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Evaluation of the Clinical Efficacy of Emotionally Focused Couples Therapy on Psychological Adjustment and Natural Killer Cell Cytotoxicity in Early Breast Cancer

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A thesis submitted to the School of Graduate Studies of the University of Ottawa in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Clinical Psychology

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DEDICATION

I wish to dedicate this dissertation to my family, Chahir, Seham, Suzie and Sarah Naaman for believing in me, and to the loving memory of my late grandmother Margo Cassis, who ignited my passion for psychology and medicine.

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As I write my acknowledgements, I realize that I have reached the end of an important phase of my academic training. Despite the sense of accomplishment and pride after five years of hard work, I am also overcome by a sense of emptiness that this has all come to an end. This feeling is attenuated when I remember all the wonderful people who helped me through this exciting, though at times very difficult, journey. First, I wish to express my gratitude to my advisor and mentor, Dr. Susan Johnson, who gave me endless emotional support and confidence to take risks and explore a foreign territory. Her energy and limitless drive have been a strong driving force during my graduate training. I am grateful for the invaluable guidance and constructive feedback of my committee members; Dr. Tim Aubry and Dr. Marta Young, who helped me throughout the process.

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ABSTRACT

Breast cancer has changed in recent years from a terminal condition to a chronic disease, which can significantly impact a couple's relationship and overall adjustment. The first objective was to survey the shared and reciprocally determined adjustment processes which unfold within couples who face breast cancer. Attachment theory was then used as the grounding framework to both understand interpersonal dynamics and to provide a rationale for offering empirically-supported Emotionally Focused Therapy (EFT) to couples experiencing unremitting psychological and relational distress following diagnosis and treatment for breast cancer.

The second objective involved evaluating the clinical efficacy of EFT on couples' psychological adjustment and patients' Natural Killer Cell Cytotoxicity (NKCC) – an important immune parameter implicated in control of metastatic disease. Twelve couples were randomized to receive either twenty sessions of EFT or Psycho-education (PE). A multiple baseline experimental design across couples was used.

Results indicated that, compared to couples randomized to PE, those who received EFT evidenced more variation on outcome variables following EFT. Specifically, more than 50% of couples who received EFT evidenced clinically significant improvement in dyadic adjustment, and quality of life, as well as attenuation in mood disturbance and trauma symptoms. Women randomized to EFT evidenced more variation in response to treatment, with half of the sample experiencing small, but clinically irrelevant up regulation, in NKCC, while the other half showed clinically significant down-regulation in NKCC. Women receiving PE showed no changes in NKCC. More importantly, shifts in NKCC were in keeping with trajectories in dyadic adjustment and clinical events unfolding during the course of treatment.

Findings provided initial support for offering EFT to couples experiencing emotional and relational following diagnosis and treatment of early breast cancer. Changes observed in NKCC, though in keeping with established relationships with psychological distress, were more tentative in nature.

INTRODUCTION

Breast disease is the most common malignancy affecting females worldwide, currently touching the lives of one out of every nine Canadian women (Canadian Cancer Statistics, 2007). Early screening technologies and medical interventions have changed one of the most salient defining features of the disease; that is from a terminal condition to one of a chronic nature with biopsychosocial implications (Sherman & Hossfeld, 1990). Longer survival has, in turn, prompted women to contend with multiple challenges for which they may have not been ready; having being diagnosed with a potentially life threatening illness, side effects of cytotoxic treatments, possibility of recurrence and an uncertain future. Upwards of 40% of breast cancer survivors have been documented to suffer from various forms of psychological morbidity, including depression, anxiety, anger and symptoms of post traumatic stress (Amir and Ramati, 2002; Derogatis, et al., 1983; Kissane et al., 2004).

Elongation of the post-acute adjustment phase, extending at times to years following completion of medical treatments has prompted researchers to examine a women's psychosocial environment and its impact on adjustment. The inextricable involvement of a woman's significant other during this particularly intense time has received increasing recognition from several researchers (e.g. Baider & Kaplan de Nour, 1988 & Northouse, 1993). Specifically, the reciprocal impact of disease variables on interpersonal processes within the marital context has been well articulated conferring a better understanding of the risk factors associated with greater psychological morbidity for both partners within a dyadic unit. Negatively charged interpersonal processes, for example, have been shown to adversely impact mental and physical health (Salovey et al, 2000), including aspects of immune function of relevance of breast cancer (Brittenden et al., 1996; Uchino et al., 1996). In contrast, a secure marital relationship, marked by emotional support and engagement, has been linked lower emotional distress, fewer

depressive symptoms (Roberts 1994, Tatelman, 1999) and better role adjustment (Northouse, 1995).

The goal of the present research was to evaluate the clinical efficacy of a structured couples-based intervention, Emotionally Focused Therapy (EFT), on the psychological adjustment of couples who have faced early breast cancer. In addition, a preliminary investigation of the impact of EFT on natural killer cell cytoxicity (NKCC) in survivors was undertaken. NKCC is one aspect of the innate immune system, strongly implicated in both the development and course of neoplastic disease (Brittenden et al., 1996).

Grounded in attachment theory, EFT conceptualizes distressed relationships in terms of insecure bonds, where attachment needs for physical or emotional closeness, comfort, and security, particularly during crisis, are not being met (Johnson, 1996). The overarching goal of EFT, therefore, is to promote secure bonding between partners, which, in turn, facilitates emotional connection, optimal adjustment and resilience in the face of adversity. The present research extends past research by offering a theoretically-informed treatment approach which takes advantage of the marital context in helping both partners mobilize their internal resources towards the creation of more secure connections. Secure connections confer a better ability to self-regulate, and are associated with emotional and physical health and well-being (Burman and Margolin, 1992, Schmaling & Sher, 2000).

The current research is presented in a series of three articles. The first manuscript surveys the literature pertinent to couples' adjustment processes in the context of early breast cancer and provides a theoretical rationale for the study. The second manuscript reports the clinical findings with respect to the efficacy of EFT on survivors' and couples' psychological adjustment. The third manuscript reviews the

scientific background supporting NKCC's role in neoplasia, and reports findings with respect to the impact of EFT on survivors' NKCC function.

MANUSCRIPT 1: COPING WITH EARLY BREAST CANCER: COUPLE ADJUSTMENT PROCESSES AND COUPLE-BASED INTERVENTION

ABSTRACT

Early breast cancer affects one in every nine women along with their families. Advances in screening and biomedical interventions have changed the face of breast cancer from a terminal condition to a chronic disease with biopsychosocial features. The present review surveyed the nature and extent of psychological morbidity experienced by the breast cancer survivor and her spouse during the post-treatment phase, with particular focus on the impact of disease on the marital relationship. Interpersonal processes shown to unfold in couples facing breast cancer couples, as well as risk factors associated with greater psychological morbidity, were reviewed. Moreover, interpersonal processes central to coping with chronic illness and adjustment were reconceptualized from the point of view of attachment theory. Attachment theory was also used as the grounding framework for an empirically supported couples-based intervention, Emotionally Focused Therapy, which is advanced as a potentially useful treatment option for couples experiencing unremitting psychological and relational distress following diagnosis and treatment for breast cancer.

INTRODUCTION

Breast cancer has become an important public health concern both in Canada and worldwide. Currently the most prevalent female malignancy across all age groups, breast carcinoma accounts for 30% of all new cancers. Within the Canadian population, 22, 300 new cases of breast cancer are diagnosed annually, of which 5300 lives are claimed (Canadian Cancer Statistics, 2007).

Trend analyses over a thirty year period from 1969 to 1999 reveal a cumulative incidence increase of 30%, which appears to have stabilized (National Cancer institute of Canada, 2007). At present one in nine Canadian women will be diagnosed with breast cancer during their life time (National Cancer Institute of Canada, 2007). Notwithstanding the steady rise in incidence, breast cancer mortality rates have dropped from 33.1 per 100, 000 women in 1990 to 23 per 100, 000 in 2007 (Canadian Cancer Statistics, 2007). The considerable gap between incidence rates and mortality is largely due to a combination of factors; enhanced risk awareness in the general population, participation in screening programs, improved detection technologies and development of more effective systemic treatments. Today, 162, 600 Canadian women have survived invasive breast cancer diagnosed at some point within the last 15 years (National Cancer Institute of Canada, 2007).

Increased survivorship has essentially transformed the disease from what was formerly accepted as a terminal condition to one of chronicity (Sherman & Hossfeld, 1990) with biopsychosocial sequelae (Engel, 1977; Cassileth, 1979). Since patients are now living longer, they are faced with multiple challenges beyond the acute phase of medical treatment. These include reckoning with having been diagnosed with a potentially life threatening illness, long term effects of toxic treatments, the possibility of recurrence even after many years of apparently successful treatment, career interruptions, and financial strain. Adequate resolution of these concerns, however,

cannot be removed from a pre-existing family context, which affects and is affected by disease and treatment variables. The pivotal role of the marital relationship has been receiving gradual recognition by researchers within the psychosocial oncology literature. Northouse (1993), for example, redefines breast cancer as a "biopsychosocial problem that occurs in the context of an intense personal relationship that affects, and is affected by, the disease process in circular reciprocity." Baider & Kaplan-De Nour (1988), similarly, describe cancer as a 'family affair'.

