GOAL PURSUIT MEDIATES EFFECTS OF A GRATITUDE INTERVENTION ON DEATH-RELATED FEAR OF RECURRENCE IN BREAST CANCER SURVIVORS

by
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ABSTRACT

One of the most prevalent and distressing concerns endorsed by breast cancer survivors is fear of cancer recurrence (FOR), and one of the most salient facets is the worry that a recurrence of cancer could cause one’s death. The primary goal of the present study was to test the effects of a brief gratitude intervention on overall FOR and death-related FOR, with pursuit of meaningful goals examined as a potential mediator. Positive affect (PA) was also examined as both an outcome of the intervention and as a mediator of observed effects of the intervention on FOR. Sixty-seven women with early-stage breast cancer were randomly assigned to either a six-week online gratitude intervention or a six-week online control condition. Although the intervention did not predict changes in overall FOR, results revealed that patients in the gratitude intervention experienced a significant decrease in death-related FOR compared to the control condition. Moreover, this effect was partially mediated by goal pursuit. The gratitude intervention was also found to prevent a decline in PA observed in the control condition; however, PA did not mediate the effects of the intervention on death-related FOR. Overall, findings support the notion that gratitude promotes psychological adaptation to cancer by promoting the pursuit of meaningful goals and subsequently reducing death-related FOR.
Chapter 1

INTRODUCTION

Excluding skin cancers, breast cancer is the most commonly-diagnosed cancer among women both in the United States and across the world, with approximately one in eight women expected to develop breast cancer in her lifetime (American Cancer Society [ACS], 2014; Ferlay et al., 2013). Although breast cancer remains the second leading cause of cancer-related death among women, breast cancer mortality has actually been declining since around 1989 (ACS, 2014). In fact, the vast majority of women diagnosed with early-stage breast cancer now survive beyond five years; currently, the five-year relative survival rate ranges from 72% for Stage III breast cancer to nearly 100% for Stage 0 breast cancer (ACS, 2014). This increase in survival means that there is a growing population of breast cancer survivors in the United States—nearly 3 million as of 2011, according to the National Cancer Institute (2014).

One of the top concerns, if not the top concern, consistently described by breast and other cancer survivors is fear of recurrence (e.g., Allen, Savadatti, & Levy, 2009; Baker, Denniston, Smith, & West, 2005; Mehnert, Berg, Henrich, & Herschbach, 2009; Simard, Savard, & Ivers, 2010; Vickberg, 2003). Fear of cancer recurrence (FOR), broadly defined as the “worry that the cancer will return or progress
in the same organ or in another part of the body” (p. 361; Simard et al., 2010), has been linked to a variety of negative consequences, including increased psychological distress (Deimling, Bowman, Sterns, Wagner, & Kahana, 2006) and decreased quality of life (Mehnert et al., 2009), as well as increased health care utilization (Lebel, Tomei, Feldstain, Beattie, & McCallum, 2013). Not surprisingly, FOR has been suggested as a specific target of intervention (e.g., Simard et al., 2013). Despite its prevalence, however, there has been little empirical work on interventions specifically designed to reduce FOR.

A growing body of literature has shown that, in addition to enhancing positive outcomes, positive emotions can also help attenuate or even “undo” negative outcomes (Fredrickson & Levenson, 1998; Fredrickson, Mancuso, Branigan, & Tugade, 2000; Roberts, 2004), which is particularly relevant when considering potential methods of reducing FOR. Fredrickson’s broaden-and-build theory of positive emotions holds that positive emotions help broaden cognition, allowing individuals to expand their momentary thought-action repertoires, and build long-lasting resources that can be drawn upon during future adversity (Fredrickson, 1998, 2001). Gratitude is one such positive emotion highlighted by Fredrickson (2001, 2004) that has been specifically explored in the literature; gratitude yields enduring personal and social benefits (McCullough, Kilpatrick, Emmons, & Larson, 2001), and has been shown to increase well-being among chronically-ill adults (Emmons & McCullough, 2003). Thus, gratitude has the potential to help promote adaptation to cancer by promoting well-being and reducing FOR.
Although gratitude has been found consistently to be associated with positive outcomes, minimal research has considered whether gratitude can attenuate negative outcomes such as FOR. Moreover, very few studies have examined gratitude in the context of adverse health conditions such as cancer. Examining the influence of gratitude on FOR, a prominent and pervasive negative outcome of the cancer experience, would represent an important contribution to the literature. Accordingly, the primary goal of the present study was to evaluate the effects of a brief, well-established online gratitude intervention on FOR in early-stage breast cancer survivors.

1.1 Fear of Cancer Recurrence and Death Worry

As noted above, FOR is an extremely salient and prevalent concern of a large number of cancer survivors; in fact, coping with FOR is the most frequently endorsed unmet need for supportive care among patients who have completed cancer treatment (Armes et al., 2009). Although there is no universally-used definition of FOR, it is best conceptualized as a multifaceted construct with both cognitive and emotional components, including anxiety and perceived risk of recurrence (Lee-Jones, Humphris, Dixon, & Hatcher, 1997; Park, Cho, Blank, & Wortmann, 2013). FOR encompasses a variety of more specific concerns about the possible sequelae of a recurrence, including worries about needing to undergo further treatment, effects on day-to-day functioning, changing roles and responsibilities, loss of femininity or sexuality, and death (Vickberg, 2003). Interestingly, reported levels of FOR have also
been found to be largely independent of a survivor’s \textit{actual} risk of recurrence (e.g., Petzel et al., 2012; Skaali et al., 2009).

Across a variety of cancer types, including breast, FOR has been associated with increased symptoms of anxiety, depression, and post-traumatic stress (Deimling et al., 2006; Gotay & Pagano, 2007; Hodges & Humphris, 2009), as well as lower levels of social support, decreased quality of life, and decreased optimism (Deimling et al., 2006; Kim, Carver, Spillers, Love-Ghaffari, & Kaw, 2012; Koch, Jansen, Brenner, & Arndt, 2013; Mehnert et al., 2009). Despite these links, FOR only moderately correlates with measures of psychological distress (Mehnert et al., 2009; Simard & Savard, 2009). Additionally, Zhao, Portier, Stein, Baker, and Smith (2009) identified FOR and emotional distress as two discrete factors in an exploratory factor analysis of a commonly-used inventory of cancer-related problems. Therefore, FOR should be considered a unique feature of cancer survivorship, distinct from general psychological distress.

