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Fear of Cancer Recurrence in Breast Cancer Survivors Before and After Follow-up Mammograms

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Fear of Cancer Recurrence in Breast Cancer Survivors

Before and After Follow-up Mammograms

by

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DEDICATION

I would like to dedicate this work to cancer survivors everywhere who are navigating their own paths to recovery. I would also like to dedicate this work to those educators and colleagues who have helped influence and propel me in my academic career prior to my graduate training including Robin Lea West, Alissa Dark-Freudeman, Dana Bagwell, Ben Mackay, Scott Warren, and Peggy Ware.

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ABSTRACT

The purpose of this study was to assess fear of cancer recurrence (FCR) in breast cancer survivors returning for regularly scheduled follow-up mammograms. FCR was hypothesized to increase prior to the mammogram, decrease from immediately pre- to immediately post-mammogram, and then increase following the mammogram. Based on the cognitive-behavioral model (CBM) of health anxiety, greater perceived risk of recurrence, worse perceived consequences of a recurrence, lower coping self-efficacy, and more engagement in reassurance-seeking behaviors were hypothesized to be associated with greater FCR in each time segment. Finally, exploratory analyses evaluated the various trajectories in FCR over time using growth mixture modeling and the CBM to predict class membership. The sample comprised 161 women who completed treatment for stage 0-IIIA breast cancer between 6 and 36 months previously. Participants completed the following measures at least 31 days prior to the scheduled mammogram: perceived risk and perceived consequences of breast cancer recurrence, treatment efficacy beliefs, coping self-efficacy, and reassurance seeking behaviors. Participants reported FCR at one month, one week, and immediately prior to the mammogram as well as one month, one week, and immediately after the mammogram using visual analogue scales (VAS) to rate anxiety and worry about cancer recurrence, the Cancer Worry Scale (CWS), and the Fear of Cancer Recurrence Inventory (FCRI). State anxiety and reassurance post-mammogram were also assessed. FCR significantly changed over time with increases in CWS scores prior to the mammogram, a significant decline on the VAS observed immediately following receipt of

results, and a significant increase on the VAS, and decrease in reassurance during the month following the mammogram. The CBM did not significantly predict change in FCR over time, but certain variables did predict fluctuations including coping-self efficacy and perceived risk in the expected directions. Finally, growth mixture models revealed two classes, high-FCR and low-FCR, which were predicted by the CBM. These study findings support the use of the CBM in predicting which cancer survivors experience greater FCR and indicates that CBM-driven interventions may prove beneficial for reducing distressing FCR.

INTRODUCTION

Fear of cancer recurrence (FCR) is emerging as an important topic in cancer survivorship research. FCR is broadly defined as the fear or worry that cancer will return or progress in the same organ or in another part of the body (Simard & Savard, 2009; Vickberg, 2003). To date, numerous studies have reported that the majority of cancer survivors endorse at least some FCR, even several years after successful cancer treatment (Baker, Denniston, Smith, & West, 2005; Deimling, Bowman, Sterns, Wagner, & Kahana, 2006; Herschbach et al., 2004; Lampic et al., 1994; Mehnert, Berg, Henrich, & Herschbach, 2009; Schroevers, Ranchor, & Sanderman, 2006; van den Beuken-van Everdingen et al., 2008). For example, in a study of women with breast cancer who had completed treatment, 39% rated FCR as a dominant concern and nearly half felt that they had moderate-to-high unmet needs about addressing these fears (Stanton et al., 2005). Even long-term survivors continue to have fears about their health. Roughly one third of breast cancer survivors averaging ten years since diagnosis reported worries about a future recurrence, concerns that their current physical symptoms may signal a recurrence, concerns about developing another type of cancer, or worry about future diagnostic tests (Deimling et al., 2006).

While some FCR may be adaptive, higher levels of FCR may be problematic. Greater FCR has consistently been found to be related to worse quality of life (Baker et al., 2005; Hart, Latini, Cowan, Carroll, & CaPSURE Investigators, 2008; Mehnert et al., 2009; Simard & Savard, 2009; Skaali et al., 2009; van den Beuken-van Everdingen et al., 2008), heightened anxiety (Deimling et al., 2006; Humphris et al., 2003; Llewellyn, Weinman, McGurk, &

Humphris, 2008; Rothrock, Matthews, Sellergren, Fleming, & List, 2004; Simard & Savard, 2009; Skaali et al., 2009), more intrusive thoughts about illness (Mehnert et al., 2009; Simard & Savard, 2009; Simard, Savard, & Ivers, 2010; Skaali et al., 2009), more depressive symptoms (Deimling et al., 2006; Humphris et al., 2003; Simard & Savard, 2009; Skaali et al., 2009), and more post-traumatic stress symptoms (Mehnert et al., 2009; Simard & Savard, 2009).

Information about the course of FCR is limited since most previous studies have used cross-sectional research designs. Among the few previous longitudinal studies, most span a time period from soon after diagnosis to up to 15 months post-treatment. These studies have reported that levels of FCR remain relatively stable following diagnosis (Humphris & Rogers, 2004; Llewellyn et al., 2008; Stanton, Danoff-burg, & Huggins, 2002). Another study following head and neck cancer survivors averaging four years after treatment found no change in FCR over a two-year time interval (Humphris et al., 2003). Only one study to date has noted significant change in FCR over time. Rabin, Leventhal and Goodin (2004) found evidence for a significant decrease in FCR from the period during chemotherapy to one month after completion of chemotherapy. In general, previous longitudinal studies have not focused on discrete time periods to detect subtle fluctuations in FCR over time and have not assessed FCR during key medical events post-treatment (i.e., cancer screening appointments). Cancer survivors report anecdotally that the repeated examinations and consultations post-treatment can elicit heightened anxiety and FCR, especially leading up to procedures, exams, or awaiting receipt of testing results (Gil et al., 2004; Okazaki et al., 2009). Hence, more research on the longitudinal course of FCR over time is warranted.

Screening Anxiety

Medical screening exams provide an interesting opportunity to study temporal fluctuations in FCR. Typically, patients report experiencing a decrease in anxiety and worry immediately following receipt of negative test results following examinations such as gastroscopy, endoscopy, and procedures conducted during general practitioner visits (i.e., blood test results, physical examinations, etc.) to identify the source of common health complaints (Laasko, Niemi, Grönroos, & Karlsson, 2008; Lucock, Morley, White, & Peake, 1997; Quadri & Vakil, 2003). However, longer-term follow-up assessments often reveal that the reassuring effect of the test result is short-lived, with patients in several studies demonstrating increases in anxiety or worry and decreases in reassurance as soon as one day after receiving the results (Donkin et al., 2006; Lucock et al., 1997; Rimes & Salkovskis, 2002). There is also evidence of individual differences in the pattern of anxiety over time, with some patients reporting no change over time (Howard et al., 2005; Laasko et al., 2008; Quadri & Vakil, 2003; Rimes & Salkovskis, 2002), and others reporting *increases* in anxiety immediately following receipt of negative results (Laasko et al., 2008; Rimes & Salkovskis, 2002; Rimes, Salkovskis, Jones, & Lucassen, 2006).

Research assessing anxiety and worry related to screening mammograms in women with no history of cancer has also revealed differing patterns of anxiety. Some studies assessing women at various times before and after a mammogram have found that anxiety is low overall and does not change significantly over time (Brunton, Jordan, & Campbell, 2005; Scaf-Klomp, Sanderman, van de Wiel, Otter, & van de Heuvel, 1997; Sutton, Saidi, Bickler, & Hunter, 1995). However, a study that measured cancer worry and risk perceptions, rather than anxiety alone, found that both cancer worry and cancer risk perceptions decrease from the period before the

mammogram to two months after (Absetz, Aro, & Sutton, 2003). Further, illness beliefs such as perceived susceptibility to cancer predicted differences in the trajectory of distress over time. Those with high perceived susceptibility experienced decreases in depressive symptoms from pre-screening to two months after screening with a return to pre-screening levels by one year after screening. In contrast, there was no change in depressive symptoms for the low susceptibility group (Absetz et al., 2003). Another study examined differences between women who felt reassured following normal mammogram screening results and those who did not (Meechan, Collins, Moss-Morris, & Petrie, 2005). Findings indicated that women who were not reassured were more likely to have reported breast changes prior to the mammogram, perhaps suggesting that they were still concerned about their medically unexplained breast symptoms (Meechan et al., 2005). The lack of consistent findings for changes in anxiety and cancer worry before and after mammograms in healthy women may be due to the fact that no available studies have assessed women intensively over time. In fact, all of these studies had assessments occurring three or more months apart, making changes in anxiety related to mammography screening more difficult to detect, especially if such anxiety is short-lived.

A limited number of studies have examined anxiety related to mammography in women who are at objectively greater risk for cancer, such as women with family or personal histories of breast cancer. In a systematic review comparing women with and without a family history of breast cancer, those with a family history had significantly higher anxiety than those with no family history during the time of the mammogram and up to six weeks after (Watson, Henderson, Brett, Bankhead, & Austoker, 2005). Longitudinal studies of cancer patients attending routine medical follow-up visits have found some evidence of fluctuations in anxiety following these appointments. Breast cancer patients attending routine follow-up visits

experienced low anxiety overall, but showed significant increases in anxiety between a few days to three weeks after the visit (Lampic et al., 1994). Unfortunately, existing longitudinal studies of cancer survivors attending follow-up medical visits have not assessed FCR with validated measures and have not assessed FCR or anxiety leading up to the appointments to determine if there are fluctuations in these concerns in anticipation of the visit.

Predictors of Fear of Cancer Recurrence

Despite how commonly FCR is reported, there has been relatively little research aimed at identifying predictors of or risk factors for FCR. Interestingly, FCR has typically not been found to be related to objective prognostic features of the cancer. Along these lines, several studies have not found a relationship between the magnitude of FCR and factors such as time since diagnosis (McGinty, Goldenberg, & Jacobsen, 2012; McGinty, Simard, Savard, & Jacobsen, 2010; Simard & Savard, 2009; Skaali et al., 2009), time since treatment completion (Humphris et al., 2003; McGinty et al., 2010; van den Beuken-van Everdingen et al., 2008), past treatment (McGinty et al., 2010; McGinty et al., 2012), or cancer stage (Llewellyn et al., 2008; Rabin et al., 2004). However, certain demographic characteristics have be linked to heightened FCR, including younger age (Deimling et al., 2006; Humphris et al., 2003; Lofters, Juffs, Pond, & Tannock, 2002; Mehnert et al., 2009; McGinty et al., 2012; Mullens, McCaul, Erickson, & Sandgren, 2004; Simard & Savard, 2009; Stanton et al., 2005; van den Beuken-van Everdingen et al., 2008) and lower education (Lofters et al., 2002; Skaali et al., 2009). In addition, several studies have found links between psychosocial variables and FCR. For example, higher perceived risk of cancer was found to be related to greater FCR in breast cancer survivors (McGinty et al., 2010; McGinty et al., 2012; Rothrock et al., 2004).

Relevant Theories

To date, most studies have not utilized relevant theories that might inform research into prediction of FCR in cancer survivors. Two such theories are Leventhal's common sense model of illness representations (CSM; Leventhal, Diefenbach, & Leventhal, 1992) and the cognitive-behavioral approach to health anxiety (Salkovskis & Warwick, 1986; Warwick, 1989). The CSM describes how cognitive appraisals of illness can influence both distress and health behaviors and has been used successfully to predict heightened distress in various medical populations (Haggar & Orbell, 2003). According to the model, health information is interpreted along a number of dimensions to form cognitive and emotional illness representations that then influence how individuals chose to cope with various health threats, depending on the interpretation. Key illness representations are beliefs about the cause, consequences, identity, emotional impact, timeline, and cyclic or stable course of an illness as well as beliefs about personal control and treatment efficacy to cure or reduce the impact of the illness (Leventhal et al., 1992; Leventhal, Leventhal, & Contrada, 1998; Moss-Morris et al., 2002). A meta-analytic review found that, in general, more negative illness representations predicted worse emotional distress in patients with a variety of medical conditions (Haggar & Orbell, 2003).

Longitudinal studies assessing distress in women with cancer have found that distress is predicted by illness perceptions including perceived timeline of the cancer, identifying more physical symptoms as related to the cancer, and feelings of personal control over the course of the cancer (Henselmans et al., 2010; Millar, Purushotham, McLatchie, George, & Murray, 2005; Ward, Viergutz, Tormey, deMuth, & Paulen, 1992). Two recent studies have found partial support for the use of Leventhal's model in predicting FCR in survivors of various cancers. In a study of patients treated for head and neck cancer, more negative perceived consequences of a

recurrence and a worse emotional representation of cancer were related to greater FCR (Llewellyn et al., 2008). In a study of women treated for breast cancer, conceptualizing cancer as a chronic or cyclic condition, rather than as an acute condition, was related to greater FCR (Rabin et al., 2004).

The cognitive-behavioral model of health anxiety is similar to the CSM in that it examines the impact of key illness beliefs on health anxiety and distress. It also addresses the impact of behaviors (i.e., reassurance seeking, checking bodily status) that may serve to maintain and reinforce elevated health anxiety (Salkovskis & Warwick, 1986; Salkovskis & Warwick, 2001; Warwick, 1989). According to the model, existing perceptions about health and relevant health threats influence the degree to which individuals become anxious about their health. If anxiety is elicited by beliefs about their health, then the individual may engage in behaviors to temporarily reduce their anxiety. Because these behaviors do not typically change the inherent risk of health problems or change the health beliefs permanently, they serve to reinforce the anxiety brought on by the illness beliefs and lead to increased anxiety in the long-term. Key illness beliefs in this model are perceived risk of the illness, perceived severity of the consequences of the illness, perceived ability to cope with the illness, and perceived effectiveness of available treatments to cure or control the illness (Warwick, 1989; Salkovskis & Warwick, 2001).

Originally, the cognitive-behavioral model was proposed to identify predictors of hypochondriasis and health anxiety (Salkovskis & Warwick, 1986; Warwick, 1989). More recently it has been used to study changes in health anxiety in individuals undergoing various medical screening consultations (Hadjistavropoulos, Craig, & Hadjistavropoulos, 1998; Rimes & Salkovskis, 2002; Rimes et al., 2006). In a study of healthy women undergoing bone mineral

density screening, illness beliefs about the severity of osteoporosis, perceived risk, ability to cope, and treatment efficacy were predictive of later anxiety. Indeed, perceived severity of osteoporosis was more strongly related to later anxiety than the actual results of the screening (Rimes & Salkovskis, 2002). Additional findings focused on predicting changes in health-related worry and anxiety over time following screening and compared those with high or low general health anxiety. Those with high health anxiety in general experienced reduced anxiety immediately following good news about their results, but their anxiety, worry about osteoporosis, and perceived risk returned to pre-screening levels after 14 months (Rimes & Salkovskis, 2002). In another study using this model, Rimes et al. (2006) assessed anxiety in healthy individuals with family histories of cancer before and six months after genetic counseling about cancer risk. Similar to their previous results (Rimes & Salkovskis, 2002), the authors found that objective risk factors were unrelated to changes in anxiety over time; however, illness beliefs including higher perceived risk, perceived coping abilities, and more severe perceived consequences of cancer, were related to health anxiety (Rimes et al., 2006). Again, they found that patterns of anxiety during health screening were predicted by having either high or low general health anxiety (Rimes et al., 2006). Those high in health anxiety showed a reduction in perceived risk of cancer and anxiety at six months, however, those with low health anxiety experienced no change in perceived risk or anxiety over time (Rimes et al., 2006). As demonstrated by these studies, the cognitive-behavioral model of health anxiety has been shown to not only predict health anxiety and cancer-specific anxiety, but also fluctuations in health anxiety over time following screening and consultations. Because FCR can be conceptualized as cancer-specific health anxiety, FCR may also be predicted by the cognitive-behavioral factors associated with fluctuations in health anxiety.

Current Study

There are several important gaps in the existing FCR research literature. First, there are few studies that have examined theory-driven predictors of FCR in prospective, longitudinal designs. Available studies have typically focused on psychological morbidity associated with FCR, but have rarely examined the sources of FCR itself. Those that have done so have focused on cognitive, but not behavioral predictors of FCR. Further, no research to date has assessed FCR intensively to determine whether there are fluctuations surrounding medical exams. Specifically, it is not clear to what degree FCR changes as a result of important cancer-related events, such as the receipt of cancer screening results following the completion of active cancer treatment. Along these lines, no study has documented FCR in relation to follow-up mammography screening in breast cancer survivors to determine if these screening appointments elicit heightened FCR and anxiety.