The aims of this article are to (i) review the nature and significance of psychological morbidity experienced by the breast cancer survivor and her spouse along the illness trajectory, with particular emphasis on the post-treatment phase, (ii) discuss the impact of breast cancer on the marital relationship, (iii) review empirically established interpersonal processes shown to unfold in couples facing breast cancer couples, as well as identify risk factors associated with greater psychological morbidity. Interpersonal processes central to coping with chronic illness and adjustment are then reconceptualized from the point of view of attachment theory. Attachment theory also provides the grounding framework for an empirically supported couples-based intervention, Emotionally Focused Therapy, which is presented as a potentially useful treatment option for couples experiencing unremitting psychological and relational distress following diagnosis and treatment for breast cancer.

Adjustment to Breast Cancer along the Illness Trajectory

Adjustment or psychosocial adaptation to cancer has been defined as an ongoing process in which the individual attempts to manage emotional distress, solve specific cancer-related problems, and gain mastery and control over cancer-related life events (Brennan, 2001, Folkman et al., 2000, Kornblith, 1998, Nicholas et al., 2000). The adjustment process, therefore, is not a single unitary concept, but rather a series of ongoing coping responses to multiple tasks associated with living with breast cancer. It

is important to distinguish between normal adaptive responses versus problematic coping in patients with breast cancer, in order to intervene appropriately. Assessment of the appropriateness of an emotional response requires taking into account several factors, including the disease stage and where the patient falls in the cancer continuum from pre-diagnosis, confirmed diagnosis, treatment, remission and recurrence (Simonton & Sherman, 1998). Such disease-related variables, while relevant, will invariably interact with a patient's inner resources, as well as those of her partner's to produce a distinct emotional response, which will vary in its adaptiveness.

Holland & Lewis (2000) describe the 'normal' or expected responses to receiving a life threatening illness, such as cancer, as consisting of three major phases; *initial response, dysphoria* and *longer term adaptation.* Initial reactions can be intense and typically involve feelings of shock, disbelief, and often denial of medical findings. Patients are often unable to clearly process or remember any information, as a result of the emotional upheaval. Once the new 'reality' is acknowledged, feelings of depression, anxiety, insomnia, anorexia, and poor concentration typically soar (Epping-Jordon et al., 1999, Jamison, Wellisch, Pasnau, 1978). With more information regarding treatment options and adequate social support, intrusive thoughts about the illness and the possibility of death gradually subside and are replaced with some feelings of hope, especially as patients may be quickly started on active treatments (e.g. chemotherapy), or scheduled for surgery. Longer term adaptation is marked by the emergence of more lasting and permanent coping styles. During the post treatment phase, adjustment typically involves utilization of a variety of coping strategies, the most useful of which has been shown to be emotionally expressive coping (Stanton et al., 2000; Stanton, Danoff-Burg, Cameron, & Ellis, 1994; Stanton, Kirk, Cameron, & Danoff-Burg, 2000). Emotionally expressive coping is defined as strategies involving active processing and expression of negative emotional reactions to stressors. By one year following diagnosis

adjustment levels tend to plateau (Northouse, 2001), with minimal spontaneous change or improvement, thereafter.

Psychological Morbidity associated with Breast Cancer

Research generally converges on the finding that a cancer diagnosis generates greater distress levels compared to any other disease (Shapiro et al., 2001). While it is true that most women manage to survive the threat of diagnosis and the invasive treatments associated with breast carcinoma (Baker, Marcellus, Zabora, Polland, Jodrey, 1997; Anderson et al., 1994), approximately one third continue to experience unremitting psychological, relational, as well as health related distress during the first two years following treatment (Dean, 1987; Morris, Greer, & White, 1977; Shields, 2000). Depression appears to be the most prevalent psychological issue in breast cancer survivors (Lansky et al., 1985) followed by anxiety (Derogatis et al., 1983).

Studies, primarily assessing patients within the first year of diagnosis, have reported rates of up to 42% experiencing psychiatric and/or psychological disturbance, in the form of depression, anxiety or both, which, in turn, compromised quality of life (Derogatis, et al., 1983; Hughes, 1982, Dean, 1987, Surtees, 1980, van't Spijker, Trijsurg, Duivenvoorden, 1997, Kissane et al., 2004). Within this proportion of psychologically distressed patients, an anxiety disorder and major depression were diagnosable in 8.6% and 9.6% of sampled patients, respectively. Similar findings have been reported in other studies (Maguire et al., 1985; Spiegel, 1996).

Life threatening illness and its highly stressful medical procedures have also been associated with the development of post-traumatic stress disorder (PTSD) or PTSD-like symptoms in some women (e.g. Doerfler, Pbert, & DeCosimo, 1994). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR, 2000, pg 464), "being diagnosed with a life-threatening illness constitutes a traumatic event". The limited number of existing studies has reported cancer-related PTSD

prevalence rates in the range of 5-10% (Alter et al., 1996; Cordova et al., 1995) that persisted up to one year post surgery in a sub-set of patients (Tjemsland et al. 1998). Indeed only a minority of breast cancer survivors do actually develop PTSD symptoms of sufficient magnitude to meet diagnostic criteria, Amir and Ramati (2002) point out that most patients develop partial or sub-syndromal levels of PTSD, which while not meeting established clinical criteria to warrant a clinical diagnosis, result in impaired quality of life that merits clinical attention, nonetheless.

Aside from severe psychiatric disturbance, which is not as common among breast cancer survivors as once thought (Bloom et al., 1987, Gordon et al, 1980, Glanz & Lerman, 1992, Moyer & Salovey, 1996), women do report having to confront significant psychosocial concerns and emotional sequelae that may be equally distressing particularly close to or at completion of medical treatment and thereafter. For example, the most potent concern for patients with early stage breast disease is fear of recurrence and uncertainty regarding the future (Gotay, 1984, Fertig, 1997, Spencer et al, 1999). In fact 30% of women describe the time of chemotherapy completion as distressing (Ward, Viergutz,, Tormey, 1992) due to loss of frequent and reassuring doctor visits and no longer being in active treatment, both of which seem to be associated with a sense of safety. Other highly rated concerns include long term effects of adjuvant treatments (e.g. fertility, feeling less feminine), financial strain and "not being able to live out important relationships and having life with a partner cut short" (Spencer et al., 1999). Body image was moderately problematic, particularly for younger women, who also experienced stronger sexual and partner-related complications in relation to older women (Spencer, Lehman, Wynings, Arena, Csarver, Antini, Derhagpian, Ironson, Love, 1999).

While the nature and degree of psychological disturbance potentially triggered by the breast cancer experience can be far reaching for the patient, the illness does

represent a health concern that ultimately impacts spouses and children too. The salience of a woman's spousal relationship in particular during a potentially life threatening illness has received increasing recognition from several researchers in the field, who contend that breast cancer is best understood as a "family problem", that affects spouses as much as patients (Northouse, 1993, Lasry et al., 2003, Baider, 1988).

Impact of Breast Cancer on the Marital Relationship

Following diagnosis of a life threatening illness, patients often cite their spouses as their primary sources of support (Lasry et al, 2003). The illness experience and associated treatment regimens are potent enough, however, to provoke various forms of emotional disturbance in patients' partners, including anxiety, depression, and fear of recurrence and losing one's partner to death (Iqbal et al., 2001). As many as 29% of sampled couples who had been receiving cancer treatment report clinically significant levels of emotional distress (Rodrigue & Hoffman, 1994).

Incidentally, there is evidence for concordance between the levels of emotional distress experienced by patients and their partners (Baider & Kaplan De-Nour, 1988, Northouse et al., 1995). Studies addressing the couple unit in particular found that, in the face of a cancer diagnosis, spouses either experienced similar levels of distress as their affected partners or even more (Ferrel, Ervin, Smith, Marek, & Melancon, 2002; Northouse, Mood, Templin, Mellon & George, 2000, Omne-Ponten, Holmberg, Bergstrom, Sjoden, & Burns, 1993). Northouse & Swain (1987), for example, observed that both patients and their spouses reported corresponding initial levels of distress that tended to improve slightly one month after surgery. In another follow-up study tracking couples 18 months post-surgery, Northouse (1989) observed that, again despite a decrease in distress scores over time, both patients and their partners reported similar levels of psychological distress. More importantly from a coping perspective, Northouse

et al., (2001) found that husbands' and wives' levels of adjustment to breast cancer, at 1 year post diagnosis, had a significant and direct effect on each other's adjustment.

Difficulties in psychosocial adjustment are not solely confined to the early phase of illness but may persist over time for both patients and husbands in a consistent fashion (Walker, 1997). Dyadic adjustment problems and elevated emotional distress occurring well into the post-treatment phase have been reported in several studies (Oberst, Scott, 1988; Hagedoorn, Bruunk, Kuijer, Wobbes, Sanderman, 2000; Ell, Nishimto, Mantell, 1988, Northouse, Mood, Templin, Mellon, George, 2000, Baider, Kaplan De-Noor, 1988). Goldberg et al., (1984), for example, found that for some couples depression tended to worsen over time for both partners. In a longitudinal study of 143 newly diagnosed breast cancer patients, undertaken by Keitel et al. (1990), found that spouses' distress levels tended to decline over time and that those who continued to experience adjustment difficulties were more likely to be married to patients with relatively higher levels of physical symptoms. In another study by Omne-Ponte et al. (1993), comparing the levels of adjustment among husbands of patients who had undergone either breast conserving surgery or mastectomy, 48% were found to experience continued emotional distress up to 13 months post-surgical treatment. This rate was similar to that reported in patients themselves, adding validity to the reciprocal effect coupled partners have on each other found in previous studies.

