	-0.201	0.291	0.818	-0.772	0.370
Intrusive Thoughts	0.138***	0.021	1.148	0.096	0.180	-1.588***	0.300	0.204	-2.176	-0.999
Negative Affect	0.129**	0.058	1.138	0.015	0.244	0.180	0.900	1.197	-1.584	1.945
Diary Day	0.004	0.004	1.004	-0.005	0.012	0.037	0.023	1.038	-0.008	0.083
Intrusive Thoughts on										
External Negative Event	0.126**	0.042	1.134	0.044	0.208	-0.662***	0.016	0.516	-1.027	-0.298
Negative Affect	0.143†	0.076	1.154	-0.006	0.292	-1.345**	0.413	0.261	-2.154	-0.536
Diary Day	-0.003	0.004	0.997	-0.012	0.005	0.047**	0.016	1.048	0.016	0.077

Note. † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP = Zero Inflated Poisson.

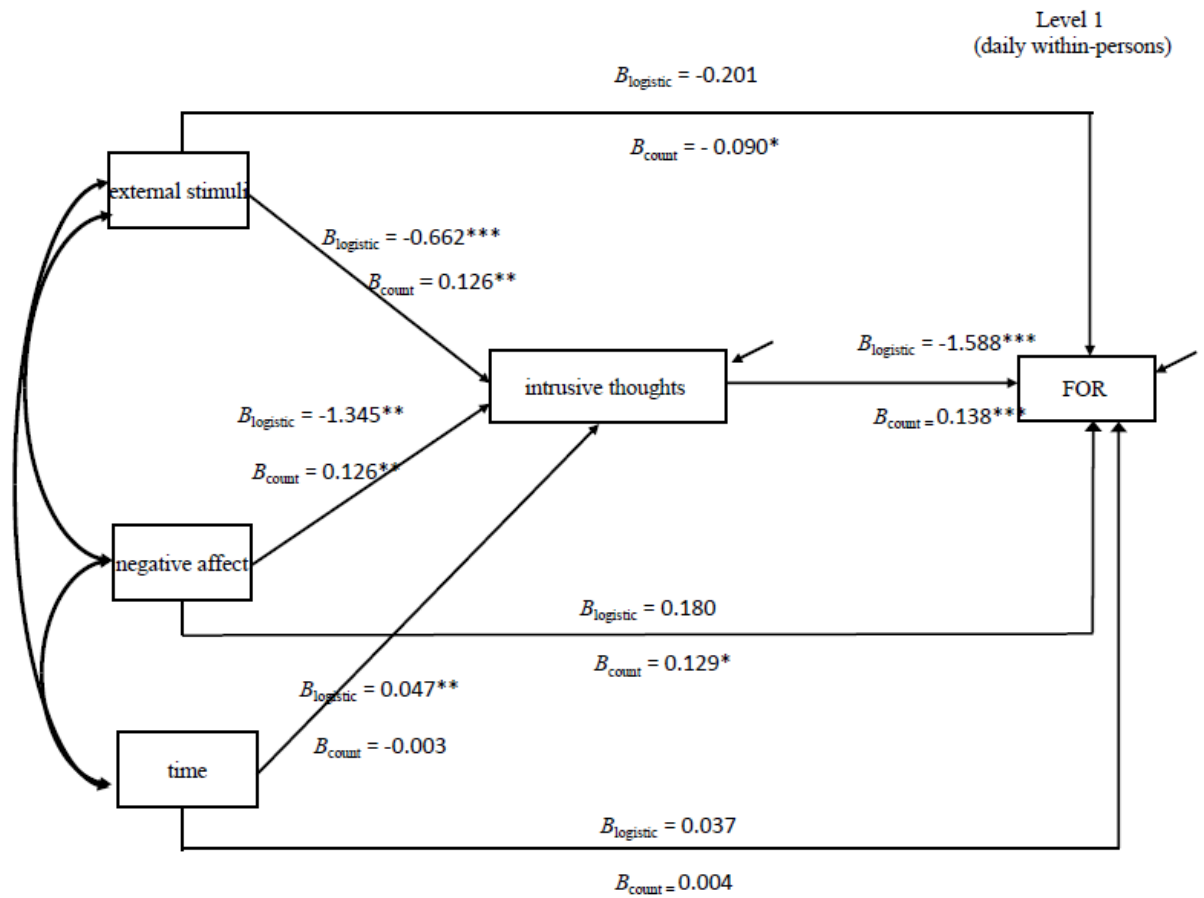


Figure 3.2. SEM estimation of the mediation of the relationship between FOR and external stimuli by intrusive thoughts.

The link between the count part of intrusive thoughts and negative external cancer stimuli was significant ($B = 0.126$, *Rate Ratio* = 1.134, $p = 0.003$). Similarly, the link between the logistic part of intrusive thoughts and negative external cancer stimuli was significant ($B = -0.662$, *Odds Ratio* = 0.516, $p < 0.001$), as was the relationship between intrusive thoughts and FOR in both the count ($B = 0.138$, *Rate Ratio* = 1.148, $p < 0.001$) and logistic ($B = -1.158$, *Odds Ratio* = 0.314, $p < 0.001$)

parts of the outcome. Finally, the relationship between external negative events and FOR, once accounting for associations with the mediator, was still significant, albeit attenuated, in the count part of the model ($B = 0.090$, *Rate Ratio* = 1.094, $p = 0.034$) and non-significant in the logistic part of the model ($B = -0.201$, *Odds Ratio* = 0.818, $p = 0.490$). As with the pattern of results listed above for internal negative events, the presence of a similarly weakened direct effect strongly suggests partial mediation of the relationship between external negative events and FOR by intrusive thoughts.