FOR has consistently been shown to be a very prevalent concern soon after the end of adjuvant treatment (e.g., Costanzo et al., 2007; Hodges & Humphris, 2009). Although a limited number of studies have specifically examined the long-term trajectory of FOR, it appears that FOR tends to remain relatively stable over time, often persisting for months and even years after treatment has ended (Baker et al., 2005; Costanzo et al., 2007; Deimling, Kahana, Bowman, & Schaefer, 2002; Deimling et al., 2006; van den Beuken-van Everdingen et al., 2008; Kim et al., 2012; Stanton, Danoff-Burg, & Huggins, 2002; Liu et al., 2011; Mehnert et al., 2009; Mellon,
Kershaw, Northouse, & Freeman-Gibb, 2007). In a review of 17 studies examining FOR, Koch and colleagues (2013) found that the majority of long-term cancer survivors worried about the progression or recurrence of their cancer, even more than five years after their diagnosis.

More specifically, fear that a recurrence of cancer could cause one’s death (hereafter referred to as “death worry”) tends to be one of the strongest and most common aspects of FOR. Vickberg (2003) found that three-quarters of breast cancer survivors endorsed at least some death worry, and almost 40% of survivors endorsed worrying about this possibility “a lot” or “extremely.” Moreover, van den Beuken-van Everdingen et al. (2008) found that moderate to high levels of death worry were endorsed by 61% of breast cancer survivors. Mahon and Casperson (1997) found that patients who had recently suffered a cancer recurrence overwhelming described death-related concerns when asked to explain the “meaning” of cancer recurrence. As with general FOR, death worry has also been found to be separate from general psychological distress (Cella & Tross, 1987); however, death worry shows weak to moderate correlations with various aspects of well-being, including increased symptoms of depression and more generalized anxiety and decreased quality of life (Cella & Tross, 1987; Krause, Rydall, Hales, Rodin, & Lo, 2014; Neel, Lo, Rydall, Hales, & Rodin, 2013; Sherman, Norman, & McSherry, 2010; Sigal et al., 2008). Additionally, Gonen et al. (2012) found that higher death worry was associated with decreased perceived life expectancy.
1.2 Gratitude and Well-Being

Gratitude is a complex, positively-valenced emotion that can be described broadly as feelings of thankfulness and appreciation. It may be triggered by receipt of a particular benefit or gesture (Lambert & Fincham, 2011; Tesser, Gatewood, & Driver, 1968) or may take the form of more nonspecific feelings of appreciation, such as feeling grateful for being alive (Lambert, Graham, Fincham, & Stillman, 2009). Research has demonstrated that gratitude is distinguishable both from other types of positive emotions and from feelings of obligation or indebtedness (Algoe & Haidt, 2009; Goei & Boster, 2005; Tsang, 2006, 2007).

Increased feelings of gratitude have consistently been associated with both individual and interpersonal benefits, including increased life satisfaction and well-being (Peterson, Ruch, Beermann, Park, & Seligman, 2007; Sheldon & Lyubomirsky, 2006), positive affect (Emmons & McCullough, 2003), and use of adaptive coping strategies (Wood, Joseph, & Linley, 2007), as well as decreased stress and depressive symptoms (Wood, Maltby, Gillett, Linley, & Joseph, 2008). Gratitude has also been linked to increased prosocial behavior (Bartlett & DeSteno, 1996; Emmons & McCullough, 2003), serving an important function in the development and maintenance of close relationships (Algoe, Haidt, & Gable, 2008; Gordon, Arnette, & Smith, 2011; Kubacka, Finkenauer, Rusbult, & Keijsers, 2011; Lambert, Clark, Durtschi, Fincham, & Graham, 2010; Lambert & Fincham, 2011).

Gratitude has been causally linked with many of these positive outcomes via experimental manipulation. For example, a six-week intervention in which
participants listed weekly things for which they were grateful produced increases in subjective well-being relative to a control group (Lyubomirsky, Sheldon, & Schkade, 2005). Seligman, Steen, Park, and Peterson (2005) found that writing and delivering a single letter of gratitude resulted in increased happiness and decreased depressive symptoms, even a month after the letter was delivered. Additionally, Emmons and McCullough (2003) demonstrated that participants with a chronic medical condition assigned to a brief gratitude-eliciting intervention reported increased life satisfaction, optimism, and positive affect, as well as sleep amount and quality.

1.3 Gratitude in the Context of Cancer

Very little research to date has focused on gratitude in the context of cancer, and only one study to date (Szczesny, 2014) has examined the relationship between gratitude and fear of recurrence specifically. Algoe and Stanton (2012) assessed gratitude in a sample of women with metastatic breast cancer and found that a tendency to feel more grateful after receiving benefits predicted increased levels of perceived social support, but only for women who were not ambivalent about expressing their emotions; women who were more ambivalent did not benefit from gratitude in this way. In a study involving non-metastatic breast cancer patients, Ruini and Vescovelli (2013) showed that women higher on dispositional gratitude reported greater post-traumatic growth and positive affect, as well as lower anxiety, depression, and hostility-irritability, than women who were lower on gratitude. These findings suggest that those who have a greater tendency to experience gratitude may actually experience positive growth as a result of their experience with breast cancer. Lastly,
Szczesny (2014) used daily-diary methods to examine gratitude in the context of couples coping with early-stage breast cancer. Results showed that, in both patients and their spouses, increased partner-directed gratitude predicted decreased fear of recurrence, and intimacy was a significant within-person mediator of this relationship.