With these considerations in mind, the purpose of this study is to examine patterns of change in fear of cancer recurrence before and after regularly scheduled mammograms in breast cancer survivors. Breast cancer survivors who have completed treatment will be surveyed longitudinally to examine the pattern of FCR over time. Assessments will be completed at the following times: one month prior to the mammogram (T1), one week prior to the mammogram (T2), immediately before the mammogram (T3), immediately after receipt of results (T4), one week after receipt of results (T5), and one month after receipt of results (T6). Participants will also report on their anxiety level, cognitions, and behaviors to evaluate how these are related to FCR.

Hypotheses. The following hypotheses will be tested:

1) There will be a significant increase in fear of recurrence over the period before participants undergo a routine mammogram (T1 to T3).

2) There will be a significant decrease in fear of recurrence over the period from shortly before to shortly after participants receive negative mammogram results (T3 to T4).

3) There will be a significant increase in fear of recurrence over the period of time after participants received negative mammogram results (T4 to T6).

In addition to these hypotheses, we will examine predictors of individual differences in fear of recurrence over time. Following the cognitive-behavioral model of health anxiety, it is hypothesized that greater perceived risk of breast cancer recurrence, worse perceived severity of breast cancer recurrence, lower perceived efficacy of breast cancer treatment, lower self-efficacy for coping with cancer recurrence, and more reassurance seeking behaviors will predict:

4) greater increase in fear of recurrence before the mammogram (T1 to T3);

5) less reduction in fear of recurrence immediately following receipt of negative mammogram results (T3 to T4); and

6) greater increase in fear of recurrence following receipt of negative mammogram results (T4 to T6).

Finally, exploratory analyses will be conducted to determine whether distinct trajectories for changes in fear of recurrence over time can be identified (T1 to T6) and whether cognitive and behavioral factors predict which trajectory patients exhibit. Additional exploratory analyses will examine if there is significant change in state anxiety before and after the mammogram (T1 to T6), and reassurance following the mammogram (T4 to T6).

METHOD

Participants

Eligibility criteria. Breast cancer survivors scheduled for regular follow-up mammography at Moffitt Cancer Center were approached to participate. Eligibility criteria were: age greater than or equal to 18 years, diagnosed with stage 0 to IIIA breast cancer, completed primary treatment for breast cancer within the past 3 years, able to read and speak English, had access to internet, and able to provide informed consent. Breast cancer survivors were excluded if they had a history of other cancers (except non-melanoma skin cancer) or evidence of disease recurrence. Statistical analyses only include participants who received negative mammography results. Participants who were recalled for further screening or additional tests after their mammogram were excluded from analyses.

Procedure

Patients were screened for eligibility via medical chart review. Eligible patients were contacted via mail with a letter from their Moffitt physician inviting them to participate and providing an option to decline via postcard. Patients who did not decline were called to confirm their mammography appointment was approaching. They were then mailed the consent form and login information to complete the initial questionnaire online five weeks before their scheduled mammogram. Because timing of assessments were presumed to detect changes in FCR, online surveys were used in place of mail-in surveys to ensure that participants were completing assessments that occurred outside the clinic on time. Participants completed questionnaires at

seven time points: a baseline questionnaire with clinical, demographic, and psychological predictors completed between 38 and 31 days prior to the mammogram appointment (T0), and six follow-up surveys assessing FCR and state anxiety one month prior to the scheduled mammogram (T1), one week prior to the scheduled mammogram (T2), immediately prior to their mammography appointment (T3), immediately following receipt of mammography results (T4), one week after receipt of results (T5), and one month after receipt of results (T6). The T0, T1, T2, T5, and T6 questionnaires were completed online. Women received reminder emails and phone calls to alert them to complete the T1, T2, T5 and T6 questionnaires within 2 days of the target date.

The T3 and T4 questionnaires were completed on the day of the mammography appointment at the clinic. On this day, patients were met by a member of the research team in the clinic waiting room to complete the T3 questionnaire prior to being called to undergo their mammogram. At Moffitt Cancer Center, all breast cancer patients receive a diagnostic mammogram which entails two views on each breast (or two views on the contralateral breast only in the case of mastectomy patients) and is completed within 15 to 20 minutes. After the mammogram is completed, patients are escorted to a different waiting area where they await the receipt of the results approximately two hours later. Results are explained by their treating surgeon or medical oncologist the same day as the exam before patients leave the clinic. Immediately after the patients received the results, they completed the T4 questionnaire in the clinic waiting area.

Measures

Demographic characteristics. A standardized self-report form was used to collect the following information at T0: age, height, weight, race, ethnicity, marital status, income, education, and menopausal status.

Clinical characteristics. The following clinical characteristics were assessed via medical chart review: stage at diagnosis, treatment(s) received (any surgeries or adjuvant treatments, including on-going treatments such as hormone therapy or herceptin), time since diagnosis, and time since treatment completion.

Perceived risk. Perceived risk of a cancer recurrence was assessed at T0 by obtaining participants' estimates of their absolute and comparative risk using items adapted from prior research (Valdimarsdottir et al., 1995). To assess absolute risk, participants were asked, "How likely do you think you are to have breast cancer again during your lifetime?" and to assess comparative risk, they were asked, "What do you think your chances are of having breast cancer again in your lifetime compared to other women your age with breast cancer who received the same treatment for the same type of breast cancer?". Response options range from 1 (*extremely unlikely*) to 6 (*extremely likely*) for the absolute risk item and from 1 (*much higher*) to 5 (*much lower*) for the comparative risk item. Based on the correlation observed in the present study (r = -.42) and methods used in other studies (McGinty et al., 2012), absolute and comparative risk estimates were converted to the same metric by finding a common product and then summed to create a total perceived risk score.

Perceived severity. The Consequences Subscale of the Revised Illness Perception Questionnaire (Moss-Morris et al., 2002) was administered at T0 to assess perceived severity of the consequences of a breast cancer recurrence. All items were adapted to refer to a "recurrence

of breast cancer" as the target illness to be considered. Items reflect the potential medical, social, financial, and psychological consequences of a breast cancer recurrence. Participants were asked to indicate how much they agreed with each consequence on a scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). This measure showed acceptable psychometric properties in previous research (Moss-Morris et al., 2002). Internal consistency was also acceptable for the current study sample (Cronbach's $\alpha = .82$).

Coping self-efficacy beliefs. The brief Cancer Behavior Inventory (CBI-B; Heitzmann et al., 2010) was administered at T0 to assess participants' beliefs about their ability to cope with the possibility of a breast cancer recurrence. The CBI-B is comprised of 16 items and measures patients' confidence in providing self-care during cancer diagnosis, treatment, and recovery. The original measure was adapted to measure patients' confidence that they could follow common self-care practices *in the event that their cancer returned*. Participants were asked to rate their confidence for maintenance of activities and independence, coping with side effects, positive attitude, seeking medical information, affective regulation, stress management and seeking support. Response options are on a Likert scale ranging from 1 (*not at all confident*) to 9 (*totally confident*). The original CBI and CBI-B demonstrated acceptable reliability in previous research and have been validated for use with cancer patients (Merluzzi et al., 2001; Heitzmann et al., 2010; Henselmans, Fleer, de Vries, Baas, Sanderman, & Ranchor, 2009). This measure demonstrated acceptable internal consistency in this sample (Cronbach's $\alpha = .92$).

Treatment efficacy beliefs. Participants were asked several questions at T0 to assess their beliefs that available treatments would be effective in prolonging the lives of women who have a breast cancer recurrence. Items were derived from a scale used to assess physician's treatment efficacy beliefs for prostate cancer (Fowler et al., 1998). Participants rated the extent

to which they believe that available treatment options can provide a survival benefit. Five treatment options were assessed including surgery, chemotherapy, radiation, hormone therapy, and a combination of these treatments. Response options range from 1 (*definitely not*) to 4 (*definitely*). This measure demonstrated acceptable internal consistency in the current sample (Cronbach's $\alpha = .73$).

Reassurance-seeking behaviors. Participants were asked at T0 to report self-checking behaviors using the 3-item reassurance-seeking behavior subscale of the Health Anxiety Questionnaire (HAQ; Lucock & Morley, 1996). Items assess the frequency with which patients are performing informal exams of their own bodies, asking others about health concerns, and reading information about illnesses to determine if they are sick. Response options are 1 (*not at all or rarely*), 2 (*sometimes*), 3 (*often*), and 4 (*most of the time*). The HAQ has shown good reliability and validity in previous research (Lucock & Morley, 1996; Lucock, Morley, White, & Peake, 1997; Meechan et al., 2005; Quadri & Vakil, 2003). The reassurance-seeking behavior subscale demonstrated relatively poor internal consistency in the current sample (Cronbach's $\alpha = .56$).

Fear of cancer recurrence. Participants completed three separate measures of fear of cancer recurrence. One month prior to the scheduled mammogram (T1), the day of the mammogram (T3), and one month after the scheduled mammogram (T6), participants completed the Fear of Cancer Recurrence Inventory (FCRI), a self-report measure of cancer recurrence fear in the past month (Simard & Savard, 2009). The FCRI consists of 42-items which can provide clinically meaningful information about the nature of FCR and yields scores for 7 subscales: triggers, severity, distress, functional impairments, insight, reassurance, and coping. Scores from each subscale are summed to create the total score, with higher scores indicating greater fear of

cancer recurrence. Preliminary validation of the English version of this measure demonstrated good psychometric properties similar to the original French version (Lebel et al., 2010; McGinty et al., 2010). There was acceptable internal consistency for this measure across all study time points (Cronbach's α ranged from .95 to .96).

At T1, T2, T3, T5 and T6, participants also completed the Cancer Worry Scale (CWS), which was modified to apply to cancer patients' concerns of a possible recurrence (Rabin et al., 2004). This measure assesses the frequency of recurrence worry over the course of the past week using the following response options: 1 (*not at all or rarely*), 2 (*sometimes*), 3 (*often*), and 4 (*a lot*). In a previous study, we found that the modified CWS is positively related to measures of psychological distress such as depression (r = .49) and negatively related to mental health (r = -.43) in breast cancer survivors (McGinty, Jacobsen, & Andrykowski, 2008). Compared to lengthier measures like the FCRI, the modified CWS is easily keyed to shorter time periods and is brief enough to reduce participant burden, while still providing information about the frequency of FCR. This measure showed acceptable internal consistency in the current sample across all time points (Cronbach's α ranged from .83 to .86).

Finally, at all assessment time points, participants completed two visual analogue scales (VAS) assessing the extent to which they were "worried about the possibility of a breast cancer recurrence" and "anxious about the possibility of a breast cancer recurrence" to provide measures of the magnitude of FCR. Possible responses ranged from 0 (*not at all worried*) to 100 (*extremely worried*) for the first item and 0 (*not at all anxious*) to 100 (*extremely anxious*) for the second. Across all study time points, the two VAS items were closely related, with correlations ranging from r = .85 to r = .94.

Anxiety. The Brief State-Trait Anxiety Inventory (STAI) was completed at T1 through T6 to assess state anxiety (Marteau & Bekker, 1992). Participants indicated the degree to which they felt calm, tense, upset, relaxed, content, and worried at the time of the assessment using a scale of 1 (*not at all*), 2 (*somewhat*), 3 (*moderately so*), and 4 (*very much so*). The brief STAI has demonstrated excellent psychometric properties in several populations, including cancer patients (Henselmans et al., 2010; Marteau & Bekker, 1992). There was acceptable internal consistency across all study time points (Cronbach's α ranged from .74 to .90).

Reassurance. Patients' subjective experience of reassurance after receipt of mammography results was assessed at each time point after the mammography appointment (i.e., T4 to T6). Participants completed two items adapted from a reassurance scale used in previous research of patients following cardiopulmonary stress test results (Donkin et al., 2006). The first item assesses overall sense of reassurance: "The extent to which you were reassured by the results of your most recent mammogram" and response options are on a scale from 0 (*not reassured at all*) to 10 (*completely reassured*). The second item assesses the desire for additional testing: "The extent to which you believe that you should have additional testing to rule out the possibility of a breast cancer recurrence" with response options ranging from 0 (*strongly disagree*) to 10 (*strongly agree*). Because these items were only moderately correlated, (r = .35 to r = .51 across all time points), they were examined separately in subsequent analyses.

Statistical Analyses

The first three hypotheses predict significant change in FCR during the period of time leading up to the mammogram (hypothesis 1), from immediately before to immediately after receipt of results (hypothesis 2), and during the period of time following receipt of results (hypothesis 3). To test for significant change in FCR over time, a series of unconditional growth

curve models using SAS PROC MIXED were conducted for each of these segments of time: T1 to T3 and T4 to T6. First, fully unconditioned models were fit to the data to estimate the average FCR (intercept) followed by growth curve models which add time as a predictor of both initial FCR and change in FCR over time (slope). Significant effects for time indicate significant change in FCR over time. Repeated measures ANOVAs were used to test change between any time point with fewer than three measurements. The average of the two VAS measures was used as the primary dependent measure for all analyses. To test whether the type of FCR measure impacts results and to demonstrate reproducibility of results, analyses included the FCRI and modified CWS as secondary outcomes for those analyses where multiple measures of FCR are available across the different times. Because two of the time segments include more than two assessment points, both linear and quadratic curves were examined for hypothesis 1 and 3. Additional exploratory analyses examined change in state anxiety (T1 to T3, T3 to T4, and T4 to T6) and change in reported reassurance following the mammogram (T4 to T6) using similar procedures for repeated measures ANOVAs and growth curve modeling outlined above.

Next, relevant predictors of FCR over time were assessed to test hypotheses 4, 5, and 6. Residualized change scores were computed between the initial FCR score and the final FCR score for each time segment (i.e., T1 to T3, T3 to T4, T4 to T6), and used as the dependent variable in a multiple hierarchical regression analysis. Univariate analyses were first conducted to examine interrelationships between FCR at each time point and demographic, clinical, and cognitive-behavioral variables to determine which variables were entered into the hierarchical regression. The initial FCR score was entered on the first step to predict the final FCR score for that particular time segment, creating a residualized change score. Demographic and clinical variables significantly related to FCR at any time point were entered on the second step in the

hierarchical regression. Relevant cognitive-behavioral predictors were entered on the third step. A significant change in the variation explained between step 2 and step 3 would support the hypotheses that cognitive-behavioral variables predict change in FCR over time after controlling for demographic and clinical factors.

Finally, growth mixture model analysis (Muthén, 2004) was conducted using Mplus Version 7 to determine whether there are multiple trajectories across all the time points. The analyses require running several potential models and determining whether single class models or models with successively larger number of classes are the best fit to the data. The initial one-class model is similar to a standard latent growth or random effects model where all participants are assumed to be derived from the same population. Various shapes were evaluated including linear, quadratic, and piecewise to determine which best depicted the nature of longitudinal change in the sample.

With each additional model, a new class is added and evaluated using several statistical fit parameters to determine overall goodness of fit for each model. The multi-class models are evaluated based on the fit indices (AIC, BIC, Deviance), entropy values which evaluate the uncertainty of classification of subjects into latent classes, and by the Lo-Mendell-Rubin test to evaluate if additional classes offer a significant improvement in model fit. For AIC, BIC, and deviance, smaller values indicate improvement in model fit. For entropy, values range from 0 to 1 and larger values indicate greater certainty in classifying subjects into the latent classes. Classes that feature fewer than 10% of the study sample are only considered if their trajectories represented a meaningful difference in slope over time or if it represents a parallel class with a substantially higher or lower mean FCR over time (Uher et al., 2010). Once the statistical fit parameters indicate that there is no improvement of fit or poorer fit with additional classes, the

iterative model testing is suspended. Finally, if more than one class is detected, logistic regression analyses are conducted to determine which demographic, medical, and psychosocial characteristics predict group membership.

Power analyses were computed for both repeated measures ANOVAs and hierarchical regression analyses. Computing power analyses for repeated measures ANOVAs rather than growth curve models provides a more conservative standard by which to estimate the appropriate sample size for this study. The first power analysis for the repeated measures ANOVAs was based on two repeated measures in one group where the repeated measures are assumed to have a small to medium correlation, $r = .30$. A sample size of 125 participants with complete data yields power of .80 to detect an effect size = .15 at alpha = .05. The second power analysis for the proposed regression analyses was based on one step containing three demographic and/or clinical variables followed by a second step containing the six psychosocial variables. The first step is expected to account for 30% of the variance. Therefore, a sample size of 120 participants with complete data yields power of .80 to detect an 8% increase in variance accounted for by the second step at alpha = .05. To provide adequate power for all analyses, a target sample size of 125 is needed. Based on these analyses and accounting for 40% missing data due to attrition and random missingness, initial plans called for 175 participants to be recruited.