C: Between-person Associations and Cross-sectional moderators of the within-person mediation. A series of multilevel ZIP models were carried out to examine between-person associations of cross-sectional variables measured earlier in the study with later average daily FOR. Average daily FOR was significantly associated with illness intrusiveness in both the logistic ($B = -0.630$, *Odds Ratio* = 0.536, $p = .002$) and count part of the model ($B = 0.173$, *Rate Ratio* = 1.189, $p < .001$), indicating that women who experienced greater levels of impairment in functioning around the beginning of adjuvant therapy tended to be the same women who had FOR and, when they did experience it, they did so to a greater degree on average. Greater trait worry (assessed using the PSWQ) was also associated with increased odds of being in the class of women that experienced FOR after treatment was completed ($B = -0.990$, *Odds Ratio* = 0.372, $p < 0.001$); no significant associations were found between worry and FOR in the count part of the model. No significant relations were found between risk perception or patient age at the start of treatment with average daily FOR. These results are summarized in Table 3.10.

Table 3.10

Multilevel ZIP Regression Results for the Series of Between-Person Regressions of Daily Average FOR on Cross-Sectional Variables

	Count Estimate	Standard Error	Rate Ratio	95% CI		Logit Estimate	Standard Error	Odds Ratio	95% CI	
				Lower	Upper				Lower	Upper
Daily Average FOR on										
Age	0.003	0.003	1.003	-0.003	0.010	0.023	0.019	1.023	-0.014	0.059
Worry	0.201	0.173	1.189	-0.137	0.539	-0.990**	0.310	0.372	-1.597	-0.382
Illness Intrusiveness	0.173***	0.029	1.029	0.116	0.231	-0.630**	0.207	0.533	-1.035	-0.225
Risk	-0.001	0.003	1.003	-0.007	0.004	-0.005	0.006	0.995	-0.016	0.006

Note. † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. ZIP= Zero-Inflated Poisson.

Analyses to probe for between-person moderators of the mediated effect (as depicted by the cross-level interactions influencing the random slope of the within-person link between negative events and intrusive thoughts in Figure 1.2) were carried out. In a first step, cross-level moderators of what is typically considered the mediational “*a*” path (the link between negative stimuli and intrusive thoughts) were considered and neither risk perception ($B = 0.001, p = ns$), illness intrusiveness ($B = 0.003, p = ns$), nor trait worry ($B = -0.002, p = ns$) had a significant effect on the size of the relationship between internal negative events and intrusive thoughts. Patient age, however, was found to modulate this effect, such that the daily relationship between internal events and intrusive thoughts was more strongly linked in older women ($B = 0.004, p < 0.001$). This direction of this effect was unanticipated, as it had initially been hypothesized that younger age would be associated with stronger linkages in the relationship with FOR.

Neither risk perception ($B = -0.003, ns$), illness intrusiveness ($B = -0.007, ns$), patient age ($B = 0.004, ns$), nor trait worry ($B = 0.051, ns$) had a significant effect on the size of the relationship between external negative events and intrusive thoughts.

3.2 Exploratory Analyses

Daily Moderators of the relationship between daily cancer-related events and FOR. Daily social constraints were associated with greater FOR in only the count part of the model ($B = 0.050, Rate Ratio = 1.051, p = .016$). This indicated that on days on which women reported perceiving more social constraints, there was a 5% increase in the level of FOR that same day. At the between-person level, social constraints were only associated with FOR in the logistic part of the model ($B = -$

0.435, *Odds Ratio* = 0.647, $p = .004$), indicating that increases above average levels of social constraints across women were associated with a 35% increase in the odds of women having FOR.

When social constraints were added as a moderator to the model examining the relationship between external cancer-related events and FOR, the main effects of social constraints and of negative events on FOR remained positive and significant ($B = 0.046$, *Rate Ratio* = 1.047, $p = .016$ and $B = 0.160$, *Rate Ratio* = 1.174, $p < .0001$ in the logistic and count parts of the model for social constraints and external events, respectively). However, the interaction between social constraints and external negative events was not significant. Similarly, no moderating role of SCS was found on the effect of internally-experienced cancer stimuli on FOR (for the count and logistic portions of the model, respectively).

Emotional approach coping was also examined as a potential moderator of the relationship between negative events and FOR. No significant moderating role of emotional approach was found on the relationship between either internal ($B = -0.006$, *ns* and $B = -0.131$, *ns*), for count and logistic parts of the model respectively) or external ($B = -0.006$, *ns* and $B = -0.131$, *ns* for count and logistic parts of the model respectively) cancer-related events.

Between-person moderators of the relationship between daily cancer-related events and FOR. Cross-level interactions were examined to determine whether cross-sectional constructs assessed prior to the start of adjuvant therapy would moderate the relationship between cancer-related stimuli and FOR. Regarding the relationship between FOR and negative external cancer-related events, only patient age ($B = 0.027$, $p = 0.058$) and worry ($B = -0.343$, $p = 0.057$) were marginally

significant moderators of the within-person relationship between FOR and external cancer stimuli; neither illness intrusiveness nor risk were significant moderators. No baseline variables emerged as significant moderators of the relationship between internal stimuli and FOR.