Taken together, studies appear to converge on the following patterns; dyads report similar levels of distress suggesting some degree of congruence in their adjustment processes; distress in couples appears to decline over time, and for a sizeable proportion of couples there continues to be elevated levels of unremitting distress even after the immediate shock and crisis of diagnosis and treatment have elapsed (Wellisch et al., 1978; Baider et al., 1984; Sabo et al., 1986; Zahlis et al., 1993). While the rates of dissatisfaction and divorce in couples facing breast cancer are not any

higher than in couples in the general population, there is evidence of more strain and conflict (Carter, Carter, & Silliunus, 1993, Northouse, Templin, Mood, & Oberst, 1998, Wai Ming, 2002). Not surprisingly, couples who were at high risk for marital breakdown were those who faced the breast cancer experience with pre-existing marital problems, where the illness had added further demands and strain on their relationship (Carter, Carter, & Siliunus, 1993, Lewis, Hammond, 1992, Lichtman, Taylor, Wood, 1987, Morris, Greer, White, 1987, Northouse, 1989).

Interpersonal Processes in Couples Facing Breast Cancer: Empirical Findings

The emotional support provided by an intimate partner can have a profound buffering effect on the stress levels experienced by the breast cancer patient as she contends with both the psychological and physiological sequelae of her illness (Krant & Johnson, 1978; Lewis & Deal, 1995; Northouse, 1984). Emotional support is conceptualized in the literature as communication of care, concern, empathy, comfort, and reassurance both verbally and nonverbally, such as through facial expressions and gestures (Helgeson & Cohen, 1996; House, 1981). Specifically, provision of emotional support by husbands has been linked to lower emotional distress, fewer depressive symptoms (Roberts 1994, Tatelman, 1999) and better role adjustment in their wives who were experiencing breast cancer (Northouse, 1995). In fact, emotional support, as opposed to informational or instrumental support (i.e. problem-solving), emerged as the most preferred type of support cited by women facing breast cancer, particularly if they experience greater impairment from their illness and treatment course (Manne, Alfieri, Taylor, & Dougherty, 1990a, ref). This is consistent with a study by Pistrang & Barker (1995) who observed that increasing feelings of vulnerability in the breast cancer patient were assuaged by intimate exchanges that were characterized by high empathy and low withdrawal from the spouse.

A woman's intimate relationship seems to provide a unique type of support that if absent or experienced aversively in this particularly stressful period will predictably lead to a greater likelihood of mood disturbance, according to a number of studies (Burg & Seeman, 1994; Carter & Carter, 1994; Koerner, Prince, & Jacobson, 1994; Paykel, 1979, Prince & Jacobson, 1995). Facing breast cancer and its associated stressors, however, can unwittingly propel couples to interact with each other in unsupportive ways, as each spouse attempts to cope and regulate perceived partner distress (Gurowka & Lightman, 1995, Lyons, Sullivan, Ritvo & Coyne, 1995). Spousal interactional patterns in the context of early breast cancer and their association with overall adjustment has been examined by a number of researchers yielding three general patterns observed in relationships; open engagement, mutual avoidance (also known as protective buffering), and pursue-withdraw (Manne, Ostroff, Norton, Fox, Goldstein, 2006, Northouse et al., 1995, Zunckel, 2002).

Couples who openly engaged were characterized by a high degree of emotional expressivity. The ability of couples to openly engage in communication of their feelings about the illness has been linked to positive adjustment, enhanced cohesiveness and decreased destructive conflict (e.g. Northouse, 1984; Spiegel et al., 1983; Vess, Moreland, Schwebel, 1985). Although these studies studied primarily women with metastatic breast cancer, others have led to complimentary findings (e.g. Stanton et al., 2000). Specifically, in a study of 92 women diagnosed with Stage 1 and 2 breast carcinoma, those found to cope using emotional expression around their diagnosis had fewer cancer-related morbidities, decreased distress and enhanced health and vigor three months post-assessment. (Stanton et al., 2000).

The second pattern, mutual avoidance, was examined in one study addressing coping processes of couples facing breast cancer where some partners, in an effort not to upset each other, withheld sharing their feelings of distress and worries (Northouse et

al., 1995), which, in turn, undermined adjustment in both partners. In a longitudinal study, Manne, Dougherty, Veach & Kless (1999) observed a similar pattern of "protective buffering" (p.235), which was associated with higher distress in wives three months later. The phenomena of protective buffering practiced by some couples was compared to open communication and active engagement in a study by Hagedoorn, Kuijer, Buunk, DeJong, Wobbes, Sanderman (2000). Predictably, the latter pattern of communication predicted higher marital satisfaction and better adjustment in the face of illness. Similarly, breast cancer survivors who confided in their partners during times of crises enjoyed better prognoses, as measured by survival (Weihs, Enright, & Simmens, 2002). These findings are particularly relevant in view of the positive relationship between quality of the marital relationship and adjustment responses in both partners (Rodrigue & Park, 1996), as well as disease recovery in patients (Burman & Margolin, 1992).

Other studies have also examined the impact of unilateral avoidance, specifically husbands' avoidance in reaction to their partners' illness, where wives desired more closeness. Sabo et al., (1986), for example, found that while their wives were undergoing mastectomies, some men tended to adopt a "protector's role" while simultaneously avoiding any open expression of feeling. Such stereotypic male behavior was experienced aversively by their spouses, in addition to being perceived as insensitive and rejecting. Avoidance of open discussion about the cancer experience and its association with greater distress is a recurring finding in the cancer literature (Spiegel, Bloom, & Gottheil, 1983; Vess, Moreland, Schwebel, & Kraut, 1988). This also parallels findings from the non-cancer literature linking husbands' withdrawal behaviour to aversive states of emotion in their respective wives (Christensen & Heavey, 1990; Christensen & Malmuth, 1995; Christensen & Shenk, 1991; Gottman, 1993; Gottman, 1994; Gottman & Levenson, 1992; Noller & Feeney, Bonnell, & Callan, 1994).

Husband's avoidance is arguably the most deleterious interactional pattern to marital functioning and adjustment. In the face of crisis, patterns of relating to one another become particularly intensified. Avoiding discussion of the cancer has been shown to lead to communication problems, even among those couples who initially reported high levels of marital satisfaction (Lichtman et al., 1987). For other couples, long standing negative patterns of communication escalate during the illness trajectory directly impacting the extent of destructive conflict and strain each partner experiences (Cohen & Wellisch 1978; Vess et al., 1985).

The third interactional pattern observed in some couples facing breast cancer, initially noted by Manne et al. (1997) entails a cycle of criticality and withdrawal from the wife and husband, respectively. Where emotional support and open engagement were unavailable, some breast cancer survivors tended to engage in criticism which was favourably experienced by as a sign of engagement (Pistrang & Barker, 1995). In such transactions, the distress associated with dispensing marital criticism is conjectured to be more tolerable than complete withdrawal on the husband's part. Unfortunately, the pursuing wife's behaviour propels further distancing and withdrawal from her husband, leading to lower marital satisfaction (Manne et al., 1997).

Examination of withdrawing or distancing behavior of some husbands in reaction their wives' illness has been examined by some studies. Specifically, some partners often report feeling burnt out secondary to chronic exposure to their wives' negative affective responses (Revenson, 1994; Wellisch, 1985) and also experience as complaints their wives disclosures about their emotional and physical reactions to their illness (Revenson, 1994). Since husbands, as previously mentioned, respond to their wives' diagnoses with their own increased mood disturbance (Baider, Perez, & Kaplan de-Nour, 1988; Carter & Carter, 1994), withdrawal from engagement is argued to be one form of affect regulation, albeit a maladaptive one. Withdrawal, as previously mentioned,

is related to an enhanced risk for mood disturbance in the ill spouse. (Grandstaff,1976; Primomo et al., 1990).

In summary, unsupportive patterns of relating predictably lead to greater marital distress, especially in the context of a life threatening illness, which can further exacerbate depressive symptoms in women (Bloom, 1982; Ptacek, Ptacek & Dodge, 1994). The distress experienced in the context of marital strife can, moreover, undermine one's ability to cope with an imminent stressor and also limit one's ability to obtain support in other relationships (Coyne, 1986). In fact, the spousal relationship has been found to be of significant emotional potency such that if troubled ensuing distress cannot be simply overcome by additional social support (Pistrang & Barker, 1995). Taken together, empirical studies examining interpersonal processes in the context of a potentially life threatening illness converge on the centrality of the marital relationship in mediating coping and overall adjustment of both partners.

While many couples clearly possess the emotional resources required to weather the crisis of a cancer diagnosis and its psychosocial implications, there is evidently variation in the manner in which couples effectively cope with this difficult experience. Understanding normative processes as well as individual variation in emotional regulation, coping and adjustment is important in relation to being able to identify couples at risk for developing unremitting distress and adjustment difficulties, in addition to offering suitable remediation. Clinical intervention, however, requires a theoretically informed framework to guide clinicians in working with such couples and the multitude of issues they face. Attachment theory arguably provides the most cohesive and well-articulated framework, which unifies both intrapersonal and interpersonal processes that emerge in the face challenge. Adult attachment theory provides the theoretical anchor for Emotionally Focused Therapy, a couples-based intervention offered to couples experiencing adjustment difficulties following breast cancer illness.