Additionally, one study presents some preliminary evidence that gratitude may influence death worry specifically. Although they explored this relationship within a sample of healthy older adults who had not been diagnosed with cancer, Lau and Cheng (2012) found that participants assigned to a brief gratitude intervention reported decreased death anxiety compared to those assigned to write about hassles or neutral topics. Interestingly, however, the gratitude intervention did not substantially impact positive or negative affect, which the authors attributed to the brevity of the intervention (participants spent only 15 to 20 minutes engaged in the gratitude induction task), suggesting that gratitude may decrease death anxiety without corresponding changes in overall affective state. Lau and Cheng (2012) theorized that increased feelings of gratitude diverted participants’ attention from regrets and other negative aspects of their lives by prompting them to refocus on the positive, which served to reduce the sense of unfulfilled wishes and regrets and enhance feelings of meaning and order in their lives; this increased sense of meaning promotes increased death acceptance and reduced death anxiety. However, as noted earlier, this study did not involve a health population, and assessment of death anxiety occurred immediately after the gratitude induction task; additional research is needed to understand any longer-term effects that gratitude may have on death worry.
1.4 Goal Pursuit as a Putative Mechanism of Gratitude Intervention Effects

Taken together, it is evident from the existing research in this area that gratitude could potentially play an important role in promoting adaptation to breast cancer, although more work is needed to understand the mechanisms of this relationship. With the exception of Szczesny (2014), no study has explicitly examined potential mediators of the relationship between gratitude and FOR. Fredrickson’s broaden-and-build theory of positive emotions (1998, 2001) could provide a framework for investigating these processes. The broaden-and-build theory posits that positive emotions—even low-activation states such as “contentment”—serve to (1) broaden cognition, allowing individuals to expand attention, thinking, and behavioral repertoires, and (2) build enduring physical, intellectual, psychological, and social resources that outlast the fleeting positive emotions that lead to their acquisition and can be drawn upon to aid in coping during future times of need (Fredrickson, 1998, 2001). Along with augmenting positive experiences and outcomes, positive emotions have also been shown to attenuate or “undo” negative outcomes (Fredrickson & Levenson, 1998; Fredrickson et al., 2000; Roberts, 2004), providing some preliminary support for the idea that positive emotions can reduce cancer-specific negative outcomes such as FOR.

Gratitude has been specifically discussed in the context of the broaden-and-build theory by Fredrickson (2001, 2004). Fredrickson (2004) posits that gratitude broadens one’s momentary thought-action repertoire to include a wide array of creative prosocial behaviors (which are not necessarily directed only at the
benefactor), meaningful interpersonal situations, and a strengthened sense of spirituality. Importantly, Fredrickson (2004) asserts that the experience of positive emotions like gratitude help individuals “envision future achievements” (p. 148) and promote goal-directed behavior. For instance, in a study of recently-bereaved adults, Stein, Folkman, Trabasso, and Richards (1997) found that those who experienced more positive emotions were more likely to develop long-term plans and goals. In addition, Emmons and McCullough (2003) showed that undergraduate students assigned to a brief gratitude intervention reported achieving more progress toward their goals.

Although it has not yet been explicitly linked to FOR, increased goal pursuit and attainment has been consistently linked with various dimensions of well-being (e.g., Lyubomirsky et al., 2005; Sheldon, Kasser, Smith, & Share, 2002; Stein et al., 1997). In fact, Lyubomirsky and colleagues (2005) proposed that “intentional activity,” including working toward important personal goals, could account for up to 40% of individual differences in overall well-being.

Other work more directly points to the potential importance of engagement in meaningful goals and activities in the relationship between gratitude and FOR, specifically death worry. Important personal goals are “essential components of a person’s experience of his or her life as meaningful” (Emmons, 2003, p. 107), and pursuit of goals has consistently been associated with a greater sense of meaning and purpose (e.g., Brunstein, Schultheiss, & Maier, 1999; Emmons, 1986; Emmons, 2005; Klinger, 1977; Mak, 2011; Park, 2010). Lau and Cheng (2012) theorized that the
influence of gratitude on death worry that they observed was mediated by an enhanced sense of meaning in one’s life, although they did not specifically test this hypothesis. Tang, Chiou, Lin, Wang, and Liand (2011) also found that cancer patients with a greater sense of purpose in life experienced less death anxiety than those who were uncertain or had no sense of purpose. Additional support for the link between meaningful goal pursuit and reduced death anxiety lies in Wong’s Meaning Management Theory (Wong, 2008; Wong & Tomer, 2011), which posits that, when exposed to the salience of their own mortality, individuals proactively search for and create meaning in their lives, in part by pursuing worthwhile goals, which promotes death acceptance and attenuates death anxiety.

Lastly, although little work has examined the link between goal pursuit and overall FOR, Mellon et al. (2007) found that cancer survivors and caregivers who attributed more positive meanings to the illness—including perceiving that the illness did not interfere with achievement of important personal goals—experienced significantly less overall fear of recurrence than those who attributed more negative meanings to the illness.

1.5 Rationale for Present Study and Hypotheses

Overall, the existing literature suggests that gratitude may have the ability to promote adaptation to cancer by decreasing some facets of FOR, especially death worry, and that this relationship may be mediated via increasing pursuit of meaningful personal goals. However, this question has never specifically been the focus of investigation, and the majority of existing research on gratitude and goal pursuit has
not explored these topics in the context of a health adversity such as cancer. Cancer survivors are an important group in which to explore the potential benefits of gratitude; in addition to the stressors of everyday life, even longer-term survivors can continue to face a number of cancer-specific stressors, including medical appointments such as follow-up mammograms, ongoing financial issues, enduring side effects of treatment, body image issues, and, in particular, coping with worries about the cancer returning. Understanding whether and how gratitude can attenuate or “undo” a cancer-specific negative outcome, such as fear of recurrence, could lead to more promising psychosocial interventions for cancer survivors and would represent a valuable contribution to the literature. Simard et al. (2013) has specifically called for research with the primary goal of developing and evaluating interventions for FOR, yet there has been very little empirical work in this area, despite the prevalence of FOR. The present study aimed to help fill this gap in the literature.