Daily Associations with next-day FOR. To probe for possible carryover effects, regression analyses were carried out on next-day FOR. Internal negative events were not associated with next-day FOR, controlling for both evening negative affect and previous levels of FOR in both the count ($B = 0.023$, *ns*) or the logistic ($B = -0.084$, *ns*) parts of the model. While external negative events were associated with greater next-day FOR in the count part of the model ($B = 0.075$, *Rate Ratio* = 1.078, $p = .022$), they were not associated with any change in the odds of experiencing FOR the next day ($B = 0.302$, *ns*).

Social constraints were also examined as a potential predictor of next-day FOR; no significant links between SCS and led FOR were found, controlling for previous levels of FOR and the previous evening's negative mood ($B = 0.026$, *ns* and $B = 0.035$, *ns*, for the count and logistic parts of the model respectively). Similarly, the relationship between intrusive thoughts and FOR was not significant in either the count or logistic parts of the model ($B = 0.021$, *ns* and $B = -0.079$, *ns*), respectively) and neither was the relationship between emotional approach and FOR ($B = -0.018$, *ns* and $B = -0.087$, *ns* for count and logistic outcomes, respectively).

Chapter 4

DISCUSSION

Fear of recurrence (FOR) is a significant concern for many cancer survivors as it has been implicated in negative psychosocial adjustment following a cancer diagnosis (e.g., Vickberg, 2003). While substantial variability is known to exist across the trajectory of FOR, in its onset, course, and persistence, few studies have examined daily predictors of fluctuations in the experience of FOR. As such, this study was motivated to study the role of daily illness stimuli as well as probe for mechanisms through which daily experiences exert their influence on FOR. In particular, we hypothesized that the daily experience of cancer-related events would predict daily FOR within-person and that this effect would be mediated by variables related to coping. Additionally, we sought to determine whether the link between cancer-related stimuli and FOR would be moderated by between-person demographic and baseline characteristics assessed earlier on in cancer treatment.

4.1 Cancer-related events and FOR

The results of this study extend the known literature on predictors of FOR by finding within-person daily links with illness triggers, consistent with conceptual models of FOR (e.g., Lee-Jones et al., 1997). Specifically, we found that the occurrence of internal stimuli (such as the experience of pain, fatigue, or skin irritation) as well as the experience of external stimuli (like having a billing issue related to their cancer treatment or interacting with medical professionals), predicted,

at a within-person level, not only the presence of daily FOR but also its extent, such that women had a greater odds of having a day with FOR and a greater likelihood of higher levels of FOR with each additional experience of an illness stimulus. The pernicious daily effects of negative events were found to persist beyond the effect of concurrent negative affect on FOR, suggesting that FOR is distinct from contemporaneous negative affect. Moreover, lead analyses were carried out to determine whether illness stimuli were associated with next-day FOR and external negative events continued to demonstrate a significant association with greater next-day FOR, indicating a carryover effect for some negative cancer-related events on one day to FOR the next day. Together, these results provide preliminary support for important aspects of theoretical models of FOR based off of Leventhal's Common Sense Model of Illness (CSM; Brownlee, Leventhal, & Leventhal, 2000) positing that reminders, inherent to daily life associated with cancer, can serve to increase worry and thoughts about possible recurrence (Easterling & Leventhal, 1989; Lee-Jones et al., 1997; Northouse, 1981). Although past studies have examined the relationship between illness stimuli and FOR, they have exclusively done so using cross-sectional methods to examine predictors of variability that can only operate at a between-persons level. This is despite the implied description of the CSM as an inherently within-person process. Consequently, these results, by showing a daily within-person link between illness stimuli and both concurrent and later FOR, are important as they are a first examination of within-person processes postulated in the CSM.

Although variability at the within-person level was of primary interest in the present investigation, between-person effects were also examined. Between-persons, the pattern of results in the association of internal negative events and FOR was

similar to that at the within-person level and replicated past findings, with one exception. Contrary to our hypothesis, the relationship between external negative events and FOR was negative, suggesting that, across individuals, the women who experienced greater average levels of negative external events were those who also reported less FOR averaged across the 21-day reporting period. As this result was in the opposite direction of what has previously been found in the literature, replication of this is likely warranted.

Past studies have found evidence linking variability in FOR across individuals to patient age, trait worry, physical impairment, and risk perception – variables that were also included and examined in the present study. Similar to previous findings, we found links between both worry and illness intrusiveness and later FOR. However, associations between both patient age and risk perception with FOR were not replicated in this study. Aside from having a relatively small sample size, one reason previous findings may not have been reflected in the findings from our study may be because of the distribution of FOR. Our measured outcome displayed considerable skewness and an excess of zeros such that it may have been difficult, even at the between-person level, for there to be enough variability to find previously established links with patient age and risk perception.

4.2 Emotional approach coping, illness stimuli, and FOR

One variable that was initially hypothesized to mediate the relationship between negative events and FOR was emotional approach coping. As hypothesized, the relationship between daily stimuli, both internal or external, and daily emotional approach was positive and significant, suggesting at the recruitment of this coping

mechanism in the face of aversive daily events. This relationship was manifest at the between-person level as well, suggesting that the effect tended to generalize across women. Contrary to our hypotheses, however, both the within-person and between-person relationships, while significant, were in the unanticipated direction. This was such that, at the daily level, emotional approach coping was found to be associated with greater odds of having a day with FOR as well as greater extent of FOR. At the between-person level, increases in emotional approach coping were associated with greater odds of women having any FOR across the diary period. Although initially unexpected, these results are in keeping with results of some research that has examined the relationship between coping strategies and distress. In particular, some studies examining the relationship between receipt of social support and distress have found concurrent social support to be associated with greater distress, consistent with Barrera's (1986) Effective Support Mobilization Model that posits that the "positive link between life stress and social support can be interpreted as evidence that exposure to stressful circumstances triggers the mobilization of enacted support" (Barrera, 1981, p. 423). As such, our findings that, when measured contemporaneously, FOR and emotional support are positively related are in keeping with the interpretation that both emotional approach coping and FOR increase because there is an activating negative event that results in both increased need for coping and distress.