Attachment theory

Attachment theory is primarily concerned with the salience of interpersonal relationships, which serve to maintain adaptation (Bowlby, 1973, 1988). Bowlby argued that humans are endowed with a biological propensity to seek and maintain proximity to attachment figures. These close relational ties serve to buffer anxiety as well as offer physical protection, particularly during times of stress (Bowlby, 1982, 1969, 1973). Within the attachment system, Bowlby outlined several universal aspects. Firstly, attachment figures confer a safe physical and emotional space, or safe haven. The secure base afforded through proximity to attachment figures allows the organism to explore the world in a non-defensive manner and thrive. Secondly, proximity seeking tendencies are behavioral manifestations of in-born affect regulation strategies aimed at protecting the individual from real or imagined threat and ensuing distress. And thirdly, due to its survival value, the attachment behavioral system is manifested throughout the human life span or from the "cradle to the grave" (Bowlby, 1979). Bowlby's theory also accounts for interpersonal differences observed in behavioral attachment systems.

Attachment theory has undergone extensive integration with research on adult relationships (Hazan & Shaver, 1987, 1994). The attachment model of adult intimacy views a relationship between couples in terms of a bond with an irreplaceable other. This psychological tie is a function of four interrelated elements; emotional, cognitive, behavioural and physiological processes that interact to optimize survival. An individual's response to any real or perceived separation from or loss of an attachment figure, particularly in the face of threat, has been shown to instigate a predictable series of responses designed to re-instill the bond and to facilitate an adaptive response to environmental demands (Bowlby, 1969, 1988). For example, research in adults has shown that departure of one partner of a dyad is associated with a heightened overt display of proximity seeking behaviours in the other partner (Fraley & Shaver, 1998).

Similarly, adults demonstrate a behavioural tendency to seek others for support while, or immediately following encountering stressful events (Lazarus & Folkman, 1984, Kobak & Duemmelr, 1994). Proximity-seeking behaviour in the face of physical/psychological stress or threat has clear survival value in that comfort and security are obtained from an attachment figure thereby restoring any psychological/physical homeostatic deviations to optimal states, which in turn enhance adaptation to or coping with the presenting stressor.

Central to attachment theory is the concept of internal working models, which accounts for the interpersonal differences observed in attachment behavioural systems (Bartholomew & Horowitz, 1991, Collins & Read, 1990, Main, Kaplan, & Cassidy, 1985). These constitute organized internal representations of the self in relation to significant others. Beliefs and feelings of oneself are partially dependent on perceived accessibility and responsiveness of an attachment figure to one's needs for security and comfort (Cassidy, 1988). Internal working models provide a cohesive framework from which attachment-related events are interpreted and revised (Bowlby, 1973).

In the context of close relationships, working models tend to give rise to attachment strategies, which are essentially habitual forms of engagement that become salient in times of fear or uncertainty, such as receiving a breast cancer diagnosis or having to undergo invasive treatments. Secure attachment is based on the perception that attachment figures are accessible and responsive to a vulnerable feeling self facing an uncertain future. The unsure self is soothed through exchanges from a responsive and attuned attachment figure. Exchanges that are marked by emotional engagement, ultimately constitute the building blocks of secure bonding and the relationship becomes defined as a safe haven.

In contrast, unresponsiveness of an attachment figure, will instigate less than secure patterned responses or attachment strategies by the individual in attempt to re-

instill some connection with an irreplaceable other. Insecure forms of engagement are limited in number and can be organized along a two dimensional model; anxiety (self) and avoidance (other) (Brennan et al., 1998). Adults endorsing elevations on attachment anxiety along with low attachment avoidance typically engage in emotionally intense pursuits of loved ones, marked by clinging and even aggressive behaviors in attempt to re-engage their significant other when feeling vulnerable. Adults who are low on anxiety and high on avoidance, on the other hand, cope with the aversiveness associated with an absent safe connection by suppressing attachment needs altogether. Such individuals employ distancing strategies to avoid distressing emotional engagement with attachment figures.

These habitual ways of engagement, also known as attachment styles in the literature (Sroufe, 1996), may be conceptualized as filters for construing attachment experiences, which affect how people cope in the face of adversity. Two characteristic features distinguish attachment strategies from fixed cognitive schema; first is the interpersonal and reciprocally reinforcing nature of attachment strategies that becomes particularly salient in close relationships. Secondly, is their emotional nature, as stressed by Bowlby (1969). Specifically, it is the emotional quality of attachment strategies which ultimately organizes dyadic interactions; but also makes them open for revision following corrective emotional experiences (Johnson, 2002).

A Theory of Affect Regulation and Coping

Attachment theory is primarily a theory of affect regulation. Attachment strategies or habitual ways of engaging one's significant other in times of threat are manifestations of a biobehavioural control system that becomes activated in the face of danger. Its activation serves to promote emotional and physical proximity towards the goal of achieving a felt sense of security. Close relational bonding has a protective impact on emotional and physical health, including restoration of immune competence, as well as

mediating optimal coping with adversity, including chronic illness Kiecolt-Glaser et al., 1993). It is the secure emotional aspect of connectedness that promotes effective self-regulation, openness to experience and new learning, and integration of information (McFarlane & Van der Kolk, 1996).

In contrast, emotional connection that is desperately needed from an attachment figure, but not forthcoming, for a variety of reasons, culminates in relational distress (Simpson & Rholles, 1994) and is associated with symptoms of post-traumatic stress and depression (Whissman, 1999). In the context of such relationships, couples find it difficult to weather a potentially traumatic experience, such as a life threatening diagnosis and its often taxing medical treatments. Specifically, the absence of secure attachment will likely result in feelings of being flooding with fear and helplessness, an inability to cope adequately and to adapt to new situations (Bowlby, 1973, 1969, Cassidy & Shaver, 1999). The relationship becomes defined as insecure and couples become readily consumed by absorbing and compelling states of negative affect that entrap them in dysfunctional cycles of interacting with one another.

Habitual ways of engaging one another in the context of close relationships; which determine the extent of secure connection created, seems to be one of the determining factors as to whether a couple can pull through in the face of trauma or not. Specifically, a large body of research clearly associates attachment strategies with variation in emotional expression, emotional regulation and goal-directed behavior in adults, such as seeking social support (Kobak & Sceery, 1988). A general model proposed by Collins & Read (1994) specifies that the various attachment strategies give rise to distinct emotional response patterns that vary both in nature (positive or negative) and intensity. This model has gained wide acceptance and is consistent with a substantial body of research from various studies examining the differential effects of attachment strategies on management of attentional resources, appraisal styles,

emotional reactivity, proclivity for moving towards significant others in times of need and eliciting their support. (e.g. Bartholomew, 1990, Mikulincer & Orbach, 1995, Milkunicer & Nachson, 1991; Zuroff & Fitzpatrick, 1995; Feeney & Kirkpatrick, 1996).

Indeed several studies have substantiated systematic differences in ways of coping with stress, which appear to be guided by different attachment strategies that are pulled for in the context of close relationships, and overall adjustment (e.g. Simpson, Roles, Nelligan, 1992, Mikulincer & Florian, 1997, Collins & Feeney, 2000). In a study of dating couples, Simpson et al. (1992) observed that, in reaction to experienced anxiety, secure women showed a tendency to seek partner support, whereas avoidant women showed the opposite pattern. Similar findings were reported by Mikulincer et al, (1993), where securely attached adults evidenced higher support seeking behaviour, in relation to their anxious or avoidant counterparts. Anxious individuals were more prone to engage in emotion focused coping that emphasized negative emotions, whereas avoidants were more likely to adopt repressive or emotion distancing tactics. Another study by Ognibene & Collins (1998) reached consistent findings. Securely attached individuals readily perceived available social support and were more like to make use of it, especially in times of stress. Anxious individuals, though employed social support strategies to some extent, also engaged in escape-avoidance maneuvers, such as smoking, drinking, eating, drug use (Brennan & Shaver, 1995). Avoidants, consistent with their negative view of others, were the least likely to reach for interpersonal support, and were most prone to engage in escape-avoidance strategies (Ognibene & Collins, Mikulincer & Nachson, 1991, Simpson, 1990).

Taken altogether, empirical research clearly supports the use of attachment theory as a theory of affect regulation that becomes activated in the face of danger giving rise to reciprocally determined attachment strategies in dealing with stress or trauma. By filtering perceptual information, shaping emotional regulation, and guiding

coping strategies, predominant ways of relating, are argued to hold important implications for adjustment and personal well-being, particularly in the face of chronic illness. Therefore, to the extent that distress is experienced and handled behaviorally, the individual will successfully adapt to changing environmental demands. A large body of research concurs that secure attachment or connectedness, which has been likened to an "inner resource", (Mikulincer & Florian,1998, pg. 144) effectively enables the individual to cope more adaptively in the face of stress, thereby optimizing adaptation. Interpersonally, individuals with secure attachment styles are able to seek and utilize support provided by significant others who through past experience have demonstrated their accessibility and responsiveness particularly in times of distress. Attachment security will, therefore, confer psychological benefits; where stressful events are managed in a manner proportionate to their gravity thereby facilitating adjustment.