RESULTS

Participants

A total of 2,584 patients scheduled for diagnostic mammograms at Moffitt Cancer Center between December 2011 and January 2013 were screened for eligibility. Of these patients, 2,092 were ineligible (see Figure 1 on page 33). The remaining 492 women were contacted to participate; of these women, 173 refused to participate, 73 could not be reached, and an additional 75 were ineligible before consent (e.g., indicated that they did not speak English, did not have Internet access, could not provide consent, cancelled the mammogram appointment, etc.). Consent forms were signed by 171 women, yielding a participation rate of 51.20% among women eligible prior to consent. Four were ineligible after consent (i.e., other cancer diagnoses, loss of internet access, or cancelled mammogram appointment), three declined, and three did not complete the initial (T0) survey in time, leaving 161 participants in the study sample at T0. The overall participation rate for those who signed consent and completed at least one study survey was 48.20%. After baseline, one participant withdrew and one patient cancelled the mammogram appointment. A total of 13 patients were recalled after their mammograms for additional diagnostic testing to rule out a cancer recurrence and one patient was later diagnosed with a different primary cancer after a negative mammogram. A total of 128 women completed all seven study surveys.

Participants' demographic and medical characteristics are shown in Table 1 (see page 42). They ranged in age from 33 to 86 years old (M = 61.48, SD = 9.60). The majority of the

participants had completed at least some college or specialized training (84.5%), were married (73.3%), had a gross annual income greater than $40,000 (77.2%), and were Caucasian (93.2%). The sample included women diagnosed at stage 0 (16.2%), stage I (55.9%), stage II (26.7%), and stage IIIA (1.2%). These women were an average of 1.74 years (*SD* = 0.74, range 0.49 years to 3.86 years) since diagnosis and 1.30 years (*SD* = 0.69, range 0.13 years to 3.30 years) since treatment completion and had completed an average of 1.16 (*SD* = 0.90, range 0 to 4) previous mammograms after treatment completion.

Participating patients (*n* = 161) were compared to non-responders (*n* = 249; i.e., those who were invited to participate and either declined or did not respond to the study request) on available demographic and clinical characteristics. Responders were significantly more likely to be stage 0 ($p < .01$) and less likely to have received both chemotherapy and radiation treatments than non-responders ($p = .05$). Also, responders were significantly younger ($p = .03$), had a longer time since diagnosis and treatment completion ($p < .001$), and had a longer duration of chemotherapy ($p = .01$).

Descriptive Statistics

The CBM variables were assessed only at baseline (T0). Participants overall perceived mild to moderate absolute risk of breast cancer recurrence (*M* = 33.28, *SD* = 8.5), with the majority of responses (52.80%) rated as 1 (*extremely unlikely*) to 2 (*somewhat unlikely*). For perceived relative risk of recurrence, the majority of responses (68.32%) were rated as 3 (*about the same*) when comparing one's own risk of recurrence to that of other breast cancer patients. As noted above, these two risk estimates were combined on a scale that ranged from 11-60 for later analyses, with higher scores indicating greater perceived risk of cancer recurrence. Perceived severity was also moderate (*M* = 22.02, *SD* = 4.60) in this sample, as scores fell near

the midrange on this measure (possible range = 6 to 30). Mean coping efficacy scores showed that patients believed that survivors overall believed they could cope with a cancer recurrence, (M = 108.09, SD = 21.49; possible range = 18 to 162). Mean treatment efficacy scores indicated that participants believed that various treatments would probably or definitely provide some benefit if cancer returned, (M = 15.20, SD = 2.01; possible range = 5 to 20). Mean values for FCR, state anxiety, and reassurance across the different measures for the pre-mammogram time period (T1-T3), immediate pre-post mammogram time period (T3-T4), and post-mammogram time period (T4-T6) are presented in Tables 2, 3, and 4 respectively (see pages 44-46).

Evaluation of Hypothesis 1

Growth curve modeling was conducted to test hypothesis 1 that changes in FCR would occur during the month leading up to the mammogram. The following measures were assessed for significant change over time during the pre-mammogram time period (T1 to T3): combined VAS for anxiety and worry, the CWS, and the FCRI. For the VAS, the unconditional growth model showed there was no significant effect of time, linear slope = 0.01, $t(158) = 0.19$, $p = .85$. Further, neither linear nor quadratic time effects were observed when the quadratic term was added to the growth curve model (p's < .05). Hence, contrary to predictions, no change over time was observed for this measure prior to the mammogram (see Table 5 on page 47). As shown in Figure 2 (see page 34), the mean VAS scores are relatively stable before the mammogram. For the CWS, there was a significant effect of time in the linear growth model, slope = 0.01, $t(158) = 2.71$, $p = .007$, (see Table 6 on page 48), demonstrating a gradual increase in CWS scores during the 30-day time period before the mammogram (see Figure 3 on page 35). When the quadratic term was added to the growth curve model, however, neither the linear nor quadratic slopes were significant (p's > .05) and model fit was not improved (i.e., deviance for

the linear growth curve and for the quadratic growth curve were both 1866.8) (see Table 6). Hence, consistent with predictions, there was a significant linear increase in the average CWS score during the month before the mammogram. For the FCRI (completed at T1 and T3 only), there was also a significant effect of time evaluated by repeated measures ANOVA, *Wilk's lambda* = 0.97, $F(1,150) = 4.00$, $p = 0.05$. Contrary to predictions, mean scores significantly decreased over time between a month before the mammogram and the day of the mammogram (see Figure 4 on page 36).

Evaluation of Hypothesis 2

A repeated measures ANOVA was conducted for the immediate pre-mammogram and immediate post-mammogram assessments (T3 to T4) for the combined VAS for anxiety and worry to test the hypothesis that there would be a significant decrease in FCR following receipt of negative mammogram results. Consistent with predictions, there was a significant decrease over time for the VAS among women who were provided feedback that there were no signs of cancer post-mammogram, *Wilk's lambda* = 0.59, $F(1,139) = 97.27$, $p < .001$ (see Figure 2).

Evaluation of Hypothesis 3

Growth modeling and repeated measures ANOVA were conducted to test the hypothesis that FCR would increase during the month following receipt of mammogram results (T4 to T6). FCR was evaluated during this time segment using the combined VAS measure and the CWS. For the VAS, the growth curve models demonstrated significant change in scores over time, with both linear, slope = 0.92, $t(143) = 3.58$, $p < .001$, and quadratic effects, slope = -0.02, $t(143) = -2.80$, $p = .006$, (see Table 7 on page 49). As shown in Figure 2, and consistent with predictions, mean scores increased from the low initial values following the announcement of the negative mammogram, with a steeper increase from T5 to T6 than from T4 to T5. For the CWS

(evaluated at T5 and T6 only), there was no change over time in the mean scores from one week to one month post-mammogram based on repeated measures ANOVA, *Wilk's lambda* = 0.99, $F(1,135) = 1.40$, $p = .24$ (see Figure 3). Thus, findings for the CWS were not consistent with predictions.

Exploratory Analyses: Change in State Anxiety and Reassurance over Time

For the brief STAI, there was a significant effect of time during the pre-mammogram time period (T1 to T3). Both linear, slope = 0.22, $t(158) = 5.11$, $p < .001$, and quadratic effects, slope = 0.005, $t(158) = 3.63$, $p < .001$, were observed (see Table 8 on page 50), indicating that state anxiety increased over time leading up to the mammogram, with steeper increases of mean anxiety scores observed immediately prior to the exam (see Figure 5 on page 37). There was also a significant decrease in state anxiety over time from immediately before to immediately after the mammogram (T3 to T4) based on repeated measures ANOVA, *Wilk's lambda* = 0.64, $F(1,139) = 77.97$, $p < .001$. Examining the brief STAI scores in the post-mammogram time period (T4 to T6) revealed no significant linear or quadratic changes over time, p's > .05 (see Table 9 on page 51).

Finally, for the reassurance measure, the scores were significantly negatively skewed and kurtotic, so a square root transformation was applied before conducting growth modeling. During the post-mammogram time period (T4 to T6), there were significant changes in reassurance over time for both the first item assessing overall reassurance and for the second item assessing the belief that additional testing to rule out a recurrence was not necessary. Specifically, for the first item, there were both linear, slope = 0.03, $t(143) = 4.90$, $p < .001$, and quadratic effects, slope = -0.001, $t(143) = -4.06$, $p < .001$ (see Table 10 on page 52). For the second item, a similar pattern emerged with linear, slope = 0.09, $t(143) = 5.43$, $p < .001$, and

quadratic effects over time, slope = -0.003, $t(143) = -4.66$, $p < .001$ (see Table 11 on page 53). Mean scores for both items show a gradual decline in reassurance over time, with a steeper decline within the first week after the mammogram (T4 to T5) than in the weeks after the mammogram (T5 to T6) (see Figure 6 on page 38).

Evaluation of Hypothesis 4

The next set of hypotheses (i.e., 4, 5, and 6) examine whether CBM variables are able to predict the observed changes in FCR across each time segment after controlling for clinical and demographic characteristics. To examine which variables predict increases in FCR during the pre-mammogram time segment (T1 to T3) (Hypothesis 4), univariate analyses were first conducted to determine which demographic, clinical, and CBM variables measured at T0 were correlated with the various measures of FCR at each pre-mammogram time point (see Tables 12-14 on pages 54-56). Because there were significant correlations between one or more FCR measures from T1 to T3 (pre-mammogram time points) and age, income, and education, these variables were included as predictors in the subsequent hierarchical multiple regressions. As for clinical variables, none were significantly related to FCR at any time point and so none were included in the subsequent analyses. Finally, the CBM variables of risk, severity, coping self-efficacy, and reassurance-seeking behaviors were significantly related to all FCR measures at all time points and so all were included in the hierarchical regression analyses. There were no significant correlations between FCR and treatment efficacy beliefs across all measures and all time points; hence, it will not be included in the subsequent analyses.

For hierarchical regression analyses, the score on the FCR measure at the final time point in the segment served as the dependent variable. The initial score on the FCR measure was entered in the first step to create a residualized change score, followed by relevant demographic

variables. The relevant CBM variables were then entered on the final step to determine if they accounted for additional variance in the FCR score at the final time point in the segment. Only FCR measures that demonstrated significant change over time were evaluated (i.e., the CWS and the FCRI).

For the CWS (see Table 15 on page 57), the initial score accounted for 53% of the variance in scores at T3 on the first step, $F(1,123) = 136.14$, $p < .001$. Inclusion of the demographic variables on the second step did not explain additional variance, $F(3,120) = 0.69$, $p = .56$. On the final step, an additional 4% of the variance was explained by the CBM variables entered as a group, $F(4,116) = 2.82$, $p = .03$. No single CBM variable was found to be a significant predictor controlling for all other CBM variables. In follow-up analyses, each CBM variable was entered on its own on the third step to determine if any separately made a significant contribution to the variance accounted for. Neither risk nor coping self-efficacy contributed significant variance accounted for when added to the model individually (see Table 16 on page 58). However, greater perceived severity of the consequences of a recurrence contributed 3% additional unique variance, $F(1,119) = 6.09$, $p = .01$, and reassurance-seeking behaviors contributed 2% additional variance, $F(1,119) = 4.31$, $p = .04$, when entered individually.

For FCRI scores, initial FCRI scores entered on the first step accounted for 73% unique variance in FCRI scores at T3, $F(1,122) = 323.54$, $p < .001$. Demographic variables on the second step accounted for 2% additional variance accounted for, $F(3,123) = 3.13$, $p = .03$, with lower education significantly predicting higher scores at T3. When CBM variables were added as a block on the final step, an additional 2% unique variance was accounted for, $F(4,115) = 3.19$, $p = .02$, with lower coping self-efficacy to handle a cancer recurrence significantly related

to higher FCRI scores at T3 (see Table 17 on page 59). Again, CBM variables were also entered on their own on the final step in additional hierarchical multiple regression analyses. The pattern of results did not change (see Table 18 on page 60). Only coping self-efficacy contributed significant unique variable above initial FCRI scores and demographic variables, $F(1,118) = 12.05$, $p < .001$.

Evaluation of Hypothesis 5

Hypothesis 5 examined whether CBM variables would account for additional variance in the decline of FCR between the immediate pre-mammogram and immediate post-mammogram time segment after controlling for relevant clinical and demographic characteristics. Similar to hypothesis 4, predictors of FCR were selected by examining which clinical, demographic, and CBM variables were correlated with FCR at either time point (see Table 14). Next, a hierarchical multiple regression analysis predicting FCR at T4 was conducted with FCR at T3 entered on the first step, relevant clinical and demographic variables on the second step, and finally CBM variables on the third step.

The following variables were identified as significant correlates of FCR during the immediate pre-mammogram to immediate post-mammogram time segment (T3 to T4) and were therefore used to predict change in FCR between T3 and T4: age, income, education, risk, severity, coping self-efficacy, and reassurance-seeking behaviors. For the combined VAS measure, the initial score at T3 accounted for 42% of the variance in scores at T4, $F(1,114) = 81.79$, $p < .001$. The addition of the demographic variables on the second step did not contribute additional variance, $F(3,111) = 1.89$, $p = .14$. Finally, the addition of the CBM variables as a group on the third step also did not contribute a significant proportion of the variance, $F(4,107) = 0.15$, $p = .96$, and none of these variables were significant predictors of VAS scores (see Table

19 on page 61). When entered separately on the final step, no CBM variable accounted for additional significant variance in VAS scores at T4 (see Table 20 on page 62).

Evaluation of Hypothesis 6

Next, predictors of change in FCR during the post-mammogram time segment (T4 to T6) were evaluated. It was hypothesized that the CBM variables would account for additional variance in the increase of FCR during the month following the mammogram after controlling for relevant clinical and demographic characteristics. Similar to hypotheses 4 and 5, predictors of FCR were selected by examining univariate relationships between FCR across the post-mammogram time points and clinical, demographic, and CBM variables (see Table 14). Then, the hierarchical multiple regression analysis was conducted to predict FCR at T6 with FCR at T4 on the first step, relevant clinical and demographic variables on the second step, and the CBM variables on the third step.

For the post-mammogram time segment (T4 to T6), the following variables were identified as significant correlates of FCR and therefore were used to predict change in FCR between T4 and T6: income, education, risk, severity, coping self-efficacy, and reassurance-seeking behaviors. Examining the combined VAS scores at T6, a significant proportion of the variance (29%) was accounted for by the initial VAS scores, $F(1,116) = 47.15$, $p < .001$. After the demographic variables were entered on the second step, an additional 5% unique variance was accounted for, $F(2,114) = 5.86$, $p = .004$, with lower income significantly predicting lower VAS scores at T6. With the addition of the CBM variables as a group on the third step, there was no significant increase in variance accounted for, $F(4,110) = 0.98$, $p = .42$ (see Table 21 on page 63). When each CBM variable was entered on its own on the final step, again, none were found to contribute significant unique variance (see Table 22 on page 64).

Exploratory Growth Mixture Models

The final set of analyses explored the use of growth mixture models to detect overall patterns of change in FCR over time. Per the analysis plan, a one-class latent growth curve model was first fit to the data over the entire course of the study (T1 to T6). For the piecewise models, each of the following was evaluated: 1) a linear piecewise model with linear slopes for the pre-mammogram (T1 to T3) and post-mammogram (T4 to T6) segments; and 2) a combined linear and quadratic piecewise model with a linear slope for the pre-mammogram and a quadratic slope for the post-mammogram segment.

Based on the fit indices presented in Table 23 (see page 65), the piecewise growth model with a linear pre-mammogram segment and quadratic post-mammogram segment was determined to best fit the data. The residual variances were constrained to be equal over time and the variance of the linear slope from T1 to T3 was constrained to 0, which reflected the lack of significant findings for systematic change over time observed for the combined VAS measure. The quadratic slope during the post-mammogram time segment (T4 to T6) was not constrained to allow for variability in the change over time for this piece. This model was used as the basis for the addition of latent classes for the growth mixture models (see Figure 7 on page 39).

Successive models were fit to the data with additional latent classes examined one at a time until there was no longer an improvement in fit. The 2-class model demonstrated an improvement in model fit according to the fit indices and significant improvement over the 1-class model according to the Lo-Mendell-Rubin test, $p < .001$ (see Table 24 on page 66). The first class included 75.5% of study subjects and the second class included 24.5% (see Figure 8 on page 40). There was very little overlap between the probabilities that each individual belonged to one class over the other. For the first class, the average probability that a member belonged to

this class was 0.970 and the probability that the member did not belong to this class was 0.030. For the second class, the average probability that a member belonged to this class was 0.996 and the probability that the member did not belong was 0.004.