In the present study, we examined the effects of an online gratitude intervention on aspects of FOR among early-stage breast cancer survivors. Specifically, it was hypothesized that those in a gratitude intervention would experience a greater decrease in both overall FOR (Hypothesis 1) and death worry (Hypothesis 2) over the course of the study than those in a control condition. It was expected that the effects of the gratitude intervention on death worry would be mediated by goal pursuit, such that, compared to the control group, those in the gratitude intervention would engage in increased goal pursuit over the course of the intervention period, ultimately leading to greater decreases in death worry (Hypothesis
3). As there is only weak evidence for the function of goal pursuit as a mediator between gratitude and overall FOR, this effect was not specifically hypothesized. Fredrickson’s broaden-and-build theory (1998, 2001) also implies that increased overall positive affect could be another outcome of such an intervention, and could possibly even act as a mediator between the intervention and any observed effects on overall FOR or death worry. Accordingly, it was expected that those in the gratitude intervention would experience a greater increase in overall positive affect over the course of the study than those in the control group (Hypothesis 4). Additionally, positive affect was hypothesized to mediate any observed effects on overall FOR and death worry (Hypothesis 5).
Chapter 2

METHOD

2.1 Participants

Participants were 67 English-speaking women who had been diagnosed with
ever-stage breast cancer (defined as Stage 0 (ductal/lobular carcinoma in situ), Stage
I, Stage II, or Stage IIIA). All women received breast cancer surgery (either
lumpectomy or mastectomy) as part of their treatment. On average, approximately
48.27 months ($SD = 20.42$) had passed between the date of surgery and the date each
participant completed her first study questionnaire. All participants were recruited
from a mid-Atlantic community cancer center with Institutional Review Board
approval. Each woman had previously been recruited shortly after her surgery to
participate in one of two prior research studies involving women with breast cancer
and their romantic partners (Belcher et al., 2011; Dasch et al., 2010; Otto, Laurenceau,
Siegel, & Belcher, in press; Pasipanodya et al., 2012), although data from romantic
partners were not collected as part of the present study. Of 103 eligible women
approached for participation in the present study, nine declined (most commonly
citing “not enough time”), 19 were unable to be reached, five were deceased, and 70
verbally agreed. Of the 70 who verbally agreed, three did not return signed informed
consent documents, leaving a final sample of 67 women.
On average, participants were 56.89 years old ($SD = 10.20$). The majority identified as White (86.6%) and non-Hispanic (95.5%). Participants tended to be very well-educated; 71.7% earned at least a bachelor’s degree. With regard to occupational status, 31.3% of women reported that they were not currently working, while 20.9% and 46.3% worked part- and full-time, respectively. Approximately 74.6% of participants reported an annual family income of over $60,000. Nine women (13.4%) reported that they had been diagnosed with at least one other type of cancer since their original breast cancer diagnosis. Additionally, eight women (11.9%) reported that they had experienced a recurrence of their breast cancer since their initial treatment, which is roughly consistent with estimates of five-year recurrence rates for a similar population of women who received adjuvant or neoadjuvant chemotherapy or hormonal therapy (Brewster et al., 2008).

With regard to relationship status, 64 participants (95.5%) were married, two (3.0%) were in a committed relationship, and one (1.5%) did not report on marital status. Of the 64 married participants, all but one (98.4%) reported being married to the same partner that they were married to when they participated in the previous couples-based studies. Mean relationship length was 30.18 years ($SD = 13.70$).

2.2 Procedure

See Figure 1 for a depiction of the study timeline. Participants were randomly assigned to one of two conditions: a six-week online gratitude intervention ($N = 34$) or a six-week online control condition ($N = 33$). The intervention was modeled on similar gratitude-eliciting interventions that have previously been found to produce
improvements in various aspects of well-being (Emmons & McCullough, 2003; Lyubomirsky, Dickerhoof, Boehm, & Sheldon, 2011; Lyubomirsky et al., 2005; Seligman et al., 2005).

All participants completed the same initial set of online questionnaires (Pre), which included demographic information. Shortly after completing the Pre questionnaires, participants were asked to complete online surveys once per week for 6 consecutive weeks. The average number of completed weekly surveys was 5.87 for a cumulative total of 393 weekly surveys across all 67 participants, resulting in a 98% compliance rate. Weekly surveys were identical across conditions, with the exception of a brief task given to participants at the end of each survey.

Participants in the gratitude intervention were asked to spend 10 minutes writing a letter expressing their gratitude to a person of their choice; they were provided with the following prompt (adapted from Lyubomirsky et al. (2011) and Seligman et al. (2005)):

*Please take a moment to think back over the past several years of your life and remember an instance when someone did something for you for which you are extremely grateful. For example, think of the people – parents, relatives, friends, teachers, doctors, health care professionals, employers, and so on – who have been especially kind to you but have never heard you express your gratitude. Although you should try to write your letter of gratitude to a new person each week, if you prefer, you can write another letter to the same person more than once. Now, for the next 10 minutes, write a letter to one of*
these individuals. Use the instructions below to help guide you through this process:

1. Use whatever letter format you like, but remember to write as though you are directly addressing the individual you are grateful to. If it is helpful to head the letter “Dear so-and-so,” or end with “Sincerely, XXX,” feel free to do so.

2. Do not worry about perfect grammar and spelling.

3. Describe in specific terms why you are grateful to this individual and how the individual’s behavior affected your life.

4. Describe what you are doing now and how you often remember their efforts.

5. Remember: Anything you write will remain strictly confidential. Although you are welcome to show or give this letter to anyone you please, for the purposes of this study, the letter you write is a private document in which you can express your gratitude freely without intent to deliver it to anyone. Should an experimenter read this entry in the future, it will be identifiable only by a subject number and not by a name.

Based on Lyubomirsky et al. (2011), gratitude letters were subsequently rated for effort by two independent coders on a 7-point Likert-type scale ranging from 0 = No effort/did not complete task to 6 = Maximum effort. Coders’ ratings were very strongly correlated ($r = .90, p < .001$); codes were then averaged to calculate a final effort code for each letter. Mean effort across all letters for all participants assigned to
the gratitude intervention was 4.64 ($SD = 1.65$). Participants in the control condition were asked to spend 10 minutes listing and briefly describing up to 20 activities that they had engaged in during the preceding weeks. Results of an independent samples $t$-test revealed that, on average, gratitude letters and control tasks were not significantly different in terms of word count ($t(64) = -1.30, p = .197$).

Immediately after completing the sixth weekly survey, participants were asked to complete another set of online questionnaires (Post). Finally, participants were asked complete follow-up sets of online questionnaires approximately 1 month ($FU1$) and 3 months ($FU2$) following the sixth weekly survey. Like the Pre questionnaire, the Post questionnaire and both follow-up questionnaires were identical across conditions.

2.3 Measures

2.3.1 Weekly Gratitude

Gratitude was calculated as the mean of three items from the weekly surveys: feeling grateful, thankful, and appreciative. For each item, participants were asked to indicate to what extent they experienced each feeling during the preceding seven days on a Likert-type scale ranging from $1 = $Very rarely or never$ to $5 = $Very often or always$. Mean internal consistency across all weekly surveys was excellent ($\alpha = 0.94$).