Understanding Coping With Breast Cancer from an Attachment Theory Perspective

Bowlby (1969) maintained that attachment behaviour is most likely activated the face of three main types of conditions; dangerous external events (e.g. a terrorist attack), physical or emotional withdrawal of an attachment figure, and departures from homeostasis with respect to physical health, such as during pain, fatigue or sickness. Breast cancer poses a substantial threat to a woman's existence and to the attachment bond existing between her and her respective partner, that which will result in activation of the attachment behavioural system of both individuals. Attachment theory further posits that, in the face of a potentially "existential plight" (Weiss, 1991, pg.5), couples will be physically and emotionally propelled towards one another. Several studies, addressing couples' reactions to a cancer threat within a marriage, reported findings consistent with this normative pattern of proximity seeking behaviour in both partners (Leiber, 1976, Friedman, Baer, Nelson, Lane, 1988).

The attachment relationship has been found to be of such potency to the adjustment of breast cancer survivors, such that if troubled, ensuing distress cannot be simply overcome by additional social support (Pistrang & Barker, 1995). The social support inherent to a marital context, however, is explicitly differentiated by attachment theory as a shared dyadic process consisting of two distinct systems; a caregiver system and a care-seeker or attachment system (Bowlby, 1982). Kunce & Shaver (1994) point out that despite the disproportionate research accorded to the attachment or care-seeker system relative to the caregiver system, the latter is in fact is a key component of the dyadic bond. It follows, therefore, that efforts at emotional regulation, coping and overall adjustment to breast cancer will, predictably, vary through the interaction of two partners' predominant ways of relating or attachment styles. Indeed the effect of one's partner's preferred mode of affect regulation and coping on one's ability to regulate stress has been empirically addressed by several researchers (e.g. Simpson et al., 1992, Simpson et al., 2002).

In an attachment-based study examining adult interpersonal processes in the dyadic system, Collins & Feeney (2000) found evidence for normative patterns, consistent with previous studies (e.g. Leiber, 1976, Friedman et al., 1988), as well as individual variation in the quality of support exchanges. Normatively, higher levels of experienced stress predicted more emotional support sought from respective partners, who in turn mobilized behavioral efforts and provided coordinated emotional and instrumental support. Caregivers demonstrated sensitivity as to the type of support elicited by their partners (emotional versus instrumental) demonstrating a pattern of attunement to partners' needs, which was, in turn, related to improved mood and felt security reported by care seekers. Partners' respective attachment styles also interacted to produce variation in the nature and quality of support exchanges.

Consistent with previous research and theoretical predictions, secure care-giver attachment was associated with higher flexibility and better coordinated efforts at care-giving (Simpson, Rholes, Orina, & Grich, 2002), more synchronized interactions and less dominance (Bouthillier, Julien, Dube, Belanger, & Hamelin, 2002, Pietromonaco, Greenwood, & Feldman Barett, 2004). Withdrawal behaviour, shown to be associated with high mood disturbance in an ill spouse (Grandstaff, 1976; Primomo et al., 1990), was also less problematic when both partners are securely attached (Senchak & Leonard, 1992).

Highly avoidant support seekers, while showing a lower likelihood of seeking help (Collins & Feeney, 2000; Mikulincer & Florian, 1995; Ognibene & Collins, 1998) when stressed, yielded a mixed pattern relative to care giving that appears to be a function of internal working models of self (anxiety dimension). For example, higher avoidance was associated with a lower likelihood of providing support to partners experiencing emotional distress (Simpson et al., 1992, Fraley & Shaver, 1998), which is consistent with Kunce & Shaver's (1994) finding of lack of caring associated with dismissing avoidant caregivers. In contrast, fearful avoidant caregivers, who are higher in anxiety, showed excessive care-giving in relation to support sought (Kunce & Shaver, 1994).

Similar to their avoidantly attached counterparts, anxiously attached caregivers, tend to provide less than optimal support in response to their distressed partners (Carnelly, Pietromonaco & Jaffe, 1996, Kunce & Shaver, 1996). Collins & Feeney (2000) observed a curious pattern in anxiously attached caregivers relative to the quality of support seeking efforts engaged in by their partners. Specifically, a partner who made indirect requests (e.g. hints) was less likely to receive support in comparison to one whose support-seeking efforts were more evident (e.g. making a direct request).

Taken together, these findings carry clinically important implications for adjustment and well-being of couples with different combinations of attachment

strategies. This point becomes clearer when, for example, the adjustment of an avoidant survivor-anxious caregiver dyad is compared to that of a secure survivor-secure caregiver couple, the latter survivor of which is more likely to both make overt pleas for emotional support, as well as receive them compared to the survivor of the former dyad.

Attachment theory, in summary, appears to provide the most comprehensive framework unifying both intrapersonal and interpersonal processes involved in coping and adjustment. Though its utility is thoroughly recognized in clinical, developmental, and personality research, application of attachment theory in the medical field, and particularly in chronic illness, has been relatively neglected (Schmidt, Nachtigall, Wuethrich-martone, & Strauss, 2002). To date, a total of three separate studies have examined patient coping and adjustment to chronic illness, including cancer, using attachment-based processes.

The first cross-sectional study by Schmidt et al. (2002) investigated whether different attachment styles bore any relationship to flexible coping in three types of medical conditions; breast cancer, chronic leg ulcers, and alopecia. Findings indicated a moderate effect size between attachment style and coping, with insecure attachment associated with less flexible coping behavior. Specifically, secure attachment was related to stronger social support seeking, in keeping with patterns observed elsewhere in the literature (e.g. Feeney & Kirkpatrick, 1996). Anxious prototypes, in contrast, evidenced more 'negative emotional coping', whereas avoidant ones engaged in distancing or distracting strategies.

In another study of melanoma survivors, Hamama-Raz & Solomon (2006) examined the relative contribution of the concepts of attachment style, cognitive appraisal and hardiness to psychological adjustment to illness. With the exception of marital status, attachment style emerged as the best predictor of adjustment in relation to all other sociodemographic (e.g. gender, employment status) as well as disease-

specific variables (e.g. stage of illness, time since diagnosis). In view of the heterogeneity inherent in conceptualizing and measuring psychological adjustment, this study used a tool which tapped both well-being and feelings of distress, thereby adding better understanding of the differential impact of attachment styles on aspects of adjustment. Using a continuous self-report measure of attachment (Brennan et al.1998), secure attachment predicted higher levels of subjective well-being and lower distress. Whereas both anxious and avoidant attachment styles were related to lower well-being, only anxious patients endorsed higher distress.

The third study using an attachment framework for understanding affective outcome involved terminal cancer patients. Consistent with findings of the previous two studies, attachment style again predicted negative affect over and above other background variables, (time since diagnosis, physical condition, age, stressful life events). Path analyses revealed a direct impact of anxious attachment on negative affect, as well as an indirect effect through mediation of social support. Avoidant attachment, on the other hand seemed to exacerbate negative affect only through curtailment of social support.

In summary, the few studies employing an attachment perspective to understanding coping with chronic illness converge on several key findings. Firstly; attachment style, or habitual ways of engagement, accounts for the largest variation in psychological adjustment to illness, beyond that associated with both patient characteristics and disease-specific variables. Secondly, secure attachment serves as an important inner resource and is associated with flexible coping, a prerequisite to successful adaptation to changing circumstances. Thirdly, although insecure attachment is inversely related to adjustment, anxious and avoidant attachment styles appear to exert this effect though different mechanisms.

Psychological Trials

The reality of increased survivorship coupled with the extensive body of research describing both the nature and extent of psychological morbidity experienced by many breast cancer survivors has prompted much intervention research primarily aimed at enhancing psychological adjustment or aspects thereof. Addressing adjustment is a relevant clinical endeavor from psychological, physiological and behavioural perspectives. For example, the relationship between difficult adjustment and compromised quality of life is both intuitive and empirically substantiated (Ganz et al., 2003). From a physiological point of view, chronic states of negative affect (particularly depression and anxiety), associated with poor adjustment to illness, tend to compromise immune function, which is conjectured to affect disease course in the long run (Anisman & Merali, 2003). The importance of optimal functional immunity (i.e. Natural Killer Cell activity) has, in fact, been underscored by independent researchers (Dagleish, 2003 & Levy et al., 1990), in light of its reliable link to disease-free periods and the control of micrometastases (Levy et al., 1990). The relationship between emotional distress, immunity and intervention research is reviewed more extensively elsewhere (Herbert & Cohen, 1993). Behaviorally, enduring affective disturbance, especially depression, can interfere with the degree to which patients accept adjuvant treatments as necessary. For instance, Colleoni et al., (2000) found that depressed patients are less likely to be proactive in seeking more aggressive treatments that may enhance their chances for survival. Furthermore, when depressed patients had agreed to undergo chemotherapy treatment, depression was shown to independently undermine the therapeutic effects of systemic treatment (Walker et al., 1999). The potentially far reaching effects of maladjustment to cancer with respect to the psychological, behavioral and physical realms have become widely recognized, which has provided impetus for the growing number of intervention studies that have spawned the field of psycho-oncology.