The 3-class model also demonstrated an improvement in fit indices and had a statistically better fit to the data than the previous 2-class model according to the Lo-Mendell-Rubin test, p = .05 (see Table 24). The three classes accounted for 74.4%, 19.3%, and 6.3% of the study sample for each class (see Figure 9 on page 41). There was also good agreement between which class members belonged to in this model. For the first class, the average probability that a member belonged was 0.996; the probability that the member belonged to the second class was 0.004, and the probability that the member belonged to the third class was 0.000. For the second class, the average probability that a member belonged to this class was 0.979, and was 0.018 and 0.003 for the first and third classes respectively. Finally, the average probability that a member belonged to the third class was 0.993; the probability that the member belonged to the first class was 0.000, and probability of membership in the second class was 0.007. However, the smallest class in the 3-class model is less than 10% of the study sample and represents a subgroup with a marginally different trajectory from what is represented by the 2-class model. Therefore, it is unlikely that this additional class represents a subgroup of patients with clinically significant differences in their FCR trajectories or overall levels of FCR before and after mammograms.

Finally, a 4-class model was tested to determine if additional classes would provide improvement in model fit. The estimation of this model was unstable, however, as the best log likelihood value was not replicated even with 1000 random starts of 10 iterations so the estimates provided should be interpreted with caution. The fit indices revealed that the model fit was somewhat improved over the previous model, with lower values for deviance, AIC, and BIC.

However, entropy did not improve from the previous model and examination of the Lo-Mendell-Rubin test revealed no significant improvement over the previous model, $p = .07$. This model also suffered from the problem of containing at least one class with fewer than 10% of the study sample and neither the trajectory nor mean FCR across time points was meaningfully different from the other classes produced in the models with fewer classes. Hence, no further iterations of multi-class models were estimated.

Based on all of the information after several iterations of multi-class models, it can be concluded that the 2-class model provides the most parsimonious and statistically satisfactory fit of the data from this sample.

Predicting class membership. Per the analysis plan, logistic regression analyses were conducted to determine whether demographic, clinical, or CBM variables predicted which patients belonged to each class identified in the model. No demographic or clinical characteristics were significant predictors of class membership in the univariate logistic regressions (see Table 25 on page 67). However, several CBM variables, including risk, severity, coping self-efficacy beliefs, and reassurance-seeking behaviors, were significant predictors. The significant predictors from the univariate analyses were used in multivariate logistic regression analyses to determine if each predicted class membership when controlling for the other CBM variables. The multivariate analyses revealed that risk, coping self-efficacy, and reassurance-seeking behaviors each significantly predicted class membership (see Table 26 on page 69). Findings indicated that those who reported greater perceived risk, lower coping self-efficacy, and greater reassurance-seeking behaviors were more likely to belong to the high-FCR class than to the low-FCR class.

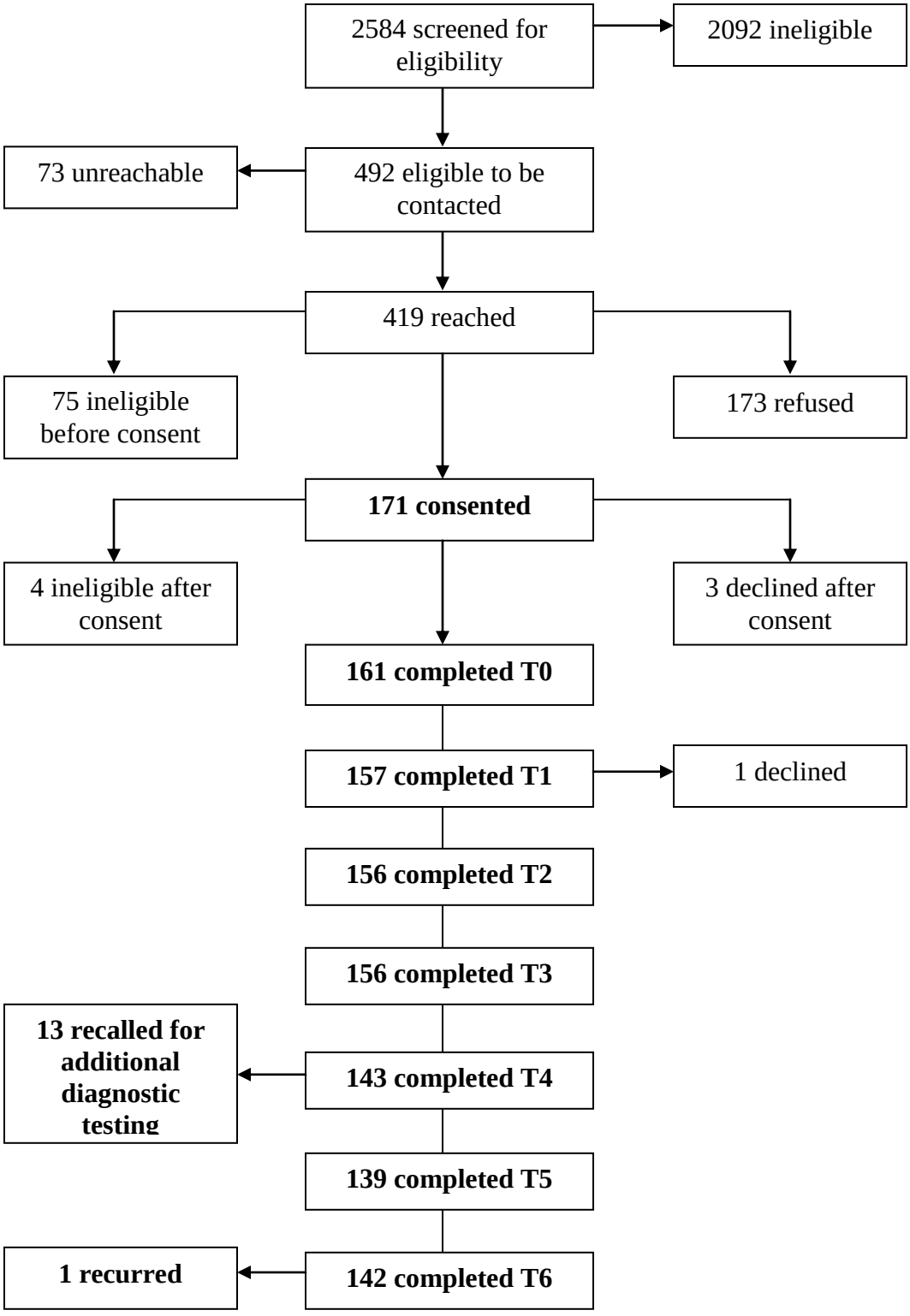

Figure 1. Response rate throughout recruitment and surveying process.

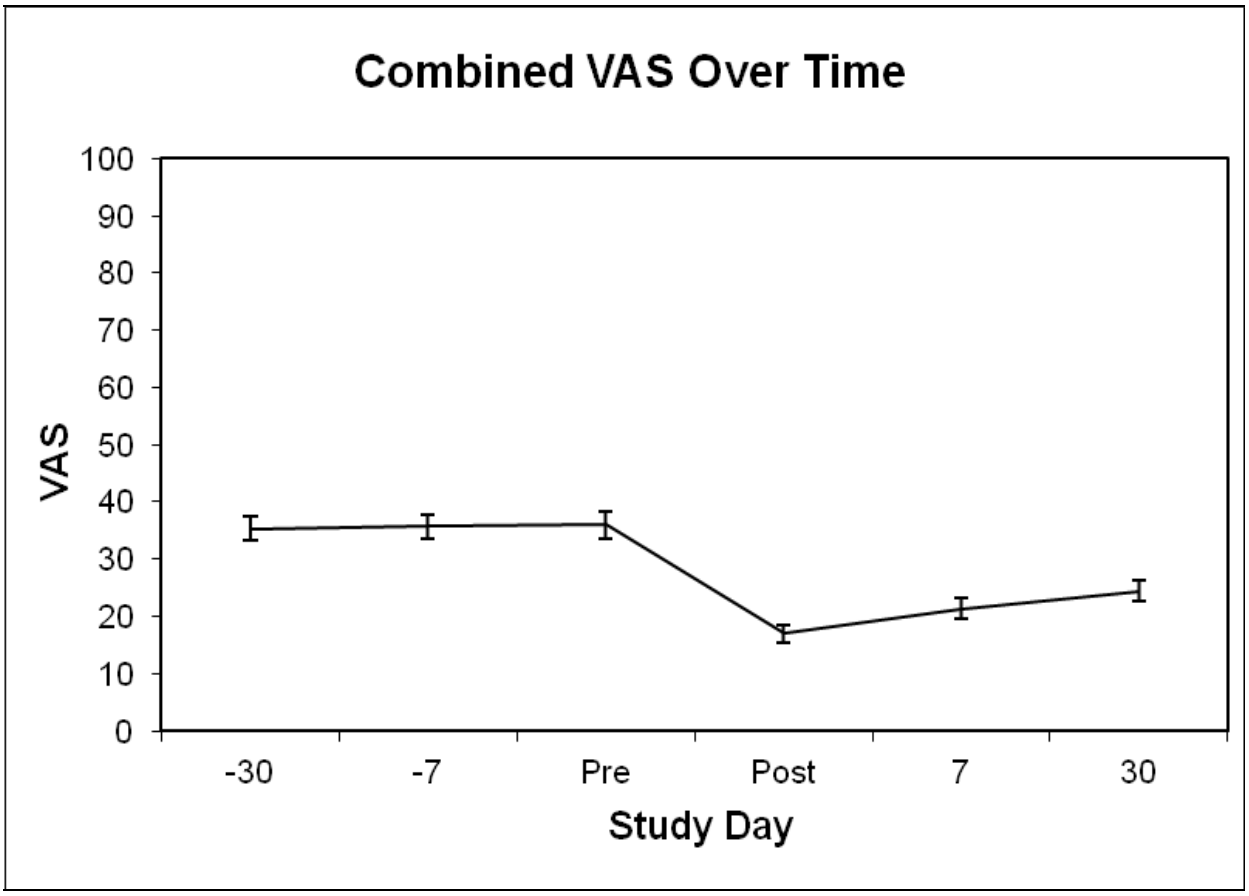

Figure 2. Mean worry and anxiety VAS scores across all study time points. VAS = Visual Analogue Scale.

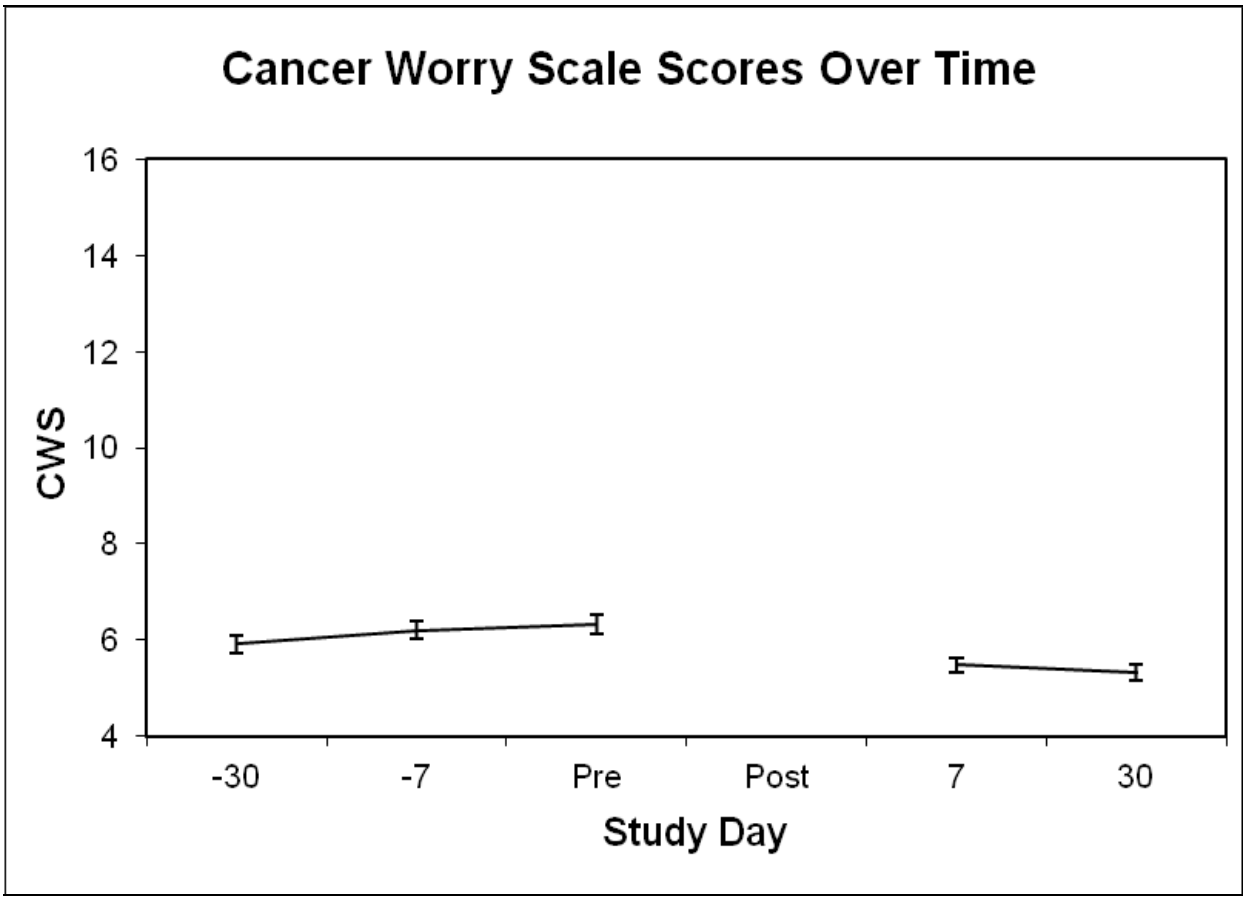

Figure 3. Mean Cancer Worry Scale scores across all study time points. CWS = Cancer Worry Scale.

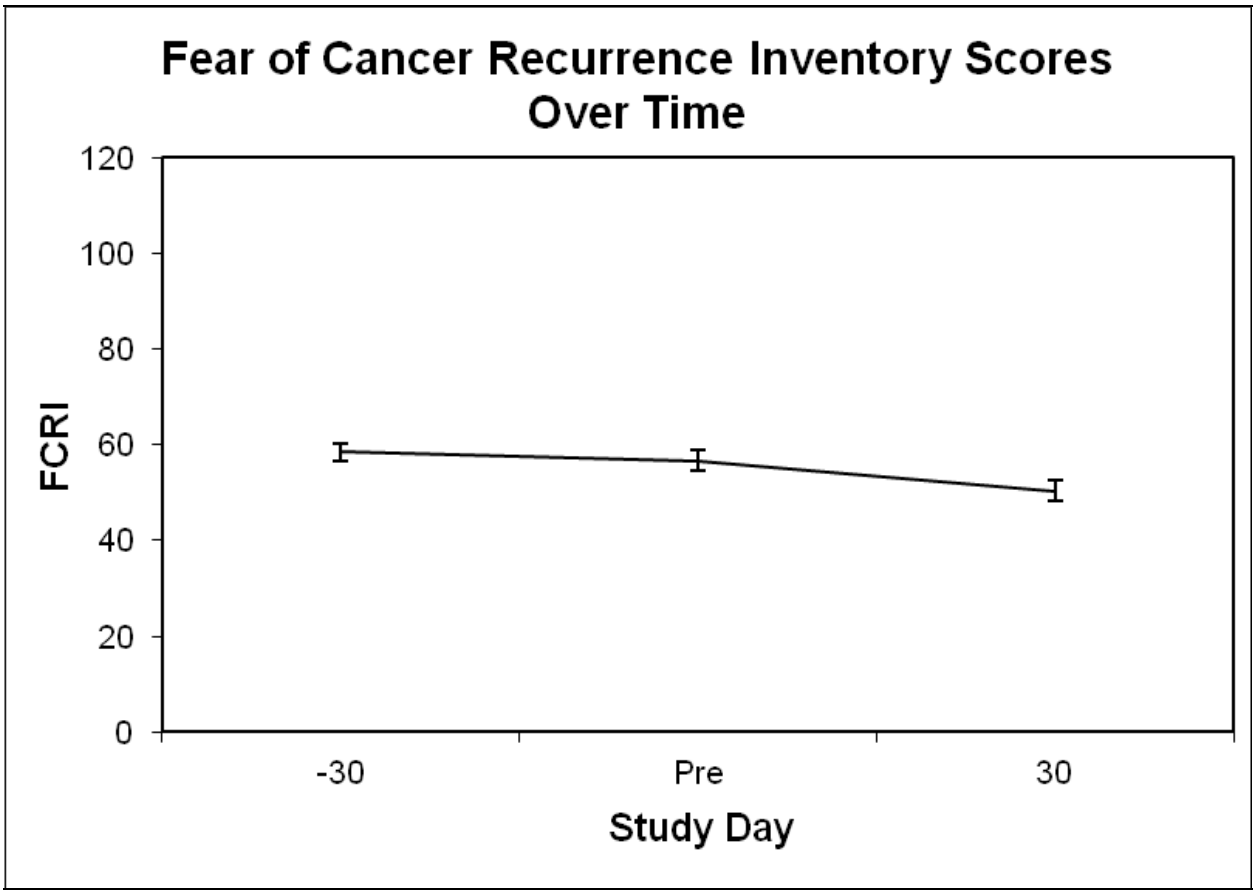

Figure 4. Mean Fear of Cancer Recurrence Inventory scores across all study time points. FCRI = Fear of Cancer Recurrence Inventory.