Lead analyses were carried out to examine whether increases in emotional approach coping would be associated with decreased FOR the next-day; however, no effects for emotional approach were found above previous levels of FOR and previous levels of negative affect. Although we found no significant effects with a day's time lag, it may still be that emotional approach coping is beneficial; however, the effects

may operate on a far longer time scale than that of a day. For instance, studies have shown engagement in emotional approach coping following primary treatment for breast cancer to be associated with decreased distress 3 months later (Stanton et al., 2000). As such, our daily design may not have been sufficiently long enough to measure the salutary effect of emotional approach coping. It had also been initially hypothesized that emotional approach would mediate the relationship between negative events and FOR; however, findings in the opposite direction of what had initially been predicted precluded testing of the effect of emotional approach as the interpretation of mediation findings would have been difficult to substantiate. Secondary analyses were carried out to examine whether emotional approach could be a moderator of the relationship between illness stimuli and FOR, but no moderating role was evident.

4.3 Relationship between daily negative events, intrusive thoughts, and FOR

Intrusive thoughts were hypothesized to be a mediator of the relationship between negative events and FOR and, as hypothesized, greater illness stimuli on one day increased the likelihood of the presence of intrusive thoughts that same day. Additionally, greater illness stimuli also tended to be associated with higher levels of intrusive thoughts that same day. Although not as substantively interesting, between-person associations for this effect were also examined, showing significant associations between the two variables across women.

Similarly, intrusive thoughts and FOR were found to be significantly associated at the within-person level. On days on which the average patient reported experiencing intrusive thoughts, there were increased odds of that day being a day

with FOR as well as increases in the extent of FOR, if it was experienced. Although tests of a calculated mediation effect were not carried out, given the challenges of zero-inflated count outcomes and multilevel data structures, results from this study are very suggestive of intrusive thoughts as a mediator in the relationship between the cancer-related events and FOR.

Secondary analyses were carried out to probe for potential moderators in this mediation; however, of the hypothesized variables, only patient age had any significant moderating role on paths in the model. Specifically, patient age was found to moderate the within-person relationship such that older women had a stronger association between external cancer-related events and intrusive thoughts. This effect was unanticipated, as age has generally been implicated with the inverse relationship such that younger women experience greater cancer-related distress. Given this, replication of this result would be warranted.

4.4 The Role of Social Constraints

While it had been initially proposed that social constraints would function a mediator of the relationship between illness stimuli and FOR, the role of social constraints was not tested in this fashion. Subsequent considerations of the variable led to the realization that it did not make much causal sense to have social constraints as an outcome of cancer-related events. Rather, while still keeping with the spirit of social constraints as a variable that can affect the relationship between illness stimuli and FOR, exploratory analyses were carried out to determine whether social constraints would modulate the link between cancer-related events and FOR. Although

social constraints were associated with greater FOR, there was no significant evidence that they moderated the relationship between negative stimuli and FOR.

4.5 Limitations and Future Directions

While there are many strengths of the current study, several limitations must also be noted. With regards to measurement, as emotional approach coping was in response to the worst event of the day, it could only be related to FOR and its predictors when the worst event of the day was cancer-related. Consequently, emotional approach coping was effectively only assessed on 28% of the days and, due to the limited amount of data, we do not know how emotional approach coping may pertain to cancer-related events outside of the ones that were sufficiently negative to be the worst one of the day. Future studies should aim to assess emotional approach coping more broadly so that it captures coping in response to multiple cancer-related stressors.

Furthermore, it is worth discussing an alternative explanation for the link between emotional approach and concurrent FOR; in particular, delineating between emotional approach coping as a more adaptive form of self-reflection and coping than rumination. As previously discussed, the identification and expression of one's emotions about difficult experiences has often been associated with psychosocial benefit (e.g., Pennebaker, 2007; Stanton et al., 2000). However, studies have also shown that focusing on one's negative feelings and aspects surrounding them (such as their causes and consequences) can also increase and prolong negative affect when the focus on emotions involves rumination and venting (e.g., Teasdale, 1988). Stanton and colleagues (1994) attempted to account for this in their construction of the Emotional

Approach Scale by eliminating items distress-laden items and those associated with negative cognitive processes like rumination and venting from existing scales of emotion-focused coping. They noted, as experimental studies have also shown, that focus on past events from a self-immersed perspective is associated with negative arousal while approach of emotions from a self-distanced perspective is associated with more adaptive processing, consistent with work on mindfulness and meditation (Brown & Ryan, 2003; Kross, Ayduk, & Mischel, 2005). Unfortunately, it is difficult to parse out the distinction between rumination/venting and emotional approach in these data as the effects of these processes may look similar in the short-term and in the absence of other correlates. As such, future studies should consider including broader measures of emotion-focused coping that include both adaptive and maladaptive forms of focus on emotions, as well as examine longitudinal effects to examine discriminant validity.