The paucity of couples-based interventions within the cancer literature is particularly conspicuous especially in view of the mounting research converging on mutually elevated distress levels in the patient and her significant other, as well as the inextricable involvement of the latter in the adjustment process. Manne, Winkel, Grana, Ross, Ostroff, Fox, Miller, Frazier, (2005) aptly point out that intervention research does 'not take advantage of the family context of cancer and a key source of support for patient, namely the partner' (634). In response to this gap, Manne et al. (2005) developed and tested the efficacy of a couple-based group intervention targeting women with early breast cancer. Consistent with prior research, higher distress levels at study entry were associated with stronger treatment gains and women describing their spouses as unsupportive benefited more compared to women with less critical husbands. A relatively small, but stable, treatment effect was found only for depression and not anxiety, general well-being or trauma symptoms surrounding the cancer (e.g. avoidance and intrusion). This study is the first to address a major gap in the psychosocial treatment literature by evaluating a short term intervention which capitalizes on resources inherent to the dyadic unit, and aims to recreate more supportive exchanges between partners. Notwithstanding, the trial was characterized by a high refusal and drop out rate leading the study researchers to speculate about the 'acceptability' of a group-based couples intervention among breast cancer dyads.

The final goal of this review is to present a theoretically driven intervention offered to breast cancer couples experiencing difficulties in adjustment. Emotionally focused therapy (EFT) is an evidenced based time limited therapeutic approach, which bears directly on the literature reviewed thus far on dyadic coping processes during stress and is rooted in a firm theory – attachment theory.

Emotionally Focused Therapy

Formulated in the early 80's, Emotionally Focused Therapy (EFT) is a structured and short term approach designed to treat relational distress (Johnson, 2004, Greenberg & Johnson, 1988). Having undergone scientific scrutiny over a span of 15 years, studies associate EFT with clinically relevant change in marital functioning (Alexander, Holzworth-Munroe, & Jameson, 199; Dunn & Schwebel, 1995), as well as stable rates of recovery (Gordon-Walker & Manion, 1998). A systematic review of randomized clinical trials assessing the clinical efficacy of EFT on marital adjustment reported a clinically robust treatment effect size of 1.3 (Johnson, Hunsley, Greenberg & Schindler, 1999). EFT has also been successfully adapted to clinical populations where relational distress was either comorbid with or exacerbated by other stressful couple or family concerns, including parenting chronically ill children (Walker, Johnson, Manion, & Cloutier, 1996), facing post-partum depression (Whiffen & Johnson, 1998), dealing with post-traumatic stress disorder (Johnson & William-Keeler, 1998). Today, EFT is recognized as one of the best articulated and evidenced based approaches for treatment of relational distress (Baucom, Shoham, Mueser, Daiuto, & Stickle, 1998, Gurman & Frankael, 2002).

Dialectically, EFT arose from a theoretical synthesis of experiential, humanistic and systemic approaches to psychotherapy. One of its major strengths is its firm grounding in an empirically supported understanding of adult attachment processes (Bartholomew & Perlman, 1994) and nature of marital distress (Gottman, 1994). This conceptual understanding, or guiding map, has served to integrate intrapersonal and interpersonal processes involved in partners' constructions of emotional experiences and dyadic interactions (Johnson, 1996). Informed by attachment theory, EFT views the marital relationship as a bond with an irreplaceable other (Cohen, 1992). One's significant other is considered to be the primary source of support, comfort and the secure base from which physical/emotional stress of illness can be faced. The

attachment bond is, therefore, characterized by a high affective valence (Johnson, 1996), and such that if threatened by unresponsiveness or inaccessibility will lead to a predictable series of events aimed to re-instill it (Bowlby, 1969).

EFT regards distressed relationships in terms of insecure bonds, where attachment needs for physical or emotional closeness, comfort, and security, particularly during adversity, are not being met. In response to attachment threat, individuals will behave in different, but a finite number of, ways to deal with the experienced distress (Hazan & Shaver, 1994). The overarching goal of EFT is to foster the creation of secure bonds between partners, which in turn facilitates emotional connection and resilience in the face of adversity.

The emotionally-mediated relationship between attachment security and relational adjustment is supported by research (Bowlby, 1988, Kobak & Hazan, 1991. As such, EFT accords emotion a key role in shaping dyadic interactions (Johnson, 2004). Specifically, emotion is viewed as a healthy and adaptive mechanism that guides perceptions, communicates needs to one self and others and organizes social interactions. In the context of intimate relationships, attachment behaviors are primarily guided and shaped by emotion. Predominant emotional experiences of felt insecurity or separation distress will, therefore, organize current interactions typically leading to problematic cycles of relating. This perspective fits with Gottman's (1994) research with respect to distressed relationships. Specifically, he found that strained relationships tend to be characterized by partners' propensity to become stuck in absorbing states of negative affect that give rise to rigid interactional patterns, which lead to further aversive states. Johnson (1996) maintains that distressed couples were readily identifiable both by their rigidly organized interactional cycles and intense negative affect.

EFT further posits that whether in the form of negative affective states or rigid interactions, distressed couple are essentially manifesting a struggle for attachment

security (Bowlby 1969). Creation of secure emotional connections between partners is, therefore, achieved by eliciting and expanding the couples' core emotional experiences that give rise to their interactional positions and then effectuating a shift in these interactional positions. One of the core assumptions of EFT is that emotional responses and interactional positions are reciprocally determined (Johnson, 2004). They are, therefore, both equally addressed in treatment. Empirical evidence for the impact of EFT in creating more secure bonds initially distressed couples has been reported (Makinen & Johnson, 2006). Secure bonds, in turn, have been shown to be powerfully associated with physical and emotional health and well-being, with resilience in the face of stress and trauma, and with optimal personality development (Burman and Margolin, 1992, Schmaling & Sher, 2000).

EFT is a structured therapeutic intervention that has been manualized (Johnson, 2004). It consists of three major stages encompassing nine steps, which delineate specific therapeutic tasks that can be delivered in approximately 10 to 15 sessions (Johnson, 2004). The first stage involves assessment and the delineation of problematic cycles between partners, such as demand/withdraw and the absorbing states of emotion that are associated with them. At the end of this stage of therapy the couple is able to dislodge from negative cycles and have stabilized their relationship. Partners start to view the cycle as the enemy rather than each other. Excerpts from treatment sessions of a couple in their fifties are provided to illustrate how EFT diffuses negative cycles that escalate secondary to breast-cancer-related needs leaving the patient alone, more vulnerable and less able to deal with the aftermath of the illness. This is a couple who entered therapy displaying a classic pursue/attack – withdraw/stonewall cycle.

SPOUSE: Things are better now. She's not on my back like before...you know it was like when I returned home from work or if I went out to see my friends, she would be waiting for me ready to pick up a fight...

PATIENT: Well, you don't hide with your friends every night like you used to...you come home at a decent hour. Oh, yes, and sober (sounds sarcastic) and I know I can at least talk to you when I'm upset about something, like when the nurse called the other day telling me that doctor wanted to see me for the mammogram findings. You came home late, but at least you weren't drinking.

SPOUSE: (becomes quiet and looks away)

THERAPIST: So, what's happening for you Jack? (still looking away) Marie just told you that she is finding you're more available now and that she can talk you. Then she sounded a little sarcastic when mentioning how you don't drink as much as before.

SPOUSE: (Long pause. Then looks at therapist). Well, it's like things going back again to the old way... I feel like she's attacking again, nothing is good enough and no matter what I do....(looks away)

THERAPIST: It's very difficult for you to hear this. My sense is that you're trying really hard and there is some part of you that feels really scared, does that fit for you?

SPOUSE: Yes, like it doesn't matter what I do, it's never good enough.

THERAPST: Hmmm. That's part of that cycle that you both get trapped in.

PATIENT: things have been getting better, I said. Last week was really tough, because I got the phone call from the clinic in the afternoon and didn't know what time you would be home so I can talk to you.

SPOUSE: I did remember that you would be may be getting that phone call following the mammogram. You just assumed that I forgot.

THERAPIST: You're disappointed that Marie doubted you?

SPOUSE: Yeah. How can I forget something like that? But it's rough, you know, I mean trying to be there all the time and making it alright. Sometimes it feels like I can never make it.

In the second stage, both partners are able to access and utilize their respective emotional experiences as a guide to their needs. They also begin to communicate these needs in a way that maximizes their partner's responsiveness. Usually the more withdrawn partner is able to express the emotional experience that evoked the withdrawal in the first place (e.g. I *was afraid of losing you to cancer)* and is able to ask their partner for the responses that will make emotional engagement more possible. For example, a withdrawn husband states that he will not tolerate sarcasm and hostile criticism but needs his wife's acceptance. The more hostile partner will then begin to explore the emotional realities that evoked the relationship dance. This usually involves expressing hurts, fears and disappointments and taking new risks with one's partner. It is at this point, as this partner is invited into a new dance that the particular incidents, such as attachment injuries may surface (e.g. *'you left me all alone when the pathology report came back positive'*) and need to be processed. This final change event, associated with success in EFT, is known as a *softening* (Johnson & Greenberg, 1988). These change events are powerful as they have the ability "to heal past injuries and wounds in the relationship" and create powerful new bonding events and the construction of a new positive cycle (Johnson, 1999, p. 21).