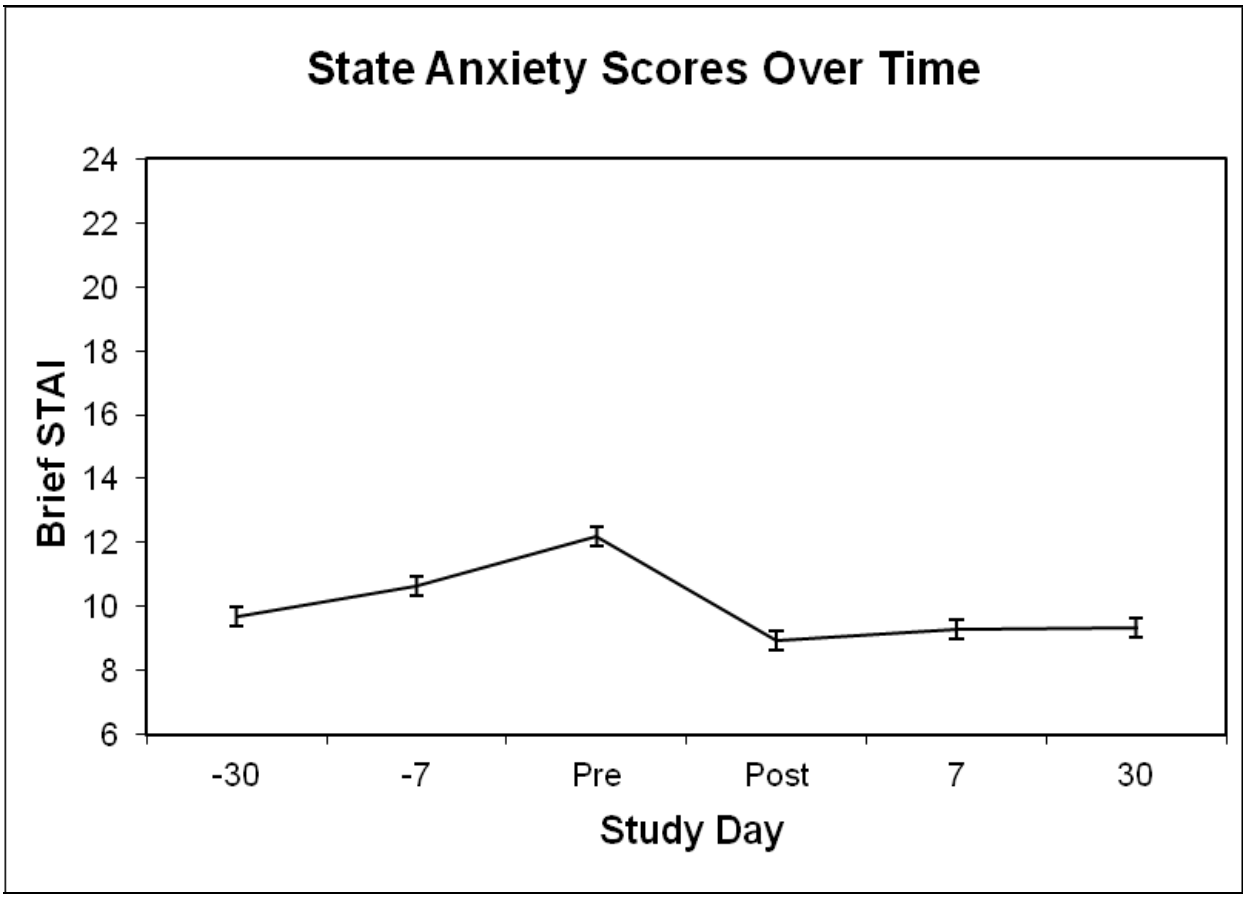

Figure 5. Mean State Anxiety scores across all study time points. STAI = Brief State Trait Anxiety Inventory.

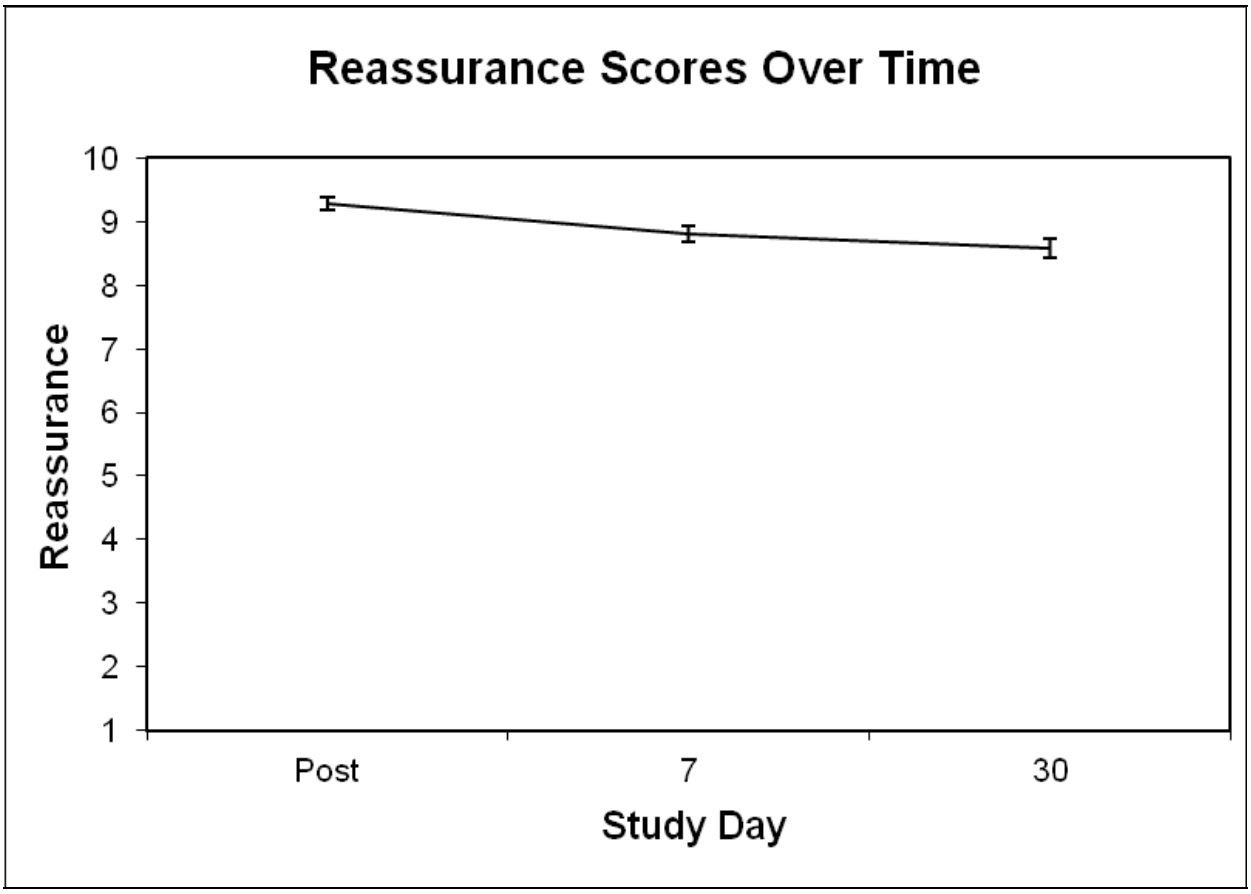

Figure 6. Mean Reassurance Scale scores across all study time points.