Although this study found evidence to suggest that there is a mediation of the relationship between cancer-related events and FOR by intrusive thoughts, these relationships were all concurrent. An important component of mediational analyses is the temporal sequence of predictor, mediator, and outcome. To conduct a strong test of mediation, the occurrence of the predictor should precede that of the mediator which in turn should precede the occurrence of the predictor (McKinnon, Fairchild, & Fritz, 2007). However, to have done so in this study, by fully lagging effects, would have resulted in limited ability to find effects as their windows of influence is unlikely to be on the order of days. Future studies should attempt to bolster the claim of directionality by having more frequent assessments in order to allow for temporal

separation of variables, but with smaller time lags than this study would have been able to accommodate.

Finally, with regards to recruitment, only about 20% of eligible women that were invited to participate in this study chose to do so. As mentioned previously, this study was part of a larger year-long study of FOR with multiple assessment points. It may be that participation rates were impacted by the length and intensiveness of the study, so consenting participants were more likely to be those that had time as a resource. Additionally, the design of the parent study was such that both women with breast cancer and their partners had to consent to participate; a consequence of this is that this study may not speak to the experiences of unpartnered women. Furthermore, several participants indicated declining participation because they found the daily diaries to be unpleasant and to only increase their FOR and distress. Although the analyses controlled for time and linear increases in FOR, our pool of study participants may represent those that were in a better position to adjust psychologically to cancer. Several previous studies of FOR have pointed out the challenges of recruitment (e.g., Simard et al., 2010), including the challenges of enrolling and retaining participants in dyadic studies, as the parent study was (Hagedoorn et al., 2015). Focusing on demographics, patients consenting to this study were largely Caucasian, middle class, and highly functional (as most still continued to work) – poorly reflecting the diversity of patients seeking care for early-stage breast cancer in DE. Indeed, census data show our sample to under-represent minorities and to be of generally higher income (US Census Bureau, 2015). Additionally, patients in this study were women that had diagnoses of early breast cancer, so we do not fully know how findings extend to women with more advanced breast cancer or patients with other types of cancers.

Beyond representativeness of the sample, it is also worth discussing the potential influence of culture on participants' response to study items. The CSM accommodates for the subjective influence that cultural factors may have on coping to illness, as illness representations are theorized to be derived from internal and external sources of information, making it quite likely that one's understanding of one's disease is significantly determined by environmental and cultural context. Indeed, studies have shown that even while the pathophysiology of diseases is culturally invariant, an individual's subject experience of illness and one's explanatory models of health problems can be very culturally dependent. (Angel & Thoits, 1987). Specific to this study, as research has documented cultural differences in the importance that individuals attach to their experience of physical symptoms, it is likely that the everyday experience of internal stimuli and the level of concern they would garner would vary widely across cultures (Karasz, Dempsey, & Fallek, 2007). Consequently, it may be that if this study were to be repeated in different cultural contexts, there may be differences in the incidence of and preoccupation towards physical symptoms. Furthermore, the link between the experience of physical symptoms and distress may also be variably attenuated or strengthened, depending on how the interpretation of internal stimuli is determined by social context..

Altogether, it is difficult to determine the extent to which this study's participants accurately represent the patient population of cancer survivors and there is the possibility that our findings, influenced by locale, participation bias, and study design, may limit generalizability. Future studies should attempt to include more diverse study participants across cultures, ethnicity, socio-economic status, and cancer diagnoses.

4.6 Implications and Overall Summary

Despite the noted shortcomings, the present study has merit in that it expands the literature on FOR by examining predictors of daily variability in FOR, consistent with conceptual models of FOR. Furthermore, it suggests at the potentially important intervening role of intrusive thoughts and the importance of cognitive processing. Indeed, research shows that expressing thoughts/feelings related to stressful or traumatic events can be helpful (e.g., Pennebaker, 2007). Moreover, given that effects of daily illness triggers were found, it may be that providing psychoeducation to all cancer survivors on the effects that previously-benign stimuli may have on FOR may be helpful in ameliorating the effects FOR as individuals are made aware of triggers. Indeed, some recent interventions have begun to incorporate both expression of concerns of recurrence as well as patient education on the antecedents of FOR.

An example of such an intervention is the Adjustment to the Fear, Threat or Expectation of Recurrence (AFTER) intervention, a CBT manualized study drawn from Leventhal's self-regulation model and designed to address fear of cancer recurrence in head and neck cancer patients (Humphris & Ozakinci, 2008). This intervention study consisted of six group sessions to discuss the likelihood of recurrences, express cancer-recurrence related fears, and understand triggers. Analyses of study results showed statistically significant improvement in FOR the intervention versus control participants (Humphris & Rogers, 2012). Beyond assisting with cognitive restructuring, so as to limit misinterpretation of physical symptoms, providing information on what to expect may also help cancer survivors anticipate future concerns and normalize their experiences. Similarly, there may also be a role

for mindfulness-based approaches to cultivate awareness or noticing of triggers and thoughts, but without judgment or the impetus to act upon them.

In sum, the findings from the present study, linking daily cancer-related stimuli to FOR at the within-person level, extend the literature on known predictors of FOR, while also testing aspects of a conceptual model of FOR. Our results suggest that a change in illness triggers on particular day affect an individual's FOR on that same day, primarily through intrusive thoughts. In line with the CSM, we found evidence for the responsiveness of daily variability in FOR to factors that are encountered in daily life.

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Appendix A

CROSS-SECTIONAL ITEMS ASSESSING RISK PERCEPTION

RISK1

1. What do you think your chance is of developing cancer again within the next 5 years?

Please drag the bar below to choose a number between 0% (no chance of getting cancer again) and 100% (definitely will get cancer again).