SPOUSE: (looks at his spouse). When the pathology report came back positive, it was like a bad dream I couldn't wake up from...I didn't know what do to...I was petrified for you, for the children...This was one I couldn't fix and I felt like a total failure.

PATIENT: I had no idea you were feeling this way. I mean you never showed it, and it seemed like everything else was more important. I felt all alone and scared to have to deal with this, you know the surgery, the chemo, it was awful...It's like seeing a whole different side of you.

THERAPIST: Jack, you felt so overwhelmed and scared yourself in the face of this new reality and didn't know how to comfort Margie.

SPOUSE: Yes. I didn't want to share my fears with her. I didn't feel it was fair..this was about her, not me. I felt like I needed to take care of her, not the other way around.

The final stage is concerned with integration and consolidation of the positive changes that occurred during therapy. By reflecting on the process of therapy and validating new emotions and new interaction patterns that have replaced the former negative interactional cycle, couples can construct clear models and narratives of their relationship. With this new ability to communicate clearly about crucial issues they can solve ongoing problems in the relationship.

Conclusions

Breast cancer is becoming increasingly recognized as a chronic illness, which impacts the entire family. While many families seem to adjust adequately in the face of such medical adversity, others become unwittingly entrapped in unremitting cycles of relational distress, exacerbated by various forms of psychological morbidity, such as depression, and anxiety. Negatively charged interactions adversely impact mental and physical health (Salovey et al, 2000). The powers of secure attachment bonds to significant others, on the other hand, have been clearly linked to emotional/physical health and well-being, as well as general resilience particularly in the face of trauma. Notwithstanding, systematic reviews have consistently lamented the conspicuous absence of theoretically-driven interventions which take advantage of the dyadic unit. EFT, a short term and empirically validated approach, is presented here as an important treatment choice for couples facing adjustment difficulties following breast cancer. Grounded in attachment theory, EFT helps couples by alleviating relational distress and restoring healthier ways of relating in a marital and familial context. By focusing on the

quality of attachment exchanges, and promoting emotional engagement, EFT offers partners the ability to respond to each other in more supportive ways, thereby creating more secure connections. Secure connections, in turn, confer more resilience. Specifically, partners are able to step away from reactive cycles of compellingly negative emotion, express their needs more clearly and to use one another as a source of support in regulation of fear, helplessness, anger, and uncertainty, often associated with breast cancer and facing the future. The relationship becomes the safe haven from which comfort may be sought when attachment needs are primed. By the end of treatment, the relationship will essentially provide the necessary antidote against feelings of vulnerability often experienced in the context of breast cancer. As the positive interactions, consolidated in treatment, become enacted over time, each partner's sense of felt security in relation to the other deepens, increasing a couple's ability to both tolerate and cope with adversity.

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MANUSCRIPT 2: EVALUATION OF THE CLINICAL EFFICACY OF EMOTIONALLY FOCUSED THERAPY ON PSYCHOLOGICAL ADJUSTMENT OF COUPLES FACING EARLY BREAST CANCER

ABSTRACT

Purpose: The shared and reciprocally determined adjustment processes which unfold within couples who face breast cancer has been readily acknowledged. The goal of the present study was to conduct a preliminary investigation of the clinical efficacy of a structured couple-based intervention, Emotionally Focused Therapy, on dyadic and psychological adjustment of partnered couples following diagnosis and treatment for early breast cancer. *Methods:* Twelve couples were randomized to receive either twenty sessions of Emotionally Focused Therapy (EFT) or Psycho-education (PE). A multiple baseline experimental design across couples was used. *Results:* Compared to couples randomized to PE, those who received EFT evidenced more variation on outcome variables following EFT. Specifically, more than 50% of couples who received EFT evidenced clinically significant improvement in dyadic adjustment, and quality of life, as well as attenuation in mood disturbance and trauma symptoms. *Conclusions:* Results provide initial support for offering EFT to couples dealing with relational and emotional distress following diagnosis and treatment of early breast cancer.

INTRODUCTION

The most pervasive female malignancy, breast cancer touches the lives of one out of nine Canadian women, along with their families (Canadian Cancer Statistics, 2007). Advances in screening and treatment have created a gulf between incidence and mortality rates, rendering the possibility of survivorship an increasingly new reality. While the majority of women diagnosed with early stage disease manage to survive, the experience can be considerably exacting for the entire family particularly during the adjustment phase following completion of medical treatments.

Studies find that upwards of 40% of breast cancer survivors report psychological morbidity in the form of anxiety, depression and cancer-related distress reaching proportions of PTSD (Kissane et al. 2004; Alter et al, 1996; Cordova et al, 1995; Khalid & Gul, 2000). Adjustment difficulties are also prevalent in spouses and are highly congruous in nature and intensity to those experienced by their wives (Ey, Compas, Epping-Jordan & Worsham, 1998, Northouse, Templin, & Mood, 2001). Difficulties in the marital relationship; feelings of vulnerability; uncertainty about the future; and fear of recurrence and death are among the highly rated concerns of couples who face breast cancer (Gotay, 1984). Incidentally, many of these adjustment difficulties persist for some couples well into the post-acute treatment phase following apparently successful medical treatment (Walker, 1997).

The mitigating role of emotional support on stress is one of the most robust findings within the coping literature (Dunkel-Schetter, 1984; Helgeson & Cohen, 1996). The adjustment process, however, is one that is shared and reciprocally determined by both partners who conjointly face the breast cancer experience (Coyne, 1976a, 1976b; Northouse, 1993). Difficulties in adjustment experienced by relational partners can unwittingly create unsupportive interactional patterns, such as avoidance of communication about the cancer, criticism or withdrawal (Spiegel, Bloom, & Gottheil,

1983; Vess, Moreland, Schwebel, & Kraut, 1988). These cycles of interaction predictably lead to greater marital distress which can further exacerbate depressive symptoms in women (Bloom, 1982; Ptacek, Ptacek & Dodge, 1994; Manne et al. 1997). The distress experienced in the context of marital strife can further undermine one's capacity to cope with an imminent stressor, in addition to limit one's ability in marshalling efforts to obtain support in other relationships (Coyne & DeLongis, 1986).

Conversely, couple relationships characterized by secure emotional bonds confer resilience in the face of trauma and are powerfully associated with physical and emotional health and well-being (Burman and Margolin, 1992, Schmaling & Sher, 2000). Scores of studies have shown that breast cancer survivors prefer emotional support (versus instrumental or informational) provided by an intimate partner that is marked by open engagement and high empathy (Dakof & Taylor, 1990; Lichtman, Taylor, & Wood, 1987, Pistrang & Barker, 1995). Such connections have, in turn, been associated with lower distress and depression (Roberts 1994, Tatelman, 1999), and better role adjustment for the survivor ((Northouse et al., 1995). Taken together, the spousal relationship is becoming increasingly recognized to be of significant importance for adjustment to illness such that if troubled ensuing distress cannot be simply overcome by additional social support (Pistrang & Barker, 1995).

In view the salient and lingering adjustment issues faced by a significant proportion of breast cancer survivors' psychological trials have spawned the field of psycho-oncology. Less than a handful of studies, however, have capitalized on the potency of the marital relationship in helping promote psychological adjustment in both partners of the dyadic unit (e.g. Scott, Halford, & Ward, 2004, Manne et al. 2005, Christensen, 1989, Shields & Rousseau, 2004). The goal of the present research is to address this important gap by conducting a preliminary study which evaluates the clinical

efficacy of a structured couples-based intervention, Emotionally Focused Therapy, on dyadic and psychological adjustment of partnered couples.

Conceptually, EFT draws on attachment theory (Bowlby, 1979, 1973, 1980) for understanding the nature of adult love. Originally formulated to describe an innate behavioral regulation system observed in infants, attachment theory posits that in the face of distress the individual will be propelled to seek comfort and protection from an attachment figure. Attachment theory has undergone extensive integration with research on adult relationships (Hazan & Shaver, 1994). Specifically, the marital relationship is viewed as a bond with an irreplaceable other (Cohen, 1992), which has clear survival value in the face of adversity.

Central to this theoretical perspective is the concept of internal working models, which refers to how the self is defined in relation to others in close interpersonal relationships. The interaction of two internal working models; one concerning self regard and others' trustworthiness, gives rise to prototypic relational styles, also referred to as *attachment styles* (Bartholomew & Horowitz, 1991, Collins & Read, 1990). Effectively, attachment styles, or habitual ways of engaging attachment figures in times of stress, guide interactions in close relationships and shape affect regulation and coping (Johnson, 1996, Sroufe, 1996). Greater attachment security is generally accepted as an important internal resource, which facilitates coping and adjustment (Mikulincer,1998).

EFT views marital distress as stemming from a struggle to meet attachment needs, such as perceiving lack of emotional support in the face of vulnerability (Johnson, 1996, 2002). Experientially, distressed couples are caught in specific absorbing states of negative affect giving rise to rigid interactional cycles, which in turn maintain aversive emotional states. Such undermining interactional patterns preclude secure bonding and exacerbate feelings of vulnerability, and distress in the face of crisis.