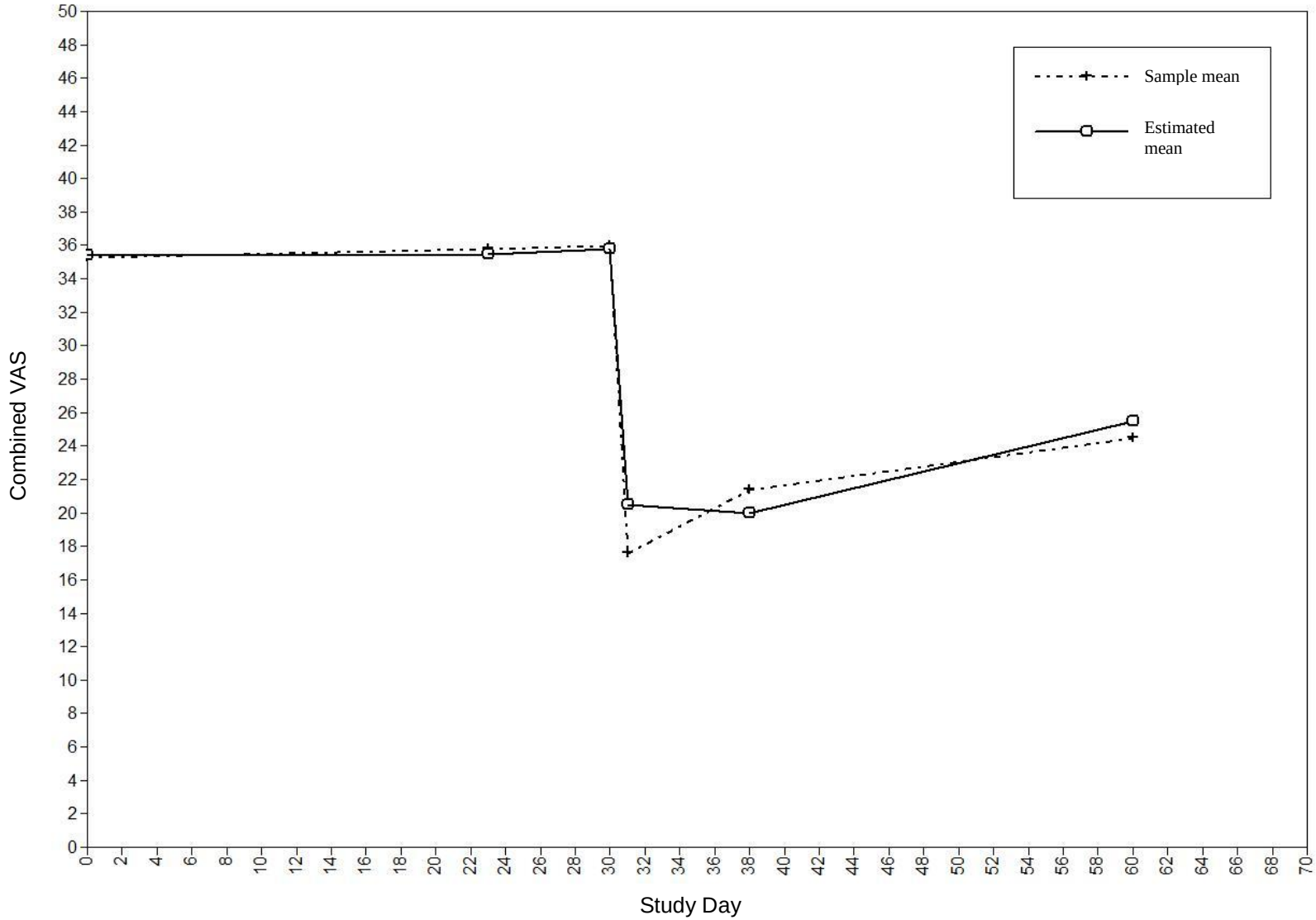

Figure 7. Latent growth curve model of worry and anxiety VAS over time

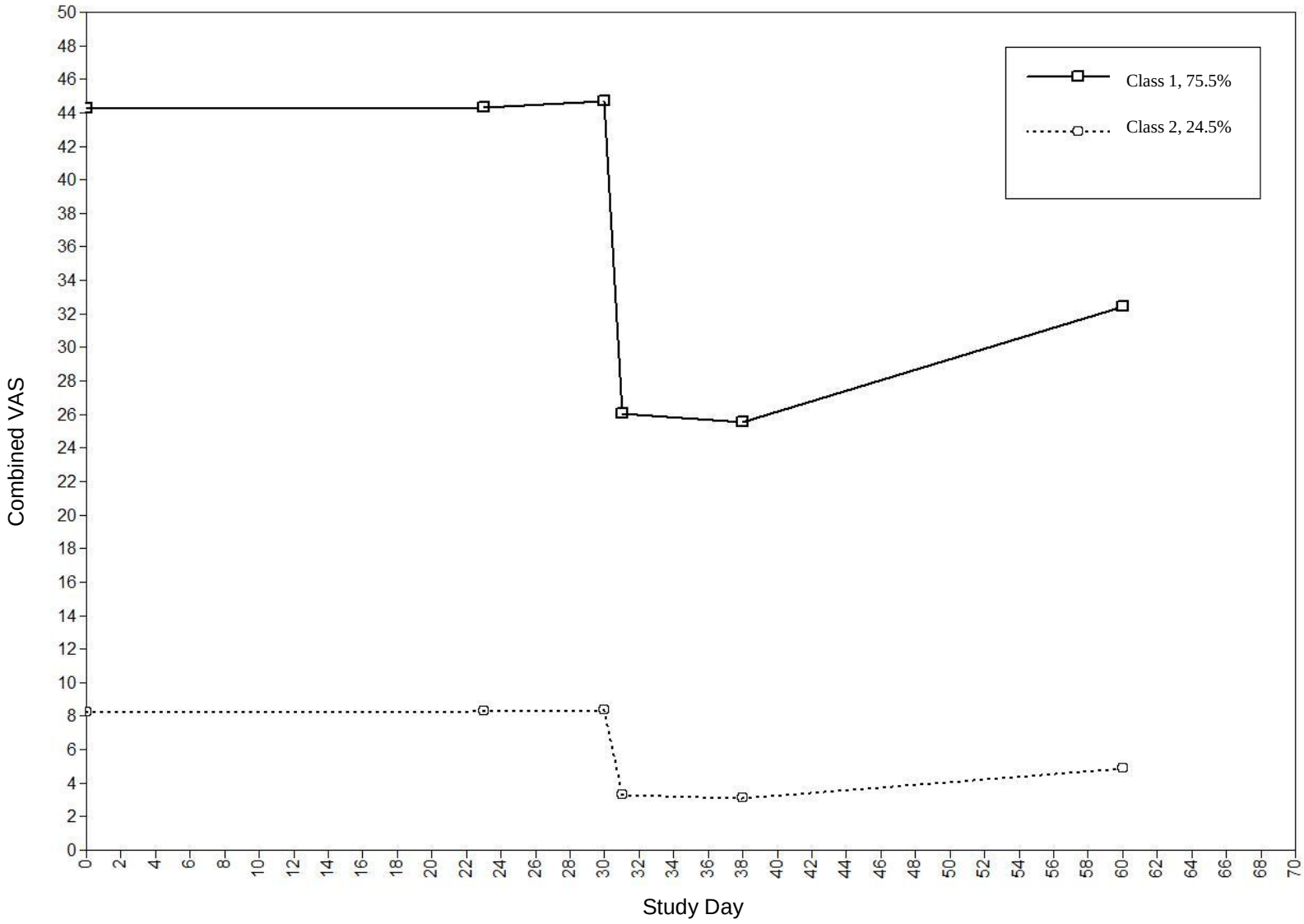

Figure 8. 2-class growth mixture model of worry and anxiety VAS over time

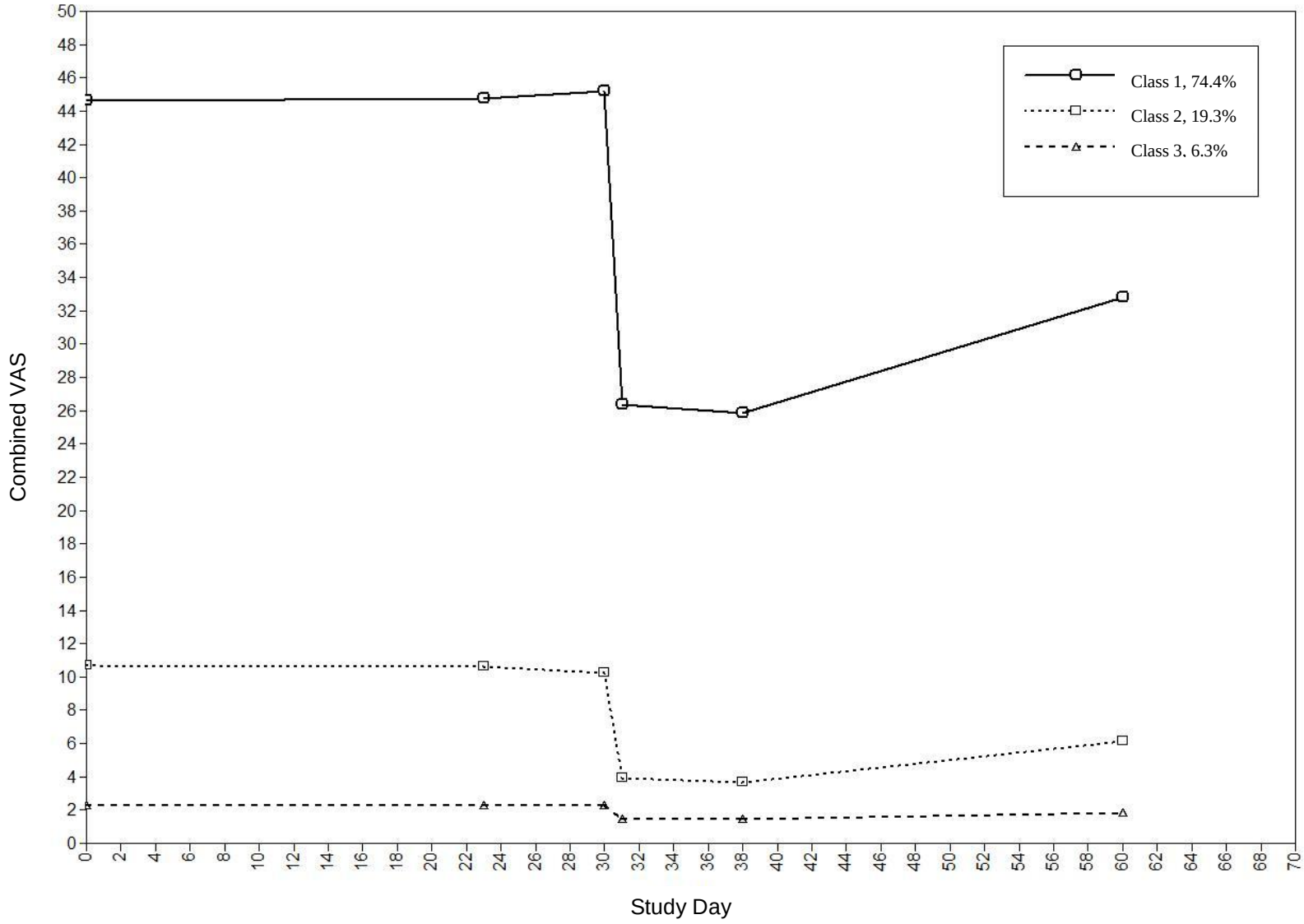

Figure 9. 3-class growth mixture model of worry and anxiety VAS over time

Table 1. *Sample characteristics*

	n	*%*
Race		
Caucasian	150	93.17
African American	3	1.86
Asian	6	3.73
Other	2	1.24
Ethnicity		
Hispanic	8	4.97
Non-Hispanic	153	95.03
Marital Status		
Single	7	4.35
Married	118	73.29
Separated	2	1.24
Divorced	17	10.56
Widowed	17	10.56
Annual Income		
< $40,000	37	22.98
> $40,000	96	59.63
Prefer not to respond	28	17.39
Education		
Less than high school	3	1.86
High school	22	13.66
Some college	48	29.81
College graduate	54	33.54
Graduate degree	34	21.12
Stage at diagnosis		
Stage 0	26	16.15
Stage I	90	55.90
Stage II	43	26.71
Stage IIIA	2	1.24
Surgery Type		
Lumpectomy	121	75.16
Bilateral Lumpectomies	1	0.62
Mastectomy	36	22.36
Lumpectomy & Mastectomy	3	1.86
Treatment		
Surgery & Radiation	93	57.76
Surgery & Chemotherapy	9	5.59
Surgery, Chemotherapy, & Radiation	34	21.12
Surgery Only	23	14.29
Adjuvant Hormone Therapy		
Yes	127	78.88
No	32	19.88

Table 1(Continued)

	n	*%*
Previous Post-Treatment Mammograms		
None	41	25.47
1	65	40.37
2	46	28.57
3	7	4.35
4	2	1.24

Table 2. *Fear of cancer recurrence and state anxiety pre-mammogram*

	M (*SD*)		
	Time 1	Time 2	Time 3
FCRI	58.47 (22.76) *n* = 156	_	56.74 (26.07) *n* = 155
CWS	5.92 (2.35) *n* = 157	6.20 (2.30) *n* = 156	6.32 (2.58) *n* = 155
Anxiety VAS	33.77 (26.23) *n* = 157	34.37 (26.82) *n* = 155	35.12 (29.78) *n* = 156
Worry VAS	36.81 (26.60) *n* = 157	37.17 (26.10) *n* = 155	36.87 (28.85) *n* = 156
Combined VAS	35.29 (25.90) *n* = 157	35.77 (25.88) *n* = 155	35.99 (28.67) *n* = 156
STAI	9.71 (3.53) *n* = 157	10.63 (4.07) *n* = 156	12.21 (4.38) *n* = 156

Note. FCRI = Fear of Cancer Recurrence Inventory; CWS = Cancer Worry Scale; VAS = Visual Analogue Scale; STAI = Brief State Trait Anxiety Inventory.

Table 3. *Fear of cancer recurrence and state anxiety immediately pre- and immediately post-mammogram*

	M (*SD*)	
	Time 3	Time 4
Anxiety VAS	35.12 (29.78) *n* = 156	16.57 (19.61) *n* = 143
Worry VAS	36.87 (28.85) *n* = 156	17.52 (19.44) *n* = 143
Combined VAS	35.99 (28.67) *n* = 156	17.04 (18.77) *n* = 143
STAI	12.21 (4.38) *n* = 156	8.94 (3.05) *n* = 143

Note. VAS = Visual Analogue Scale; STAI = Brief State Trait Anxiety Inventory.

Table 4. *Fear of cancer recurrence, state anxiety, and reassurance post-mammogram*

	M (*SD*)		
	Time 4	Time 5	Time 6
FCRI	_	_	50.43 (24.52) *n* = 142
CWS	_	5.48 (1.87) *n* = 139	5.32 (2.01) *n* = 142
Anxiety VAS	16.57 (19.61) *n* = 143	19.85 (21.50) *n* = 139	23.04 (21.54) *n* = 142
Worry VAS	17.52 (19.44) *n* = 143	22.94 (22.28) *n* = 139	25.92 (23.02) *n* = 142
Combined VAS	17.04 (18.77) *n* = 143	21.40 (21.55) *n* = 139	24.48 (21.59) *n* = 142
STAI	8.94 (3.05) *n* = 143	9.29 (3.29) *n* = 139	9.32 (3.41) *n* = 142
Reassurance #1	9.29 (1.22) *n* = 143	8.80 (1.47) *n* = 139	8.58 (1.71) *n* = 142
Reassurance #2	8.90 (2.13) *n* = 143	7.60 (3.06) *n* = 139	7.46 (3.07) *n* = 142

Note. FCRI = Fear of Cancer Recurrence Inventory; CWS = Cancer Worry Scale; VAS = Visual Analogue Scale; STAI = Brief State Trait Anxiety Inventory.

Table 5. *Unconditional growth curve models examining the effect of time on worry and anxiety VAS scores before the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	35.63	1.89	18.81	<.001	35.75	2.07	17.24	<.001	35.44	2.17	16.33	<.001
Linear Slope					0.01	0.05	0.19	.85	-0.11	0.25	-0.44	.66
Quadratic Slope									-0.00	0.01	-0.49	.62
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	498.42	64.45	7.73	<.001	538.20	76.50	7.04	<.001	538.16	76.46	7.04	<.001
Time					0.00	0.01	0.60	.27	0.00	0.01	0.59	.28
Residual	218.66	17.62	12.41	<.001	217.59	17.53	12.41	<.001	217.33	17.51	12.41	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	4174.6	2	4180.6	4194.1	4173.1	4	4183.1	4198.5	4172.9	4	4184.9	4203.3

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters; VAS = Visual Analogue Scale.

Table 6. *Unconditional growth curve models examining the effect of time on Cancer Worry Scale scores before the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	6.15	0.17	35.33	<.001	6.30	0.19	33.63	<.001	6.30	0.19	32.38	<.001
Linear Slope					0.01	0.00	2.71	.01	0.01	0.02	0.53	.60
Quadratic Slope									-0.00	0.00	-0.06	.96
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	4.33	0.54	7.96	<.001	4.67	0.63	7.38	<.001	4.67	0.63	7.38	<.001
Time					0.00	0.00	0.81	.21	0.00	0.00	0.81	.21
Residual	1.50	0.12	12.41	<.001	1.37	0.16	8.78	<.001	1.37	17.51	8.77	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	1876.3	2	1882.3	1895.8	1866.8	4	1878.8	1897.3	1866.8	4	1880.8	1902.4

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters.

Table 7. *Unconditional growth curve models examining the effect of time on worry and anxiety VAS scores after the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	21.12	1.49	14.13	<.001	18.65	1.59	11.71	<.001	17.21	1.67	10.28	<.001
Linear Slope					0.22	0.06	3.94	<.001	0.92	0.26	3.58	<.001
Quadratic Slope									-0.02	0.01	-2.80	.01
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	265.24	38.35	6.92	<.001	294.63	44.11	6.68	<.001	297.26	43.97	6.76	<.001
Time					0.19	0.06	3.12	<.001	0.19	0.06	3.25	<.001
Residual	168.75	14.28	11.81	<.001	113.29	13.92	8.13	<.001	108.56	13.35	8.13	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	3626.8	2	3632.8	3646.3	3597.2	4	3609.2	3627.6	3589.5	4	3603.5	3625.0

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters; VAS = Visual Analogue Scale.

Table 8. *Unconditional growth curve models examining the effect of time on State Anxiety scores before the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	10.83	0.27	40.30	<.001	11.71	0.32	37.11	<.001	12.12	0.33	36.31	<.001
Linear Slope					0.07	0.01	7.21	<.001	0.22	0.04	5.11	<.001
Quadratic Slope									0.00	0.00	3.63	<.001
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	8.70	1.31	6.65	<.001	11.20	1.78	6.30	<.001	11.26	1.76	6.38	<.001
Time					0.00	0.00	1.26	.10	0.00	0.00	1.30	.10
Residual	8.27	0.67	12.44	<.001	6.90	0.55	12.44	<.001	6.64	0.53	12.44	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	2546.6	2	2552.6	2566.1	2490.5	4	2500.5	2515.8	2477.6	4	2489.6	2508.0

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters.

Table 9. *Unconditional growth curve models examining the effect of time on State Anxiety scores after the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	9.17	0.22	42.18	<.001	9.05	0.24	37.81	<.001	8.92	0.26	34.45	<.001
Linear Slope					0.01	0.01	1.06	.29	0.07	0.05	1.45	.15
Quadratic Slope									-0.00	0.00	-1.25	.21
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	4.91	0.81	6.00	<.001	5.67	1.03	5.49	<.001	5.71	1.03	5.53	<.001
Time					0.00	0.00	3.00	.001	0.01	0.00	3.09	.001
Residual	5.61	0.47	11.83	<.001	4.09	0.50	8.21	<.001	4.03	0.49	8.20	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	2118.4	2	2124.4	2137.9	2106.0	4	2118.0	2136.4	2104.5	4	2118.5	2139.9

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters.

Table 10. *Unconditional growth curve models examining the effect of time on Reassurance Scale scores (item 1) after the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	1.38	0.03	42.79	<.001	1.31	0.03	42.54	<.001	1.26	0.03	37.54	<.001
Linear Slope					0.01	0.00	5.13	<.001	0.03	0.01	4.90	<.001
Quadratic Slope									-0.00	0.00	-4.06	<.001
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	0.12	0.02	6.54	<.001	0.09	0.02	5.36	<.001	0.09	0.02	5.48	<.001
Time					0.00	0.00	1.89	.03	0.00	0.00	1.97	.02
Residual	0.09	0.01	11.77	<.001	0.08	0.01	11.80	<.001	0.08	0.01	11.80	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	425.0	2	431.0	444.5	383.7	4	393.7	409.0	367.7	4	379.7	398.1

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters.

Table 11. *Unconditional growth curve models examining the effect of time on Reassurance Scale scores (item 2) after the mammogram*

	Fully Unconditional Model				Linear Growth Model				Quadratic Growth Model			
Fixed Effects	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*	*Coef.*	*SE*	*T-ratio*	*p*
Intercept	0.93	0.07	12.88	<.001	0.76	0.07	10.42	<.001	0.60	0.08	7.52	<.001
Linear Slope					0.01	0.00	4.85	<.001	0.09	0.02	5.43	<.001
Quadratic Slope									-0.00	0.00	-4.66	<.001
Random Effects	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*	*Est.*	*SE*	*Z-value*	*p*
Intercept	0.55	0.09	6.07	<.001	0.43	0.09	4.93	<.001	0.46	0.10	4.67	<.001
Time					0.00	0.00	1.26	.10	0.00	0.00	0.66	.26
Residual	0.60	0.05	11.83	<.001	0.54	0.05	11.83	<.001	0.48	0.06	8.11	<.001
Model Fit	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*	*Dev.*	*Param.*	*AIC*	*BIC*
	1173.9	2	1179.9	1193.4	1144.4	4	1154.4	1169.8	1124.2	4	1138.2	1159.7

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; Coef. = Coefficient Estimate; Dev. = Deviance; Param. = Number of Parameters.

Table 12. *Correlations of clinical, demographic, and Cognitive-Behavioral Model variables and Cancer Worry Scale across all study time points*

	T1	T2	T3	T4	T6
Clinical Characteristics					
Stage	.12	.10	.03	.02	.05
Time since Diagnosis	.06	.09	.02	.12	.07
Time since Treatment	.05	.10	.05	.09	.04
Mastectomy (yes or no)	-.03	-.12	-.12	.01	.01
Chemotherapy (yes or no)	.02	.02	-.05	.02	-.01
Radiation (yes or no)	.05	.07	.05	.12	.01
Chemotherapy + Radiation (yes or no)	.04	.07	-.02	.06	-.02
Hormone Therapy (yes or no)	.02	.00	.02	.12	.00
Family History of Breast Cancer (yes or no)	.05	.07	.06	.00	.08
Number of Previous Mammograms	.11	.14	.12	.09	.03
Demographic Characteristics					
Age	-.15	-.11	-.16	-.08	.01
Race (white or not)	.10	-.05	.02	-.09	.03
$40K Income (yes or no)	-.36***	-.29***	-.33***	-.31***	-.28**
College Education (yes or no)	-.34***	-.26**	-.26***	-.29***	-.21*
Marital Status (married or not)	-.06	-.07	-.15	.05	.11
Menopausal Status	-.07	.01	-.07	-.06	.05
CBM Variables					
Perceived Risk	.32***	.28***	.31***	.16	.21*
Perceived Severity	.40***	.37***	.42***	.37***	.31***
Coping Self-Efficacy Beliefs	-.48***	-.47***	-.41***	-.39***	-.38***
Treatment Efficacy Beliefs	-.08	.00	-.07	-.05	-.02
Reassurance-Seeking Behaviors	.25**	.24**	.31***	.33***	.29***

Note. CBM = Cognitive-Behavioral Model.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 13. *Correlations of clinical, demographic, and Cognitive-Behavioral Model variables and Fear of Cancer Recurrence Inventory across all study time points*

	T1	T3	T6
Clinical Characteristics			
Stage	.12	.12	.09
Time since Diagnosis	.14	.10	.10
Time since Treatment	.10	.07	.04
Mastectomy (yes or no)	-.04	-.07	-.10
Chemotherapy (yes or no)	.08	.06	.13
Radiation (yes or no)	.06	.05	.13
Chemotherapy + Radiation (yes or no)	.11	.08	.14
Hormone Therapy (yes or no)	.03	.07	.04
Family History of Breast Cancer (yes or no)	.07	.01	.05
Number of Previous Mammograms	.12	.09	.08
Demographic Characteristics			
Age	-.16*	-.19*	-.15
Race (white or not)	.06	.07	-.03
$40K Income (yes or no)	-.27**	-.35***	-.25**
College Education (yes or no)	-.27***	-.35***	-.26**
Marital Status (married or not)	-.02	-.02	.06
Menopausal Status	-.09	-.04	-.04
CBM Variables			
Perceived Risk	.36***	.31***	.29***
Perceived Severity	.51***	.48***	.52***
Coping Self-Efficacy Beliefs	-.41***	-.48***	-.47***
Treatment Efficacy Beliefs	-.02	-.06	.00
Reassurance-Seeking Behaviors	.39***	.31***	.36***