2.3.2 Positive Affect

Positive affect (PA) was assessed using identical measures at each weekly survey (referred to as “weekly PA”), as well as at three of the four main assessment points ($Pre$, $FU1$, and $FU2$; referred to as “long-term PA”). Long-term PA was not
assessed at *Post* because weekly PA was assessed using the same items at the sixth weekly survey, which was completed immediately before *Post*. PA was assessed with nine items assessing “low-activation” positive and negative affect, modeled on work by Lyubomirsky and colleagues (2011). Low-activation positive affect items were selected in lieu of the commonly-used Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988) because the PANAS subscales represent a wider range of more highly-activated affective states (e.g., enthusiastic, excited, scared, ashamed), which were not expected to be impacted as strongly by the present gratitude intervention.

For each item, participants were asked to indicate to what extent they experienced each feeling during the preceding seven days on a Likert-type scale ranging from 1 = *Very rarely or never* to 5 = *Very often or always*. Negative affect items (*negative, bad, unpleasant, and sad*) were reverse-coded and averaged with positive affect items (*positive, pleasant, happy, contented, and good*) to calculate an overall mean level of weekly PA. Although negative and positive affect in general have been conceptualized as independent constructs (e.g., Diener, 1984; Diener & Emmons, 1984; Watson et al., 1988), the particular items used in the present study more closely represent opposite ends of a single continuum—e.g., positive is the opposite of negative, pleasant is the opposite of unpleasant, etc.—suggesting that these items may be combined to form a single affect variable. Mean internal consistency of weekly PA across all six weekly surveys was excellent (α = 0.92). Mean internal consistency of long-term PA across *Pre, FU1,* and *FU2* was also excellent (α = 0.92).
2.3.3 Weekly Goal Pursuit

Goal pursuit was calculated as the mean of two items from the weekly surveys:
(1) “During this past week, I spent time doing activities that are meaningful to me;”
and (2) “During this past week, I spent time pursuing goals that are worthwhile and
important to me.” Each item was rated on a 5-point Likert-type scale ranging from 1 =
*Very rarely or never* to 5 = *Very often or always*. Each participant’s weekly goal
pursuit scores were then averaged to calculate a mean level of goal pursuit across the
six-week intervention period. Mean internal consistency of the goal pursuit measure
across all weekly survey was good (α = 0.85).

2.3.4 Fear of Recurrence: Overall FOR and Death Worry

Overall FOR was assessed at *Pre, Post, FU1*, and *FU2*. Overall FOR was
calculated as the mean of the first four items of the Concerns About Recurrence Scale
(CARS; Vickberg, 2003): (1) “How much time do you spend THINKING about the
possibility that your breast cancer could recur?” (2) “How much does the possibility
that your breast cancer could recur UPSET you?” (3) “How often do you WORRY
about the possibility that your breast cancer could recur?” and (4) “How AFRAID are
you that your breast cancer may recur?” Each item was rated on a 6-point Likert-type
scale ranging from 1 = *Not at all* to 6 = *All the time*. Mean internal consistency of
overall FOR across all four main assessment points was excellent (α = 0.95).

Death worry is one facet of FOR that is captured in the “Death” subscale of the
CARS (Vickberg, 2003), assessed at *Pre, Post, FU1*, and *FU2*. Death worry was
calculated as the score of the mean of two items: (1) “I worry that a recurrence of
breast cancer would threaten my life,” and (2) “I worry that a recurrence of breast cancer would cause me to die.” Each item was rated on a 5-point Likert-type scale ranging from 1 = Not at all to 5 = Extremely. Importantly, the items on the death worry subscale have no overlap with the items on the overall FOR scale. Mean internal consistency of death worry across all four main assessment points was excellent (α = 0.92).
Figure 1.

*Study timeline.*

```
Randomization:
* Gratitude (N=34)
* Control (N=33)

Pre  Post  FU1  FU2
1  2  3  4  5  6

Weekly Surveys
* Gratitude letter
* Control task

1 month

3 months
```
Chapter 3

RESULTS

3.1 Data Analytic Approach

Analyses were conducted using Mplus 7 (Muthén & Muthén, 1998-2012). A maximum likelihood-based approach was used to handle missing data, allowing us to make use of all available data from all variables in a model and producing unbiased parameter estimates under the missing-at-random assumption (Enders, 2010). For estimation of the total effect of the intervention, a latent growth curve approach was used to model between-person differences (using treatment group as a predictor) in within-person change (slope) for each hypothesized outcome across the four main intervention assessment points (Pre, Post, FU1, and FU2). Subsequently, the growth curve model was embedded in a larger mediation model (see Figure 2) where goal pursuit as a mediator was regressed on the binary treatment condition indicator (a path) and the latent slope from the growth curve portion of the model was regressed simultaneously on both goal pursuit (b path) and the binary treatment condition indicator (c’ path).

For estimation of mediation effects, latent growth curve mediation modeling with bootstrapping was used. Bootstrapping, a nonparametric method based on repeated resampling with replacement, is recommended to test for statistical
significance of mediated or indirect effects in mediation models, as confidence intervals based on the normal distribution for the mediated effect are known to be biased (Bollen & Stine, 1990; MacKinnon, Fairchild, & Fritz, 2007; Shrout & Bolger, 2002). Per MacKinnon and colleagues (2007): “These mediated effect confidence intervals tend to lie to the left of the true value of the mediated effect for positive mediated effects and to the right for negative mediated effects” (p. 601). Therefore, results for mediation models below are reported as estimated mediated effects and corresponding bootstrapped 95% confidence intervals. A given effect is determined to be statistically significant if zero is not included in the confidence interval.

3.2 Descriptive Statistics and Manipulation Check

Descriptive statistics (including correlations, means, and standard deviations) for the main study variables are presented in Table 1. A manipulation check was performed to determine whether the gratitude intervention produced greater feelings of average weekly gratitude than the control condition during the six-week intervention phase. Results of an independent samples t-test revealed mean gratitude during the intervention period did not differ significantly between the control condition ($M = 4.02, SD = 0.70$) and the gratitude intervention ($M = 4.10, SD = 0.66$) ($t (65) = -0.53, p = .599$).