0 10 20 30 40 50 60 70 80 90 100
% | 1

Page Break

RISK2

2. What do you think your chance is of developing cancer again at any point in your lifetime?

Please drag the bar below to choose a number between 0% (no chance of getting cancer again) and 100% (definitely will get cancer again).

0 10 20 30 40 50 60 70 80 90 100
% | 1

Appendix B

CROSS-SECTIONAL ITEMS ASSESSING ILLNESS INTRUSIVENESS

The following items ask about how much your illness and/or its treatment interfere with different aspects of your life. PLEASE SELECT THE ONE NUMBER THAT BEST DESCRIBES YOUR CURRENT LIFE SITUATION.

	Not very much 0	1	2	3	4	5	Very much 6
1. Health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Diet (i.e., the things you eat and drink)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Active recreation (e.g., sports)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Passive recreation (e.g., reading, listening to music)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Financial situation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Relationship with your spouse/partner	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. Sex life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Family relations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Other social relations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Self-expression / self-improvement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Religious expression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Community and civic involvement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix C

CROSS-SECTIONAL QUESTIONNAIRE ITEMS ASSESSING TRAIT WORRY

Please rate how typical each of the following statements is of you.

	Not at all typical of me 0 (1)	1 (2)	2 (3)	3 (4)	Very typical of me 4 (5)
1. If I do not have enough time to do everything, I do not worry about it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. My worries overwhelm me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I do not tend to worry about things.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Many situations make me worry.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I know I should not worry about things, but I just cannot help it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. When I am under pressure I worry a lot.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I am always worrying about something.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I find it easy to dismiss worrisome thoughts.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. As soon as I finish one task, I start to worry about everything else I have to do.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I never worry about anything.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. When there is nothing more I can do about a concern, I do not worry about it anymore.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I have been a worrier all my life.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I notice that I have been	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

worrying about things.					
14. Once I start worrying, I cannot stop.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I worry all the time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I worry about projects until they are all done	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix D

DAILY DIARY ITEMS ASSESSING CANCER-RELATED EVENTS

The next items describe some events that may or may not have occurred today. Please indicate whether or not each event occurred today.

Internal/Physical Cancer-Related Stimuli

	Event did <u>NOT</u> occur today	Event did occur today
6. Noticed changes in physical appearance (e.g., scars, hair loss, change in complexion).	<input type="radio"/>	<input type="radio"/>
11. Fatigue.	<input type="radio"/>	<input type="radio"/>
12. Noticed skin irritation.	<input type="radio"/>	<input type="radio"/>
13. Had swelling or trouble moving my arm.	<input type="radio"/>	<input type="radio"/>
14. Cognitive difficulties (e.g., issues with memory, everyday decision making, focusing, finding words)	<input type="radio"/>	<input type="radio"/>
15. Tingling or loss of sensation in hands or feet	<input type="radio"/>	<input type="radio"/>

Please indicate your physical pain AT THIS MOMENT.

- 0 No pain
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8

- 9
- 10 Worst imaginable pain

External Cancer-Related Stimuli

	Event did <u>NOT</u> occur today	Event did occur today
7. Had a long wait in doctor's office.	<input type="radio"/>	<input type="radio"/>
8. Billing/insurance issue.	<input type="radio"/>	<input type="radio"/>
9. Received negative news from physician.	<input type="radio"/>	<input type="radio"/>
10. Frustrating interaction with medical professional (physician, nurse, etc.).	<input type="radio"/>	<input type="radio"/>

Appendix E

DAILY DIARY ITEMS ASSESSING INTRUSIVE THOUGHTS

1. We are interested in better understanding the thoughts (small or large) that people who are coping with cancer may have in their everyday life. Did you notice having any thoughts about cancer *today*?

- No
 Yes

The next two questions are about the thoughts you had about cancer *today*.

	Not at all 0	A little bit 1	Somewhat 2	Quite a bit 3	Extremely 4
3. Were the thoughts you had today about cancer unwanted ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Were the thoughts you had today about cancer upsetting ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix F

DAILY DIARY ITEMS ASSESSING EMOTIONAL APPROACH COPING

To what extent did you do each of the following in response to today's worst event?

	Not at all 0	A little bit 1	Somewhat 2	Quite a bit 3	Extremely 4
22. I took time to figure out what I was really feeling.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. I realized that my feelings were valid and important.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. I allowed myself to express my emotions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix G

DAILY DIARY ITEMS ASSESSING SOCIAL CONSTRAINTS ON DISCLOSURE

Sometimes, even when your spouse or partner has good intentions, he or she may say or do things that bother or upset you. Please rate how much your spouse/partner did the following things *today*.

	Not at all 0	A little bit 1	Somewhat 2	Quite a bit 3	Extremely 4
1. How much did your spouse/partner change the subject when you tried to discuss your concerns about your illness?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. How much did your spouse/partner minimize your problems related to your cancer experience?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. How much did your spouse/partner tell you to try not to think about the cancer?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. How much did your spouse/partner make you feel as though you had to keep your feelings about your cancer to yourself, because they made him/her feel uncomfortable or upset?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix H

DAILY DIARY ITEMS ASSESSING FEAR OF CANCER RECURRENCE

The following questions ask about thoughts and feelings you may have had today about the possibility of **cancer recurrence**. By **cancer recurrence**, we mean *the possibility that breast cancer could return or progress in the same place or in another part of the body, OR having a different, new cancer*.