Note. CBM = Cognitive-Behavioral Model.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 14. *Correlations of clinical, demographic, and Cognitive-Behavioral Model variables and worry and anxiety VAS across all study time points*

	T1	T2	T3	T4	T5	T6
Clinical Characteristics						
Stage	.08	.01	.05	-.04	.02	-.03
Time since Diagnosis	.05	.10	.01	.03	.02	.07
Time since Treatment	.05	.10	.01	.03	.05	.09
Mastectomy (yes or no)	-.03	-.08	-.14	.03	.07	.03
Chemotherapy (yes or no)	.09	.10	.03	.08	.05	.04
Radiation (yes or no)	.04	.06	.06	-.01	.03	.00
Chemotherapy + Radiation (yes or no)	.09	.09	.05	.05	.09	.03
Hormone Therapy (yes or no)	-.02	.02	.01	-.04	.05	.05
Family History of Breast Cancer (yes or no)	.14	.03	.01	-.04	-.04	-.13
Number of Previous Mammograms	.03	.04	.02	.02	-.02	.06
Demographic Characteristics						
Age	-.18*	-.09	-.22**	-.04	.02	.00
Race (white or not)	.04	-.07	.04	.03	-.08	-.13
$40K Income (yes or no)	-.23**	-.14	-.31***	-.21*	-.23*	-.23*
College Education (yes or no)	-.22**	-.18*	-.29***	-.29***	-.21*	-.16
Marital Status (married or not)	-.20*	-.11	-.12	.06	-.03	-.02
Menopausal Status	-.11	-.03	-.14	-.06	-.03	-.04
CBM Variables						
Perceived Risk	.46***	.31***	.38***	.34***	.26***	.24**
Perceived Severity	.37***	.30***	.41***	.22**	.19*	.21*
Coping Self-Efficacy Beliefs	-.43***	-.31***	-.42***	-.33***	-.33***	-.32***
Treatment Efficacy Beliefs	-.11	-.03	-.09	-.08	-.09	-.05
Reassurance-Seeking Behaviors	.21**	.21**	.20**	.15	.20**	.19*

Note. CBM = Cognitive-Behavioral Model; VAS = Visual Analogue Scale.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 15. *Hierarchical regression analysis predicting Cancer Worry Scale scores at time 3 from demographic and Cognitive-Behavioral Model variables*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.53		136.14***
T1 CWS	.59***			
Step 2: Demographic Variables		.53	.00	0.69
Age	-.02			
Income	-.06			
Education	.05			
Step 3: CBM Variables		.57	.04	2.82*
Risk	.01			
Severity	.11			
Coping Self-Efficacy	-.10			
Reassurance-Seeking Behaviors	.13†			

Note. $N = 125$. CBM = Cognitive-Behavioral Model; CWS = Modified Cancer Worry Scale.
† $p < .10$. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 16. *Hierarchical regression analyses predicting Cancer Worry Scale scores at time 3 from demographic and Cognitive-Behavioral Model variables entered individually on the 3rd step*

Predictor	β	R^2	ΔR^2	ΔF
		.53		136.14***
Step 1: Initial Score				
T1 CWS	.70***			
Step 2: Demographic Variables		.53	.00	0.69
Age	-.04			
Income	-.07			
Education	.07			
Step 3: CBM Variables				
Risk	.04	.53	.00	0.28
Severity	.18**	.56	.03	6.90**
Coping Self-Efficacy	-.11	.54	.01	2.51
Reassurance-Seeking Behaviors	.13*	.55	.02	4.31*

Note. $N = 125$. CBM = Cognitive-Behavioral Model; CWS = Modified Cancer Worry Scale.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 17. *Hierarchical regression analysis predicting Fear of Cancer Recurrence Inventory scores at time 3 from demographic and Cognitive-Behavioral Model variables*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.73		323.54***
T1 FCRI	.74***			
Step 2: Demographic Variables		.75	.02	3.13*
Age	-.08†			
Income	-.02			
Education	-.10*			
Step 3: CBM Variables		.77	.02	3.19*
Risk	-.03			
Severity	-.01			
Coping Self-Efficacy	-.18***			
Reassurance-Seeking Behaviors	.03			

Note. $N = 124$. CBM = Cognitive-Behavioral Model; FCRI = Fear of Cancer Recurrence Inventory.
† $p < .10$. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 18. *Hierarchical regression analyses predicting Fear of Cancer Recurrence Inventory scores at time 3 from demographic and Cognitive-Behavioral Model variables entered individually on the 3rd step*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.73		323.54***
T1 FCRI	.80***			
Step 2: Demographic Variables		.75	.02	3.13*
Age	-.07			
Income	-.04			
Education	-.11*			
Step 3: CBM Variables				
Risk	.01	.75	.00	0.06
Severity	.05	.75	.00	0.68
Coping Self-Efficacy	-.17***	.77	.02	12.05**
Reassurance-Seeking Behaviors	.00	.75	.00	0.00

Note. $N = 124$. CBM = Cognitive-Behavioral Model; FCRI = Fear of Cancer Recurrence Inventory.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 19. *Hierarchical regression analysis predicting worry and anxiety VAS scores at time 4 from demographic and Cognitive-Behavioral Model variables*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.42		81.79***
T3 Combined VAS	.63***			
Step 2: Demographic Variables		.45	.03	1.89
Age	.11			
Income	-.07			
Education	-.07			
Step 3: CBM Variables		.45	.00	0.15
Risk	.04			
Severity	-.05			
Coping Self-Efficacy	-.03			
Reassurance-Seeking Behaviors	.01			

Note. $N = 116$. CBM = Cognitive-Behavioral Model; VAS = Visual Analogue Scale.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 20. *Hierarchical regression analyses predicting worry and anxiety VAS scores at time 4 from demographic and Cognitive-Behavioral Model variables entered individually on the 3rd step*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.42		81.79***
T3 Combined VAS	.63***			
Step 2: Demographic Variables		.45	.03	1.89
Age	.12			
Income	-.07			
Education	-.06			
Step 3: CBM Variables				
Risk	.03	.45	.00	.20
Severity	-.04	.45	.00	.24
Coping Self-Efficacy	-.02	.45	.00	.06
Reassurance-Seeking Behaviors	.00	.45	.00	.00

Note. $N = 116$. CBM = Cognitive-Behavioral Model; VAS = Visual Analogue Scale.
*$p < .05$. **$p < .01$. ***$p < .001$.

Table 21. *Hierarchical regression analyses predicting worry and anxiety VAS scores at time 6 from demographic and Cognitive-Behavioral variables*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.29		47.15***
T4 Combined VAS	.45***			
Step 2: Demographic Variables		.36	.05	5.86*
Income	-.25**			
Education	.13			
Step 3: CBM Variables		.37	.01	0.98
Risk	.06			
Severity	-.05			
Coping Self-Efficacy	-.14			
Reassurance-Seeking Behaviors	.07			

Note. N = 118. CBM = Cognitive-Behavioral Model; VAS = Visual Analogue Scale.
*p < .05. **p < .01. ***p < .001.

Table 22. *Hierarchical regression analyses predicting worry and anxiety VAS scores at time 6 from demographic and Cognitive-Behavioral Model variables entered individually on the 3rd step*

Predictor	β	R^2	ΔR^2	ΔF
Step 1: Initial Score		.29		47.15***
T4 Combined VAS	.48***			
Step 2: Demographic Variables		.36	.05	5.86*
Income	-.27***			
Education	.13			
Step 3: CBM Variables				
Risk	.08	.36	.00	1.08
Severity	.03	.36	.00	0.15
Coping Self-Efficacy	-.13†	.37	.01	2.86
Reassurance-Seeking Behaviors	.05	.36	.00	0.36

Note. N = 118. CBM = Cognitive-Behavioral Model. VAS = Visual Analogue Scale.
† $p < .10$. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 23. *Unconditional growth curve models for worry and anxiety VAS over all study time points*

Models	*Param.*	Δ*Param.*	*-2LL*	Δ*-2LL*	*AIC*	*BIC*
Linear Growth Curve	11		-3917.82		7857.64	7891.47
[a]Quadratic Growth Curve	15	4	-3900.39	17.43*	7830.79	7876.92
[b]Linear Piecewise Growth Curve	12	3	-3891.60	8.79*	7807.21	7844.11
[c]Piecewise Growth Curve with Linear Pre-Mammogram Segment and Quadratic Post-Mammogram Segment	11	1	-3856.30	35.24*	7734.72	7768.54

Note. *N* = 160. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; -2LL. = Log likelihood (Deviance); Param. = Number of Parameters; VAS = Visual Analogue Scale.
*Indicates a significant improvement in model fit over the previous model at the $p < .05$ level.
[a]Variance for linear slope for T1 to T3 was constrained to 0.
[b]Residual variances were set to equal 0 and variance for linear slope for T1 to T3 was constrained to 0.

Table 24. *Growth mixture models*

Models	*Param.*	Δ*Param.*	*-2LL*	Δ*-2LL*	*AIC*	*BIC*	*Entropy*
1 Class	11		-3856.36		7734.72	7768.54	
2 Classes	23	12	-3683.64	172.72*	7413.27	7484.00	0.961
3 Classes	32	9	-3643.61	40.03*	7351.22	7449.62	0.976
4 Classes	29	3	-3632.12	11.49*	7322.24	7411.42	0.897

Note. *N* = 160. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; -2LL. = Log likelihood (Deviance); Param. = Number of Parameters.

Table 25. *Sample description and univariate predictors of class membership*

Characteristic	Total (N = 160)	Fear of Recurrence Class		Univariate Logistic Regression		
		Low (n = 40)	High (n = 120)	OR	95% *CI*	p-value
Demographic Characteristics						
Age (years)						
M (*SD*)	61.48 (9.60)	63.22 (9.01)	60.91 (9.79)	0.97	0.94, 1.01	.19
Education						
% college-educated	84.47	87.50	83.33	0.71	0.25, 2.05	.53
Marital Status						
% married	73.29	77.50	71.67	0.73	0.32, 1.70	.47
Parent of a child						
% parents	11.18	7.50	12.50	1.76	0.48, 6.43	.39
Annual household income						
% >$40,000	72.18	82.14	69.23	0.49	0.17, 1.40	.18
Clinical Characteristics						
Disease Stage						
% stage 0 or 1	72.05	72.50	71.67	0.96	0.43, 2.14	.92
Treatment						
% chemotherapy & radiation	21.12	12.50	24.17	2.23	0.80, 6.22	.13
% chemotherapy	5.59	7.50	5.00	0.65	0.16, 2.72	.55
% radiation	58.49	67.50	55.93	0.61	0.29, 1.30	.20
% surgery only	14.47	12.50	14.41	1.18	0.41, 3.43	.76
Surgery Type						
% mastectomy	24.22	25.00	23.33	0.91	0.40, 2.10	.83
Current hormone therapy						
% yes	79.87	82.05	78.99	0.82	0.33, 2.08	.68
Previous mammograms						
% ≥ 1 post-treatment	74.53	80.00	72.50	0.66	0.28, 1.58	.35

Table 25 (Continued)

Characteristic	Total (N = 160)	Fear of Recurrence Class		Univariate Logistic Regression		
		Low (n = 40)	High (n = 120)	OR	95% *CI*	*p*-value
Cognitive-Behavioral Model Variables						
Risk						
M (*SD*)	33.28 (8.35)	27.55 (8.42)	35.10 (7.43)	1.13	1.07, 1.20	<.001
Severity						
M (*SD*)	22.01 (4.60)	20.63 (4.63)	22.43 (4.49)	1.09	1.01, 1.18	.03
Treatment Efficacy Beliefs						
M (*SD*)	15.20 (2.01)	15.35 (2.08)	15.14 (2.00)	0.95	0.80, 1.13	.57
Coping Self-Efficacy Beliefs						
M (*SD*)	108.09 (21.49)	117.63 (16.84)	104.88 (22.06)	0.97	0.95, 0.99	.002
Reassurance-Seeking Behaviors						
M (*SD*)	6.34 (1.80)	5.78 (1.69)	6.53 (1.81)	1.31	1.03, 1.66	.03

Note. CI = Confidence Interval; M = Mean; OR = Odds Ratio; SD = Standard Deviation.

Table 26. *Multivariate predictors of class membership*

Variable	OR	95% *CI*	*p*-value
Risk	1.13	1.06, 1.20	<.001
Severity	0.96	0.87, 1.06	.45
Coping Self-Efficacy Beliefs	0.98	0.95, 1.00	.05
Reassurance-Seeking Behaviors	1.36	1.04, 1.77	.03

Note. CI = Confidence Interval; OR = Odds Ratio.

DISCUSSION

FCR demonstrated predictable changes over time before and after follow-up surveillance mammograms in breast cancer survivors. As predicted, a significant reduction in FCR was observed from immediately before to immediately after negative mammogram results were communicated. There was also partial support for the hypothesis that FCR increases before the mammogram and increases over the month following the disclosure of mammogram results. Contrary to expectations, CBM variables did not reliably predict change in FCR over time when controlling for previous FCR, but the model was generally predictive of distinct class trajectories in FCR over time. The results of the present study are considered in more detail below, along with limitations, implications, and future directions.

Change in Fear of Cancer Recurrence over Time

The first aim of the present study was to determine if FCR in breast cancer survivors fluctuated significantly before and after mammography screening. Hypothesis 1, which stated that FCR would increase in the month prior to the mammogram, was partially supported as scores on the CWS demonstrated a significant increase leading up to the mammogram appointment. However, other measures (i.e., combined VAS measure) revealed no significant change leading up to the mammogram or demonstrated a significant decline (i.e., FCRI). These findings suggest that the various measures used may be tapping different aspects of FCR. The CWS assesses the amount of thoughts, worries, mood disturbance, and daily activity disturbance related to worries about cancer recurrence in the past week. It focuses on the frequency of these

thoughts and the frequency of the interference of these thoughts. As noted above, women with a history of breast cancer reported increasing thoughts, concerns, and related interference from these concerns leading up to their mammogram. However, there was no change in the VAS measures of anxiety and worry about recurrence prior to the mammogram. Rather than assess frequency, these state measures assess the magnitude of the anxiety and worry being experienced at that moment. It may be that the frequency of thoughts and the associated interference increases prior to the mammogram, but that the intensity of the anxiety and worry remains largely the same during this time period. Finally, the FCRI addresses a longer period of time (e.g., the past month), and so participants were reporting their FCR for the two months prior to the mammogram when they completed this measure at T1 and T3. It is not clear why a statistically significant decline occurred over this time period, but it may be that reports from the past month are less accurate given the heavy reliance on participants' recall of FCR. It should also be noted that, while statistically significant, the observed *p*-value was on the margin of significance ($p = .05$) and the decline in FCRI scores represented a small change in the degree of FCR reported between these two time points.

The clearest and most dramatic change in anxiety and worry about recurrence occurred during the immediate pre-mammogram to immediate post-mammogram assessment period. As hypothesized (Hypothesis 2), participants reported a significant decline in FCR as measured by the VAS measures as soon as they were given results from their physician that demonstrated no evidence that the cancer had recurred. These results are consistent with other research evaluating the impact of negative medical test results on patients with various health statuses; medical exams that reveal no signs of disease or disorder help to alleviate health-related and general

anxiety in the short-term (Donkin et al., 2006; Lucock et al., 1997; Rimes & Salkovskis, 2002; Quadri & Vakil, 2003).

Following the mammogram, additional assessments revealed significant linear and quadratic increases in anxiety and worry about recurrence on the VAS measures. These findings support the hypothesis (Hypothesis 3) that within one month post-mammogram participants would experience an increase in FCR levels. However, when evaluating past week cancer recurrence worry using the CWS during this time segment, there was no significant change over time. It is important to note that the CWS was administered at T1, T2, T3, T5, and T6, but was not collected during the immediate post-mammogram assessment point (T4). Scores on the VAS measures were at their lowest at T4, but then leveled off from T5 to T6, meaning that there were smaller changes in FCR after the first week post-mammogram. Hence, it may be the case that the significant increase in FCR happens sooner than the first week post-mammogram, which could explain the lack of change for the CWS. This pattern is similar to results of other studies of health anxiety after a medical exam such as gastroscopy, stress tests in healthy patients, or routine oncology follow-up visits in survivors of various cancers. The most dramatic effect of reassuring results occurred within the days after receipt of the results, with health anxiety and worry levels rather quickly increasing and reassurance decreasing back to baseline levels (Donkin et al., 2006; Lampic et al., 1994; Lucock et al., 1997). Again, the present study was consistent with the previous research demonstrating a very brief reprieve from health-related and general anxiety granted by a negative medical test result (Donkin et al., 2006; Lampic et al., 1994; Lucock et al., 1997).