As noted above, all gratitude letters were coded for effort. For those assigned to the gratitude intervention ($N = 34$), the relationship between effort and reported gratitude was examined. Mean effort exhibited a moderate but nonsignificant positive correlation with mean reported gratitude across the six-week intervention period ($r = \quad$)
Weekly effort was also tested as a time-varying predictor of weekly gratitude, controlling for time. Because of the placement of the letter-writing task at the end of each weekly survey, effort on each week’s letter was explored as a predictor of the following week’s reported gratitude. Results indicated that putting more effort into a given letter was a marginally-significant predictor of increased gratitude at the following week’s survey ($B = 0.10, z = 1.75, p = .080$).

### 3.3 Total Effects of Intervention on FOR Outcomes

#### 3.3.1 Effects of Intervention on Slope of Overall FOR (Hypothesis 1)

Results of a latent growth curve model in which the outcome was the slope of overall FOR across the four main assessment points are presented in Table 2. The model demonstrated excellent fit to the data ($\chi^2(7) = 9.65, p = .21$; CFI = 0.99; RMSEA = 0.075, 90% CI = 0.00, 0.18). A significant but unexpected difference in intercepts was discovered such that those in the gratitude intervention began the study 0.68 units higher on overall FOR, which was measured on a 6-point scale, than those in the control condition ($z = 2.16, p = .030$). Turning to simple slope effects, neither the gratitude intervention ($B = -0.05, z = -1.62, p = .106$) nor the control condition ($B = -0.03, z = -0.89, p = .373$) demonstrated significant changes in overall FOR across the study period (Pre to FU2). Additionally, the difference between these slopes was nonsignificant ($B = -0.02, z = -0.55, p = .582$). Overall, results indicated that condition was unrelated to slope of overall FOR, which remained relatively flat across the study period in both conditions.
3.3.2 Effects of Intervention on Slope of Death Worry (Hypothesis 2)

Results of a latent growth curve model in which the outcome was the slope of death worry across the four main assessment points are presented in Table 3. The model demonstrated excellent fit to the data ($\chi^2(8) = 3.78, p = .877; \text{CFI} = 1.00; \text{RMSEA} = 0.00, 90\% CI = 0.00, 0.07$). As expected, there was no significant difference between intervention and controls participants in death worry at the beginning of the study ($B = 0.55, z = 0.34, p = .104$). Focusing on simple slopes, patients in the gratitude intervention experienced a significant decrease in death worry ($B = -0.10, z = -2.43, p = .015$), while death worry in the control group remained relatively stable across the study period ($B = 0.04, z = 1.14, p = .254$). The difference between these slopes was also significant ($B = -0.141, z = -2.55, p = .011$) and, using the procedure recommended by Feingold (2009), represented a medium-sized effect ($d = -0.45$) based on Cohen’s (1988) guidelines. Overall, results indicated that those in the gratitude intervention (compared to control condition) experienced a significantly greater decrease in death worry across the study period.

3.4 Goal Pursuit as a Mediator of Intervention Effect on Death Worry

Goal pursuit was then examined as a potential mediator of the relationship between condition and death worry slope (Hypothesis 3). We specified a latent growth curve mediation model with death worry slope across the four main assessment points as the main outcome ($Y$), condition as the predictor ($X$) and mean levels of goal pursuit during the intervention period as the mediating variable ($M$). The model demonstrated excellent fit to the data ($\chi^2(11) = 7.11, p = .791; \text{CFI} = 1.00$;
RMSEA = 0.00, 90% CI = 0.00, 0.09). Results are presented in Table 4 (see Figure 2 for an illustration of this model).

With regard to the \( a \) path—the effect of condition on goal pursuit—estimated average level of goal pursuit during the intervention period was 0.36 units higher for those in the gratitude intervention compared to those in the control condition (\( z = 2.55, p = .011 \)) representing a medium-sized effect (\( d = -0.62 \)). For the \( b \) path—the effect of goal pursuit on death worry slope—spending more time pursuing meaningful goals predicted a steeper decline in death worry across the study period (\( B = -0.09, z = -2.10, p = .035 \)) representing a small-to-medium-sized effect (\( d = -0.28 \)). For the \( c' \) path—the direct effect of condition on death worry slope—being in the gratitude intervention predicted a steeper decline in death worry, independent of goal pursuit, across the study period (\( B = -0.11, z = -2.00, p = .045 \)) representing a medium-sized effect (\( d = -0.36 \)). Using the formula \( c = c' + ab \), which indicates that the total effect is equivalent to the direct effect plus the indirect (or mediated) effect (MacKinnon et al., 2007), the model-implied total effect was significant (\( B = -0.14, z = -2.53, p = .012 \)). Finally, the mediated effect, the product of the \( a \) and \( b \) paths, was also statistically significant (\( B = -0.03 \), bootstrapped 95% CI = -0.08, -0.004) indicating that approximately 22% of the intervention’s effect on death worry was mediated by goal pursuit.

3.5 Role of Positive Affect

As noted earlier, Fredrickson’s (1998, 2001) broaden-and-build theory suggests that generally increased PA could result from the present gratitude intervention (Hypothesis 4) despite not being an explicit target of the intervention, and
could even act as an alternative mediator between condition and changes in FOR outcome levels (*Hypothesis 5*). Therefore, the specific role that PA played in this intervention was tested.

First, PA was examined in a latent growth curve model in which the outcome was the slope of long-term PA across *Pre, FU1*, and *FU2*. The model demonstrated excellent fit to the data ($\chi^2(3) = 1.77, p = .622$; CFI = 1.00; RMSEA = 0.00, 90% CI = 0.00, 0.17). Results of this model, presented in Table 5, showed that those in the control condition experienced a significant decline in PA over the course of the study ($B = -0.05, z = -2.10, p = .036$), while PA for those in the intervention group remained stable ($B = 0.04, z = 1.64, p = .101$). The difference between these slopes was also statistically significant ($B = 0.10, z = 2.63, p = .009$). This suggests that, although the gratitude intervention did not predict increases in long-term PA, it appears to have prevented the decline observed in the control condition.