	Not at all 0	A little bit 1	Somewhat 2	Quite a bit 3	Extremely 4
2. I was worried, afraid, or anxious about of the possibility of cancer recurrence.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I was sad, discouraged, or disappointed about the possibility of cancer recurrence.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I was frustrated, angry, or outraged about the possibility of cancer recurrence.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I felt helpless or resigned about the possibility of cancer recurrence.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. I felt that I worried excessively about the possibility of cancer recurrence.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Other people thought that I worried	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

excessively about the possibility of cancer recurrence.					
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Appendix I

DAILY DIARY ITEMS ASSESSING NEGATIVE AFFECT

Below are a number of words that describe different feelings. For each item, indicate to what extent you feel this way **AT THIS MOMENT** by checking the appropriate circle.

	Not at all 0	A little bit 1	Somewhat 2	Quite a bit 3	Extremely 4
1. sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. angry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. afraid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. lonely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. blue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. scared	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. frightened	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix J

CONSENT FORM WITH STAMPED IRB APPROVAL



Informed Consent Document

Surviving Cancer Together

You are being asked to take part in a research study about emotional well-being in women with breast cancer and their spouses/partners receiving care at Christiana Care Health System Breast Center and Helen F. Graham Cancer Center. This project is a joint effort between Christiana Care's Cancer Program and the Department of Psychology at the University of Delaware. This project is funded by the National Cancer Institute (NCI) of the National Institutes of Health (NIH).

Participation in the study is entirely voluntary. The nature of the study, the risks, inconveniences, discomforts, and other pertinent information about the study are explained below. You are urged to discuss any questions you have about this study with Dr. Scott Siegel at the Helen F. Graham Cancer Center at 302-623-4890.

Why is this study being done?

The purpose of this study is to examine the long-term experiences of women with breast cancer and their spouses/partners following breast cancer surgery, including emotional well-being, relationship quality, and concerns for the future; this study hopes to determine the trajectory of emotional well-being following surgery, what can influence it, and what its consequences are in the everyday lives of breast cancer survivors and their spouses/partners.

This study plans to recruit at least 60 couples. All volunteers will be recruited from Christiana Care's Breast Center and Helen F. Graham Cancer Center.

What is involved in the study?

If you and your spouse/partner agree to take part in this research study, both of you will be asked to complete an online (Internet-based) daily diary for 21 consecutive mornings and evenings at two different times for a total of 84 online diary entries. The morning diary will require approximately 5 minutes or less, while the evening diary will require approximately 12 minutes. Both of you will be asked to complete the online diary at the end of adjuvant treatment (e.g., hormonal therapy, chemotherapy, radiation) and at your first follow-up mammogram. The diary questions will ask you about aspects of your relationship with your spouse/partner, your mood, thoughts, and pain.

You and your spouse/partner will also be asked to complete several longer questionnaires every 3 months, up to 5 separate times, starting at the beginning of adjuvant treatment and ending at your first follow-up mammogram. These questionnaires (called the 3-Month Check-Up Surveys) will ask

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about your mood, thoughts, quality of life, and relationship quality. Each of these 3-Month Check-Up Surveys will take 45-60 minutes to complete.

You and your spouse/partner will also be asked to wear an accelerometer (a small device worn on your wrist to measure your physical activity) at all times for each 21-day diary period. This part of the study would require a home visit prior to each 21-day diary period by a pair of research assistants in order to demonstrate how to use the accelerometer. Additionally, partners of breast cancer patients (but not the patients themselves) will be asked to provide a small hair sample to measure stress hormones. The hair sample would be collected by the research assistants during the home visit. The research assistants would measure your height and weight.

Lastly, as part of the second home visit, we will also ask you and your partner to participate in an optional additional component during the home visit, which will consist of 4 additional brief questionnaires and 2 videotaped conversations: 1) a 10-minute warm-up conversation, followed by 2) a 15-minute conversation focused on cancer-related concerns. The research assistants will provide detailed instructions for these conversations at the time of the home visit. The 4 brief questionnaires will include questions about your mood, thoughts, and your relationship with your spouse/partner related to the conversation you just had.

Regarding the videotaping procedure, we would like to videotape with sound for the purpose of coding and analyzing the interactions between you as participants when discussing concerns you may have as a result of an upcoming mammogram. An internally developed coding system will be used to understand what takes place during the interaction. Only members of the research team for this study will be reviewing the video recordings. Recordings are strictly confidential and will be kept in a locked room on password-protected computer server when not being observed to protect your privacy.

Other than the videotaped portion of the study, you should only enroll in this study if you intend to complete all parts of the study over the next year.

Please check one of the following statements:

I AGREE to participate in the optional and videotaped portion of the second home visit.

I DO NOT agree to participate in the optional and videotaped portion of the second home visit.

How long will you be in this study?

Expected participation in this study is approximately 1 year.

What are the risks of the study?

As a participant of this study, there are very few risks associated. In the event that you feel anxious, worried, or uncomfortable by any of the questions asked during the online daily diary or questionnaires, you can choose not to answer those questions without jeopardizing any medical

treatment that you receive. You are free to withdraw from the study at any time without consequence.

Are there benefits to taking part in the study?

As a participant you may learn more about yourself and possible methods used to manage stress associated with a cancer diagnosis. We hope the information learned from this study will inform and facilitate the design of additional programs to reduce the stress our patients experience after being diagnosed with cancer. We also hope the information learned from this study will help us to design additional programs to help couples manage the stress of being diagnosed with cancer.

What about confidentiality?