When general state anxiety as measured by the brief STAI was examined, similar patterns as for FCR emerged but with some key differences noted. STAI scores demonstrated both

significant linear and quadratic increases leading up to the mammogram, followed by a significant decrease immediately post-mammogram, and then no change in the month after the mammogram. The differences in the observed patterns between general state anxiety and the state FCR measures demonstrate that FCR is distinct from general state anxiety. While participants endorsed no change in FCR magnitude leading up to the mammogram as measured by the combined VAS measure, there were significant increases in STAI scores prior to the mammogram with a steeper incline in STAI scores as the appointment day approached. The brief STAI assesses feeling calm, tense, upset, relaxed, content, and worried but did not provide a context for the anxiety levels experienced. It may be that FCR magnitude does not vary during this time (i.e., women do not suddenly report changes in anxiety and worry about recurrence when they have received no new information or input from physicians), but the increase in cues related to cancer including reminders about their impending appointment may trigger some generalized anxiety.

When reassurance was assessed post-mammogram, the significant increase in worry and anxiety about recurrence on the VAS measures was matched with a significant decline in the degree to which participants reported feeling reassured by their mammogram. These findings add to the reliability of the finding from this and previous studies that reassurance post-mammogram is relatively brief and short-lived (Donkin et al., 2006; Lampic et al., 1994; Lucock et al., 1997).

Taken together across all study time points, the longitudinal patterns observed support and extend qualitative studies in which patients report that follow-up appointments and surveillance cancer screenings following completion of cancer treatment can trigger heightened FCR (Brook, 2011; Horlick-Jones, 2011; Okazaki et al., 2009; Thompson et al., 2010). The

overall patterns of FCR, state anxiety, and reassurance before and after the mammogram were also consistent with previous studies of health anxiety and reassurance from medical examinations that evaluated both cancer patients returning for medical follow-up visits and patients with no history of cancer receiving gastroscopy, endoscopy, or stress test results (Donkin et al., 2006; Lampic et al., 1994; Lucock et al., 1997; Quadri & Vakil, 2003). This finding bolsters the idea that FCR can be conceptualized as a subset of health anxiety, as patients with or without a medical condition appear to have similar patterns of reactions to medical tests as breast cancer survivors do when undergoing mammograms (Salkovskis & Warwick, 1986; Salkovskis & Warwick, 2001; Warwick, 1989; Warwick & Salkovskis, 1990).

Predicting Change in Fear of Cancer Recurrence over Time

The second aim evaluated whether the CBM could be used to predict the changes observed in FCR. Cross-sectional univariate analyses revealed that CBM variables were related to FCR at each time point in the predicted directions, with the notable exception of treatment efficacy beliefs. The lack of findings for this variable may be due to how it was measured in the present study. In this study, participants simply rated how effective they believed various treatments could be for reducing risk of recurrence. Overall, patients reported little variability in these beliefs; they generally believed that most treatments could be effective. However, it is not clear from this measure how participants viewed their own treatment efficacy. Perhaps results would vary if alternative items were used that were more sensitive to patient beliefs about treatment efficacy, especially if assessing patient beliefs about their own treatment efficacy, rather than general agreement or disagreement that various treatments can effectively reduce risk of cancer recurrence. It may be that personal treatment efficacy beliefs would be more variable and more likely to be associated with FCR than generic treatment efficacy beliefs.

The hypothesis that the increases in FCR pre-mammogram could be predicted by CBM variables (Hypothesis 4) was partially supported. When accounting for relevant clinical and demographic characteristics, at least one CBM variable accounted for additional unique variance in FCR during the time period prior to the mammogram depending on the specific outcome measure. When predicting change in CWS scores, greater severity and greater reassurance-seeking behaviors predicted greater increases in FCR. However, only greater reassurance-seeking behaviors independently predicted increases in FCR prior to the mammogram. This finding is consistent with the Thewes et al. (2012) study, which found that patients who engaged in more self-exams and went to more unscheduled medical visits to discuss FCR (examples of reassurance-seeking behaviors) reported higher FCR levels than those who did not. For analyses predicting change in FCRI scores, both education and coping self-efficacy (i.e., the degree of confidence that one can cope successfully with the tasks associated with a possible cancer recurrence), were negatively associated with FCRI scores immediately prior to the mammogram when controlling for initial FCRI scores. Research examining the role of general coping and cancer-related coping self-efficacy has found similar relationships. Specifically, greater coping self-efficacy has been found to be related to lower FCR in cross-sectional studies of breast cancer patients in the year after diagnosis and up to eight years post-diagnosis (Melchior, Buscher, Thoren, Grochocka, Koch, & Watzke, 2011; Ziner, Sledge, Bell, Johns, Miller, & Champion, 2012). In the present study, baseline cancer-related coping self-efficacy predicted later FCRI scores over and above the initial FCRI scores, while more general self-efficacy measures for coping with stressful situations did not predict FCR when controlling for initial values one year prior (Melchior et al., 2011). These findings indicate that beliefs about cancer-related coping self-efficacy are predictive of FCR, but general self-efficacy beliefs are not.

The hypothesis that the decreases in FCR from immediately pre-mammogram to immediately post-mammogram could be predicted by CBM variables (Hypothesis 5) was not supported. The addition of the CBM variables did not predict the significant declines in the combined VAS measure observed immediately after the mammogram results were discussed with the physician. The only significant predictor in this model was the initial combined VAS measure at just prior to the mammogram. This result can be interpreted as the effect of the reporting of good results being so strong and universal for the majority of patients that there was not sufficient variability in the pattern available to be predicted by CBM variables. It suggests that the vast majority of patients experienced a reduction in FCR, no matter their own clinical or demographic characteristics, or individual cognitions and behaviors.

Similarly, the hypothesis that the increases in FCR post-mammogram could be predicted by CBM variables (Hypothesis 6) was not supported. The significant increases evident on the combined VAS measure during the post-mammogram time period were not influenced by individual variability in CBM variables. However, analyses did reveal that lower income participants reported larger increases on the combined VAS measure during the month following the mammogram. No other clinical or demographic variables were related to changes on the combined VAS measure. It appears that the passage of time and initial combined VAS measure levels are the best predictors of the eventual increases in scores back to baseline levels.

In summary, while CBM variables were good predictors of FCR cross-sectionally, few CBM variables were predictive of the changes in FCR over time. Initial FCR was a consistently good predictor of later FCR in all time segments across measures, suggesting that patients who experience higher levels will tend to report higher levels over time and across different situations compared to other patients. This finding is consistent with the findings from previous

longitudinal studies that found evidence for stability in FCR over time (Ghazali, Cadwallader, Lowe, Humphris, Ozakinci, & Rogers, 2013; Humphris et al., 2003; Humphris & Rogers, 2004; Llewellyn et al., 2008; Stanton et al., 2002). Few demographic characteristics and no clinical characteristics were related to FCR either cross-sectionally or longitudinally, which fits with results of previous studies which also did not find relationships with these variables (see Crist & Grunfeld, 2013 and Koch, Jansen, Brenner, & Arndt, 2013 for helpful reviews of demographic and clinical characteristics related to FCR).

Individual Differences in Fear of Cancer Recurrence Trajectories over Time

The exploratory analyses evaluated whether distinct classes of patients who experienced unique patterns of change in FCR existed. Based on growth mixture modeling, two classes were identified: the first class resembled the overall mean pattern observed for the overall sample and the second class represented a subgroup of patients who experienced the same pattern with both lower overall levels of FCR and more gradual slopes over time. The first class included three quarters of the study sample and appeared to capture the prototypical trajectory for FCR before and after a mammogram. While variability remained in this group, no consistent patterns emerged within this class that would justify additional subclasses. The second class, which included approximately a quarter of the participants in this study, demonstrated relatively little variability between subjects.

Examination of predictors revealed that demographic and clinical characteristics were not significantly related to class membership. However, the following CBM variables were independently predictive of class membership: perceived risk, coping self-efficacy, and reassurance-seeking behaviors. Hence, the CBM has utility in predicting which breast cancer survivors are likely to experience heightened FCR.

Strengths and Limitations

There are many notable strengths of the current study. First, this was the first prospective investigation of FCR before and after a medically significant event in the survivorship phase. Second, various types of FCR measures were utilized allowing for examination of the magnitude and frequency of cancer-related worry, anxiety, and fears related to cancer recurrence. Third, both within- and between-subject differences in FCR were examined along with their relationships to various demographic, clinical, and psychosocial characteristics. Fourth, distinct trajectories were evaluated using growth mixture modeling. Finally, the study tested the utility of an established theoretical model of health anxiety to determine to what degree FCR can be predicted by a set of modifiable cognitive and behavioral factors.

Several important limitations must also be noted. First, as has been pointed out in several previous studies of FCR (Petzel et al., 2012; Simard & Savard, 2009; Simard et al., 2010; Thewes et al., 2012), it is difficult to determine whether study participants adequately represent the patient population from which they are drawn. Only 51% of invited women chose to participate. Based on anecdotal evidence, several women noted that they were declining participation because they were too fearful and did not want additional reminders of cancer or the possibility of a recurrence. Consequently, the possibility that study findings may be influenced by participation bias cannot be ruled out. Second, the study sample included only women previously diagnosed with early-stage breast cancer and so the study findings cannot be generalized to other groups of cancer patients. Third, the primary outcome variable was the combined VAS measure, which has not been previously validated for assessing FCR. However, this measure demonstrated good psychometric properties in the current sample and was highly correlated to the other more established measures of FCR used. Fourth, the evaluation of patient

treatment efficacy beliefs focused on general beliefs about various treatments, but not on beliefs about treatments previously received. Alternative measures which assess patient's perceptions of efficacy of their own treatment may be more predictive of FCR than our more generic cancer treatment efficacy beliefs scale. Finally, it is important to note that lack of significant findings for change over time does not necessarily imply stability in FCR over time. It is more appropriate to interpret those findings as lack of systematic change over time across patients as individual patterns of change were highly variable, but not always in similar directions, across participants.

Theoretical Implications

The study findings demonstrated that FCR changes over time in a predictable fashion before and after surveillance screening exams. Furthermore, plotting individual combined VAS scores over time reveals a very broad range of trajectories experienced by participants in this study. Hence, it is important to recognize that, while two classes were identified in the models, momentary concerns about recurrence do demonstrate substantial variability that is difficult to predict consistently both within and across patients. This between-person variability fits with patient accounts of the so-called "Sword of Damocles" phenomenon associated with FCR; worry and anxiety about recurrence may loom for most, but these concerns tend to become more prominent or bothersome depending on circumstances which may vary greatly between patients (Cesario, Nelson, Broxson, & Cesario, 2010; Koch et al., 2013; Lee-Jones, Humphris, Dixon, & Hatcher, 1997; McCaughan, Prue, Parahoo, McIlfatrick, & McKenna, 2012).

The present study determined that CBM variables were related to FCR cross-sectionally and predicted class membership for varying trajectories in FCR over time. When CBM variables were used as predictors of change for each time segment, there was limited support for the

theoretical model. However, when these same variables were used to predict the high-FCR and low-FCR classes, the CBM variables were the best predictors over and above other individual characteristics. These findings demonstrate the utility of using growth mixture modeling when evaluating FCR and theoretical models for understanding it.

While the current study identified several predictors of heightened FCR, additional predictors of change in FCR over time and class membership should be evaluated in future research. Dispositional variables such as neuroticism or optimism, and coping styles, and specific triggers of FCR, such as somatic symptoms, exposure to others' illness, death, or cancer, and cancer-related anniversaries, have been found to be related to FCR in previous cross-sectional studies (Crist & Grunfeld, 2013; Koch et al., 2013) and may predict differences in trajectories over time. Finally, this study demonstrated varying patterns between FCR and general state anxiety. Future research should further evaluate to what extent FCR and other forms of anxiety, especially health-related anxiety, may differ.

Clinical Implications

This study has several implications for clinical practice. Overall, women with a history of breast cancer report low to moderate FCR even during the time period surrounding follow-up surveillance cancer screening. Mammogram results do appear to provide a dramatic reduction in FCR for the majority of patients and reassurance from these examinations remains relatively high during the month after the appointment. However, the reduction in FCR is brief and patients can be told that repeated examination is not the best method for reducing their own FCR for the long-term and that such reassurance-seeking behaviors are related to greater FCR.

Providers should also be aware that those women who report low FCR are likely to continue to report low levels and women reporting high FCR are likely to continue to report high

levels and have steeper changes in their FCR before and after a mammogram appointment, even if provided with negative results, as evidenced by the finding that initial FCR was always the strongest predictor of later FCR. Examination of the subclasses from the growth mixture models revealed a sizable minority of patients who likely would not need or request services to help them cope with or reduce FCR. However, the majority of patients would likely benefit from some sort of psychoeducation about FCR and what may make a person more at risk of developing distressing FCR levels.

In addition, several modifiable characteristics related to the experience of heightened FCR were identified, which may help inform future interventions designed to reduce FCR in patients with a history of cancer. The findings suggest that future research should test the efficacy of CBM-informed interventions in reducing FCR, especially those that focus on providing patients with more accurate recurrence risk perceptions, reducing reassurance-seeking behaviors such as excessive self-exams, and improving self-efficacy for dealing with the possibility of a recurrence. There are several interventions which already target at least some of these factors, such as reassurance-seeking behaviors (Bailey, Mishel, Belyea, Stewart, & Mohler, 2004; Humphris & Ozakinci, 2008) and risk perceptions (Humphris et al., 2008). Interventions might also focus on social modeling from patients who are successfully coping with recurrence (Stanton et al., 2005) and teaching patients new skills for handling medical or interpersonal situations associated with distress to increase coping self-efficacy (Marks & Allegrante, 2005). Future research should evaluate whether all of these characteristics (higher perceived risk, lower coping self-efficacy, and greater reassurance-seeking behaviors) need to be addressed to reduce reported FCR or if targeting either one or a subset of these characteristics is effective in treating

FCR. CBM variables should also be evaluated as possible underlying mechanisms of change in such interventions.

Summary and Conclusions

This study represents the first theory-driven, prospective longitudinal assessment of FCR focused around a medically meaningful event. Across time, FCR fluctuated in the expected directions, with increases observed prior to the mammogram, a significant decline observed immediately following receipt of results, and a gradual, but significant increase in FCR and decrease in reassurance observed during the month following the mammogram. The CBM did not significantly predict change in FCR over time, but certain variables did predict fluctuations including coping-self efficacy and perceived risk. Moreover, growth mixture models revealed high-FCR and low-FCR classes which were predicted by the CBM. Future research should examine the utility of the CBM for informing FCR interventions for patients experiencing distressing or excessive FCR.

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APPENDICES

Appendix A: IRB Approval Letter

USF
UNIVERSITY OF
SOUTH FLORIDA

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
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7/11/2011

Paul Jacobsen, Ph.D.
H Lee Moffitt Cancer Center
12902 Magnolia Drive
MRC-PSY

RE: **Expedited Approval** for Initial Review
IRB#: Pro00004435
Title: Fear of Cancer Recurrence in Breast Cancer Survivors Before and After Follow-up Mammograms

Dear Dr. Jacobsen:

On 7/8/2011 the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol. Please note that your approval for this study will expire on 7/8/2012.

Approved Items:
Protocol Document(s):

McGinty.Dissertation Protocol.05.26.11.doc 0.01

Consent/Assent Documents:
Informed Consent Form.pdf 0.01
Please use only the watermarked/stamped consent form(s) found under the "Attachment Tab" in the recruitment of participants.

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural

beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please note, the informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on the form. Valid consent must be documented on a copy of the most recently IRB-approved consent form.

Your study qualifies for a waiver of the requirements for the documentation of informed consent for the retrospective review of medical records as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45 CFR 164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

A Partial Waiver of HIPAA Authorization for Recruitment has been approved for you to conduct a retrospective review of medical records generated between June 1, 2007 and June 30, 2011, involving breast cancer survivors diagnosed with Stage 0-11, who completed treatment and at least one, but no more than two follow up surveillance mammograms. HIPAA Authorizations will be obtained upon enrollment from those individuals who will be selected.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John A. Schinka, Ph.D., Chairperson
USF Institutional Review Board

Cc: Christina Calandro, USF IRB Professional Staff

ABOUT THE AUTHOR

Heather L. McGinty was born and raised in Jacksonville, FL. She completed her undergraduate degree in Psychology at the University of Florida in Gainesville, FL with a minor in Philosophy and a certificate in Aging Studies. She obtained her Ph.D. in Clinical Psychology from the University of South Florida in 2014, where she trained in the specialty area of Psychosocial Oncology under the mentorship of Paul B. Jacobsen, Ph.D. at the H. Lee Moffitt Cancer Center in Tampa, FL. She completed her clinical psychology internship training at the University of Florida in 2014 and will continue her training as a postdoctoral fellow in psychosocial oncology in the Department of Medical Social Sciences at the Feinberg School of Medicine at Northwestern University in Chicago, IL.