Because differences in long-term PA were observed between conditions, mean weekly PA was also examined as a potential alternative mediator of the observed relationship between condition and death worry, described above, using a latent growth curve mediation model. The model demonstrated excellent fit to the data ($\chi^2(11) = 9.53, p = .573$; CFI = 1.00; RMSEA = 0.00, 90% CI = 0.00, 0.12). Results, displayed in Table 6, revealed that although those in the gratitude intervention continued to experience a greater decline in death worry across the study period ($B = -0.13, z = -2.29, p = .022$), condition did not predict differences in mean weekly PA during the intervention period ($B = 0.11, z = 0.83, p = .408$). Mean weekly PA also
did not predict changes in death worry across the study period ($B = -0.09, z = -1.53, p = .126$). Therefore, weekly PA was not a significant mediator of the intervention’s effect on death worry slope.
Figure 2.

Depiction of model for Hypothesis 3: Effects of condition on slope of death worry from Pre to FU2, mediated by goal pursuit. Effects of interest are bolded.
Table 1.

*Bivariate correlations, reliabilities, means, and standard deviations for main study variables.*

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<td>.70***</td>
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<td>-.34**</td>
<td>-.24†</td>
<td>-.31*</td>
<td>-.21†</td>
<td>-.28*</td>
<td>-.19</td>
<td>-.39**</td>
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Note. †p<.10, *p<.05, **p<.01, ***p<.001. FOR = overall fear of recurrence; DW = death worry; PA = positive affect. Cronbach’s α for each measure is displayed on the diagonal.
Table 2.

*Effects of condition (gratitude intervention vs. control condition) on slope of overall FOR from Pre to FU2 (N=67).*

<table>
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<tr>
<th>Effect</th>
<th>Estimate</th>
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<td>0.22</td>
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Table 3.  

*Effects of condition (gratitude intervention vs. control condition) on slope of death worry from Pre to FU2 (N=67).*

<table>
<thead>
<tr>
<th>Effect</th>
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<tr>
<td>Control Condition</td>
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Table 4.

*Effects of condition (gratitude intervention vs. control condition) on slope of death worry from Pre to FU2 mediated through mean weekly goal pursuit (N=67).*

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Table 5.

*Effects of condition (gratitude intervention vs. control condition) on slope of long-term PA from Pre to FU2 (N=67).*

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Table 6.

*Effects of condition (gratitude intervention vs. control condition) on slope of death worry from Pre to FU2 mediated through mean weekly PA (N=67).*

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<th>p</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA on Condition (<em>a path</em>)</td>
<td>0.11</td>
<td>0.14</td>
<td>.408</td>
<td>-0.15</td>
<td>0.37</td>
</tr>
<tr>
<td>Death Worry Slope on PA (<em>b path</em>)</td>
<td>-0.09</td>
<td>0.06</td>
<td>.126</td>
<td>-0.19</td>
<td>0.03</td>
</tr>
<tr>
<td>Death Worry Slope on Condition (<em>c’ path</em>)</td>
<td>-0.13</td>
<td>0.06</td>
<td>.022</td>
<td>-0.25</td>
<td>-0.02</td>
</tr>
<tr>
<td>Mediated effect</td>
<td>-0.01</td>
<td>--</td>
<td>--</td>
<td>-0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>Total effect</td>
<td>-0.14</td>
<td>0.06</td>
<td>.013</td>
<td>-0.26</td>
<td>-0.03</td>
</tr>
<tr>
<td>Proportion mediated effect</td>
<td>0.07</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

95% CI
Chapter 4

DISCUSSION

Fear of recurrence is consistently among the top concerns endorsed by cancer survivors (Allen et al., 2009; Baker et al., 2005; Mehnert et al., 2009; Simard et al., 2010; Vickberg, 2003) and has been associated with numerous negative outcomes, including increased psychological distress and decreased quality of life (e.g., Deimling et al., 2006; Mehnert et al., 2009). Simard et al. (2013) wrote of the need for more research to support the development and evaluation of interventions to reduce FOR, yet there has been very little empirical work in this area, despite the prevalence of FOR. The present study aimed to help fill this gap in the literature.

Specifically, the effects of a six-week online gratitude intervention on overall FOR and death worry were examined in a sample of early-stage breast cancer survivors. It was hypothesized that the gratitude intervention would produce a greater decrease in both overall FOR (Hypothesis 1) and death worry (Hypothesis 2) over the course of the study compared to a control condition. Moreover, it was expected that the effects of the gratitude intervention on overall FOR and death worry would be mediated by goal pursuit, such that the gratitude intervention would promote increased goal pursuit during the intervention period, leading to reductions in death worry (Hypothesis 3). The potential role of positive affect, both as an outcome of the
intervention (*Hypothesis 4*) and as an alternate mediator between the intervention and death worry (*Hypothesis 5*), was also tested.

Results indicated that Hypothesis 1 was not supported: condition did not predict the slope of overall FOR, which remained relatively flat across the study period in both the gratitude intervention and the control condition. It was found, however, that those assigned to the gratitude intervention reported significantly higher levels of overall FOR at the beginning of the study than those in the control condition. This difference likely represents a failure of random assignment, which may have been due to the use of a relatively small sample size (Strube, 1991).

Results demonstrated support for Hypothesis 2 as condition significantly predicted the slope of death worry. Those in the gratitude intervention experienced a significant decrease in death worry, whereas those in the control condition saw no change in death worry across the study period. Results also supported Hypothesis 3: goal pursuit mediated the effect of condition on death worry slope, such that those in the gratitude intervention reported higher levels of goal pursuit during the six-week intervention and subsequently showed a steeper decrease in death worry across the study period, compared to those in the control condition. As there was significant mediation, yet the $c'$ coefficient remained statistically significant, the relationship between condition and death worry slope was not entirely accounted for by goal pursuit (James, Mulaik, & Brett, 2006; MacKinnon, Fairchild, & Fritz, 2007); approximately 22% of the total effect of condition on death worry was mediated by
goal pursuit. Thus, there is evidence that goal pursuit partially mediated the effect of condition on slope of death worry.

Contrary to Hypothesis 4, those in the gratitude intervention did not experience increases in long-term PA across the study period, although the intervention appeared to have prevented a significant decline in PA that was seen among those in the control condition. However, Hypothesis 5 was not supported: PA was not found to be a significant mediator of the observed relationship between condition and slope of death worry across the study period.