Efforts will be made to keep your personal information confidential. The confidentiality of any central computer record will be carefully guarded and no information by which you can be identified will be released or published. You will be assigned a code number, which will be used in place of your name to identify your questionnaires. Any paper study records will be stored in a locked file cabinet. Computerized data from the study will be encrypted and password-protected and accessible only to study personnel. The key that links your name to your ID number will be kept in a separate, encrypted and password-protected database accessible only to study personnel. The results of the study will be presented in a summary fashion, will not be included in any medical record, and will not be available to any other parties, such as insurance companies. Data will be entered and stored into the central main server and will be kept online for 2 years after the study has been terminated. Data will then be archived and stored at the Department of Psychological & Brain Sciences at University of Delaware and in the Psychosocial Oncology Department of the Helen F. Graham Cancer Center. Questionnaire data will be archived for seven years. Representatives of the Christiana Care Institutional Review Board and the University of Delaware Institutional Review Board are eligible to review research records as a part of their responsibility to protect human subjects in research.

What about compensation?

You should only enroll in this study if you intend to complete all parts of the study over the next year. For completing both daily diary assessment periods in their entirety, the 5 additional assessments that occur every 3 months, and both home visits, you and your spouse/partner will each receive a total of \$540 (\$1080 as a couple). Specifically, you and your partner will each receive:

- For each of the two 21-day diary periods:
 - \$2 per morning diary entry and \$3 per evening diary entry, plus a \$20 bonus for completing all 42 entries over the 21 day period (for a total of \$125 per diary period, or \$250 total per person)
- For the two home visits:
 - \$40 per person per home visit (for a total of \$80 per person for both home visits)
 - Additional \$40 per person for participation in the additional optional component (described above) during the second home visit, including the 4 brief questionnaires and 2 videotaped conversations

- For the (up to) five 3-Month Check-Up Surveys:
 - \$40 per person for the 1st questionnaire
 - \$25 per person for the 2nd questionnaire
 - \$30 per person for the 3rd questionnaire
 - \$35 per person for the 4th questionnaire
 - \$40 per person for the 5th questionnaire

What are the costs?

There is no cost for your participation in this research study. Participation in this research study does not include monetary reimbursement for any medical and psychological care, treatment, and/or tests generated outside of this study. No monetary compensation will be offered for wages lost or for any other reason because of injury resulting from this study. Although unlikely, if you are injured as a result of taking part in this research study, emergency care, hospitalization, and outpatient care will be made available by the hospital and billed to you. No money will be offered by the hospital as compensation for a research-related injury.

Whom do you call if you have questions or problems?

You are free to ask questions at any time about this research study. If you would like any additional information about this study you may contact one of the two principal investigators:

<p>Scott Siegel, Ph.D. Licensed Psychologist Cancer Psychology Helen F. Graham Cancer Center 4701 Ogletown-Stanton Road, Ste. 2183 Newark, DE 19713 (302) 623-4890 ssiegel@christianacare.org</p>	<p>Jean-Philippe Laurenceau, Ph.D. Professor of Psychological & Brain Sciences University of Delaware 110 Wolf Hall Newark, DE 19716 (302) 831-2309 jlaurenceau@psych.udel.edu</p>
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Can you withdraw from the study? What are your rights as a participant?

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time without affecting your future care. Refusing to participate will involve no penalty or loss of benefits.

Can you be removed from the study?

Your participation in the project may be terminated if you fail to complete the required questionnaires in the appropriate time frame. Every effort will be made to maintain your participation.

Other Options

You do not have to take part in this study.

Where can you get more information about this study?

If you have questions about the research, or the rights of participants in research projects at Christiana Care Health Systems, if you have questions about this study or your rights as a person



taking part in a research study, or if you believe you have been injured in any way by taking part in this study, you may contact the Christiana Care Institutional Review Board which is concerned with protection of persons taking part in research studies at Helen F. Graham Cancer Center. You may reach the Christiana Care Institutional Review Board office by calling (302) 623-4983. You also have the right to contact the Chair of the Human Subjects Review Board, University of Delaware, at (302) 831-4007.

By signing below, you indicate that you have read this form, received acceptable answers to any questions, and willingly consent to participate.

You will receive a copy of this form. You may also request a copy of the protocol.

Participant's Signature	Time	Date	Print Name
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Witness' Signature	Time	Date	Print Name
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Principal Investigator's Signature	Time	Date	Print Name
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Christiana Care Institutional Review Board

RESEARCH PARTICIPANT BILL OF RIGHTS

As a participant in a research study or as someone who is asked to give consent on behalf of another person for such participation, you have certain rights and responsibilities. It is important that you fully understand the nature and purpose of the research and that your consent be offered willingly and with complete understanding. To aid in your understanding, you have the following specific rights:

1. To be informed of the nature and purpose of the research in which you are participating.
2. To be given an explanation of all procedures to be followed and of any drug or device to be used.
3. To be given a description of any risks or discomforts which can be reasonable expected to occur.
4. To be given an explanation of any benefits which may be expected to the subject as a result of this research.
5. To be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.
6. To be informed of any medical treatment which will be made available to the subject if complications should arise from this research.
7. To be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.
8. To be made aware that consent to participate in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of your medical care.
9. To be given a copy of the signed and dated written consent form.
10. To not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching your decision to consent or to not consent to participate in the research.
11. Your signature on the Informed Consent does not waive any of your legal rights.

If you have any further questions or concerns about your rights as a research participant, please contact the Christiana Care Institutional Review Board at (302) 623-4983.