These findings are largely in line with Fredrickson’s (1998, 2001) broaden-and-build theory of positive emotions where gratitude is theorized to broaden cognition, promoting focus on future achievements, and expand behavioral repertoires to include pursuit of meaningful goals Fredrickson (2004). This increased engagement in goal pursuit then promotes death acceptance and attenuates death worry by promoting a sense of meaning on one’s life (Wong, 2008; Wong & Tomer, 2011). The broaden-and-build theory (Fredrickson, 1998, 2001) also posits that there is an “undoing” effect of positive emotions (Frederickson et al., 2000), which may help explain direct effects of gratitude on death worry.

4.1 Gratitude Manipulation

Interestingly, despite the fact that the intervention produced some of the hypothesized effects on FOR, results of a manipulation check suggest that the letter-writing task did not actually increase reported feelings of gratitude during the intervention. There are several plausible explanations for this somewhat surprising
finding. One possibility is that there was a dose-response effect of the intervention, and spending only 10 minutes once per week writing letters of gratitude was not sufficient to yield observable differences in reported feelings of gratitude in this sample; however, other research has made use of similarly brief gratitude-elicitation tasks (e.g., Emmons & McCullough, 2003; Lyubomirsky et al., 2011; Lyubomirsky et al., 2005; Seligman et al., 2005) that have produced lasting improvements in well-being. For example, writing and delivering a single letter of gratitude was found to boost happiness and reduce depressive symptoms up to a month later (Seligman et al., 2005). Few studies which have implemented similar interventions designed to elicit gratitude have actually verified that the intervention increased feelings of gratitude; even when gratitude is directly tested as an outcome, it is often tested very soon after the intervention is administered (e.g., Froh, Sefick, & Emmons, 2008).

It is also plausible that there was a ceiling effect; the women in the present study reported very high levels of gratitude even before beginning the intervention, leaving little room for improvement on this construct; at the first weekly survey, mean gratitude was 4.14 ($SD = 0.79$) on a 1-to-5 scale (reported before completing the first intervention task). Another likely explanation is that the placement of the intervention at the end of each weekly survey contributed to the apparent lack of an effect of the intervention on feelings of gratitude. That is, participants reported on their levels of gratitude before completing the intervention task; thus, any effects of the intervention on gratitude would need to last a full week in order to be detected on the next weekly survey.
Although it failed to measurably increase reported gratitude, the intervention still produced effects on goal pursuit and death worry. The core idea behind Fredrickson’s (1998; 2001) broaden-and-build theory is that positive emotions are short-lived, but can have broad, long-term consequences. As Fredrickson (2004) summarized, “the lasting benefits of people's fleeting experiences of gratitude and other positive emotions—benefits [range] from personal and social development, to individual health and well-being, and community strength and harmony” (p. 145). Therefore, it seems probable that the intervention did increase gratitude, which produced longer-lasting effects in the form of increased goal pursuit and decreased death worry; however, these feelings of gratitude were simply too fleeting to be captured using once-weekly surveys.

4.2 Limitations and Future Directions

Importantly, because of the use of random assignment to either the gratitude intervention or control condition, the intervention can be construed as causally linked to goal pursuit and changes in death worry and positive affect. Nevertheless, the effect of goal pursuit on changes in death worry was not experimentally manipulated and is open to the threat of confounding. Although feelings of gratitude did not measurably increase due to the intervention, it is noteworthy that improvements in goal pursuit and death worry were observed, as the participants were already functioning very well in many areas at the beginning of the study; at the Pre assessment, participants reported low levels of anxiety, depression, and physical symptoms, and high levels of flourishing, optimism, life satisfaction, and subjective
happiness. However, this level of well-being is not necessarily representative of all early-stage breast cancer survivors, and certainly not all cancer survivors in general, even more than four years after diagnosis and surgery. As noted earlier, women in the present study had previously participated in intensive longitudinal research involving women with breast cancer and their romantic partners. It is plausible that cancer survivors who consent to participate in two relatively demanding studies are not representative of the broader population of cancer survivors. Future research should examine these processes among those with different tumor sites and especially among male cancer survivors, as the present study included only female participants. It will also be beneficial to determine if similar gratitude interventions could be used to lessen death anxiety among patients with more advanced or metastatic cancer, in whom the possibility of dying from cancer would likely be much more salient.

Use of a more intensive longitudinal methodology may also prove useful to improve understanding of these processes on a smaller time scale; if the intervention increases gratitude, but these effects do not last a full week, daily assessments would be better suited to capture these changes. Szczesny (2014) found that intimacy mediated the effects of gratitude on FOR in a dyadic context; however, the present study did not include participants’ romantic partners. Future research should explore whether the intervention could produce similar effects in partners of cancer survivors, who often endorse similar or even greater levels of FOR as the patients themselves (Hodges & Humphris, 2009; Mellon et al., 2007). Lastly, results indicated that goal pursuit partially mediated the effect of condition on death worry slope across the study.
period. Because the direct effect remained sizeable and statistically significant, more work is needed to fully understand the mechanisms of the gratitude intervention effect.

4.3 Conclusion

Overall, our findings indicate that a brief, online gratitude intervention can help reduce fears that a recurrence of cancer could cause one’s death, one of the most prevalent and intense aspects of fear of recurrence (e.g., Mahon & Casperson 1997; van den Beuken-van Everdingen et al., 2008; Vickberg, 2003). There was evidence that the benefits of the intervention were induced, in part, by increasing engagement in meaningful goal pursuit. In addition to reducing death worry, as observed in the present study, goal pursuit has been linked with a variety of other aspects of well-being (Lyubomirsky et al., 2005; Sheldon, et al., 2002; Stein et al., 1997) and contributes to a sense of meaning and purpose in one’s life (Emmons, 2003). Overall, the present study provides some support for the notion that feeling grateful can help promote adaptation to the cancer experience, even years after diagnosis and surgery.
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Appendix

HUMAN SUBJECTS REVIEW BOARD APPROVAL LETTER

DATE: August 24, 2011

TO: Jean Philippe Laurenceau
FROM: University of Delaware IRB

STUDY TITLE: [174027-3] Couples Coping with Cancer

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

APPROVAL DATE: August 24, 2011

EXPIRATION DATE: September 10, 2012

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # 7

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design whereby the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.
If you have any questions please contact Jody-Lynn Berg at (302) 831-1119 or jberg@udel.edu. Please include your study title and reference number in all correspondence with this office.