The salient goal of EFT is, therefore, to promote secure bonding between partners, which is, in turn, powerfully associated with physical and psychoemotional well-being and resilience (Burman and Margolin, 1992). This is achieved by helping couples elicit and expand their core emotional experiences that give rise to their interactional positions. Germane to this process is that emotional processes, as well as interactional positions, are reciprocally determined – and as such both are equally addressed in therapy. For a complete description of steps and therapeutic tasks addressed in EFT, see Johnson (1996).

The current study extends past research by evaluating a theoretically motivated therapeutic approach, which has also demonstrated strong empirical support in other clinical populations with respect to clinical efficacy and recovery rates (e.g. Johnson, Hunsley, Greenberg, & Schindler, 1999; Walker, Johnson, Manion, & Cloutier, 1999; Dessaules, 1991).

METHOD AND MATERIALS

Participants

The target population for this study was women diagnosed and treated for early breast cancer, as well as their respective partners, who were experiencing psychological maladjustment. Approval of the research protocol was obtained by the Ottawa Hospital Ethics Research Board. This study took place at the Ottawa Regional Cancer Center, a teaching facility affiliated with the University of Ottawa Medical School. Criteria for study inclusion were the following; (a) patient had a confirmed diagnosis of early breast carcinoma of stages I (T1 N0 M0), IIA (T0 N1 M0, T1 N1 M0) or IIB (T2 N1 M0, T3 N0 M0); (b) patient was at least one year post diagnosis; (c) patient completed all adjuvant treatments (surgery, chemotherapy, radiation), except for hormonal therapy; (d) patient was married or cohabitating for at least two years, and partner was willing to participate

for full duration of study; (e) couple was conversant in either English or French, (f) couple was experiencing significant relational distress, as measured by a combined average score of in the range of 78 to 97 points on the dyadic adjustment scale (DAS), described below.

Couples meeting any of the following criteria were excluded from study entry and were referred to services in the community instead; (a) existence of severe cognitive impairment; (b) history of severe and persistent mental illness (e.g. thought disorder, chronic suicidality, substance abuse); (c) physical violence in current relationship; (d) use of psychotropic medication; and (e) either partner receiving concurrent psychotherapy (individual, marital or group).

Procedure

Potentially eligible women were identified by participating oncologists, who obtained verbal consent from patients to be approached by a research associate either immediately following a routine out-patient visit or by telephone. During this initial contact the nature and purpose of study were explained in detail. Couples indicating interest were invited to attend an in depth clinical interview at the Ottawa Couples and Family Institute (OCFI) conducted by a doctoral candidate. All couples signed a written patient information and consent form approved by the Ottawa Hospital Ethics Review Board. The clinical interview served to ensure that couples met all eligibility criteria, including clinically relevant levels of marital distress, using the DAS measure.

Following the initial interview, couples were randomly assigned to one of two treatment conditions; Emotionally Focused Therapy (EFT) or Psycho-Education (PE). The latter condition essentially served as a control condition, in order to rule out the hypothesis that treatment effects could have been simply attributed to couples' exposure to a therapist or spending time together for a certain length of time. Couples assigned to the

EFT condition were further stratified to one of three series; according to specific cancer staging information available in their respective medical charts. The study design was an A-B multiple baseline design across couples (Barlow & Hersen, 1984; Kazdin, 1992). During the pre-treatment phase, all couples filled out, on a weekly basis, a package of standardized assessment measures. Couples differed only in the number of pre-treatment assessment measures completed. Specifically, couples stratified to baseline A completed two weekly assessment measures, baseline B couples completed three, baseline C couples completed four and baseline D completed three weekly assessment measures.

Following pre-treatment assessment, couples were randomly assigned to clinicians who treated them using EFT or PE, depending on their randomization status. Following the first treatment session, all couples filled out another set of assessment measures. Assessment was subsequently repeated at the following points; treatment mid-point (following 10-12 sessions), treatment termination (following 20 sessions) and follow-up (at 3 months post treatment completion). Each couple was assigned a unique number, which was used as identification on assessment measures. Couples were instructed to refrain from writing any identifying information on assessment measures.

Table 1 Stratification of cancer staging and treatment allocation by baseline

Baseline	Cancer Stage	Baseline Period	Treatment Condition
A	Stage I	2	EFT
B	Stage IIa	3	EFT
C	Stage IIb	4	EFT
D	Stages I, IIa, IIb	3	PE

A multiple baseline experimental design was selected in view of the preliminary nature of this study. Several aspects rendered this design advantageous; each couple served as

its own control; the repetition of treatment in a staggered fashion provided replication, and tested for order effects. Once introduced, the intervention did not to be reversed or withdrawn, both of which are unfeasible and unethical in this type of research. Moreover, inference of a relationship between treatment and outcome was possible without needing to resort to a large sample size. Incorporation of a couple control condition permitted inferences about any treatment changes to be attributable specifically to EFT versus dyads spending time together or with a therapist.

Treatment Conditions

Emotionally Focused Therapy (EFT). Treatment consisted of up to 20 weekly 60 minutes of psychotherapy sessions. EFT entails three steps, which encompass nine therapeutic tasks, manualized in Johnson, (1996).

Psychoeducation (PE). To ensure equivalence in treatment 'dose' or exposure to a therapist, couples assigned to the PE treatment condition met with a clinician for 20 weekly 45 minute workshops. The workshops were conducted in a structured and didactic format. Couples were provided with an outline of topics to be covered; epidemiology of breast cancer, medical treatment approaches, effects on psychological health and marital relationships, clinical trials, complementary and alternative medicine, financial and practical support. Couples randomized to this condition were given the option to be treated with EFT following their participation in the PE condition. All treatment sessions were audiotaped with couples' consent.

Clinicians and Setting

Clinicians were psychologists or Master's level clinicians with at least 7 years of experience in treating couples using the EFT model. All clinicians attended consultation

meetings with Dr. Susan Johnson, a licensed clinical psychologist who is also the originator of EFT. Treatments were offered at OCFI.

Measures

Demographic questionnaire

A demographic questionnaire was given to each couple admitted to the study. This included information about patient and spouses ages, ethnicity, educational level, income range, employment; number of children, age at diagnosis, since diagnosis and completion of treatment, drinking history, familial history of breast cancer and current medications.

Coping

Attachment style was used as a proxy for coping behaviour or habitual ways of interrelating with attachment figures. This was judged to be a 'covariate' that would shed light on mechanisms underlying differential impact of EFT on clinical outcome across couples. Attachment style was assessed using the Experiences in Close Relationships Scale (ECR; Brennan, Clark & Shaver, 1998). The ECR is a 36-item attachment measure which assesses attachment behaviour along two dimensions; avoidance and anxiety. Each question is scored on a seven item Likert scale. Results yield scores on both dimensions; avoidance and anxiety, which when collapsed yield four attachment styles; secure; preoccupied; fearful-avoidant; and dismissing-avoidant. Reliability of the items in both dimensions is high with alphas of .94 for the avoidance dimensions and .91 for the anxiety dimension. This measure was completed by each partner at baseline, treatment termination and 3 months follow up.

Marital adjustment

Marital adjustment was assessed Dyadic Adjustment Scale (DAS; Spanier, 1976). The DAS is a 32-item self-report rating scale designed to measure the quality of adjustment

between married or cohabiting couples. The scale yields a total adjustment score, as well as scores on four subscales: Satisfaction (10 items), Consensus (13 items), Cohesion (5 items), and Affectional Expression (4 items). The scale has a theoretical range of 0-151 point with higher scores indicative of less distress and better adjustment. The mean total scale scores were 114.8 for happily married couples and 70.7 for divorced couples. The distress cut-off point for this study was set at 97 points, which is at one standard deviation below the mean for a happily married sample of couples. Any couple scoring below 97 was considered distressed. The average of the each partner's score yields the couple's mean total score.

Mood disturbance

Mood disturbance was measured using the Profile of Mood States (POMS; McNair, Lorr, & Droppelman, 1971, 1992). The POMS provides a comprehensive measure of emotional distress by tapping into 6 types of moods; depression, anxiety, anger, confusion, fatigue, and vigor, in addition to a total mood disturbance index (TMD). Consisting of 65 items, each item is described as a mood adjective and is scored on a 4 point Likert scale. Internal consistencies for each of the 6 factors were near 0.90 or above. Stability coefficients from intake to pre-treatment were 0.70, 0.74, 0.71, 0.65, 0.66, 0.68 for anxiety, depression, anger, vigor, fatigue, and confusion, respectively. The TMD index is more reliable, due to intercorrelations among the 6 primary POMS factors (McNair et al., 1992). POMS has been used extensively to both characterize mood disturbance in a breast cancer population, Lichtman, & Wood, 1884) and to assess treatment outcome in psychotherapy studies (Spiegel, Bloom & Yalom, 1981).

Trauma Symptoms

Trauma symptoms were assessed using the Davidson Trauma Scale (DTS; Davidson et al., 1997). The DTS assesses frequency and severity of intrusion, hyperarousal, avoidance/numbing following a traumatic event. Reliability of the clinical scales ranged

from 0.82 to 0.91. The scale has also undergone several validation studies; a correlation of 0.78 ($p<0.001$) was found between the Clinician-Administered PSTD Scale (CAPS; Blake et al. 1995) and DTS. Similarly the Impact of Events Scale (IES), developed by Horowitz et al., (1979), measuring frequency of intrusion and avoidance symptoms, correlates significantly ($r=0.64$ $p< 0.0001$) with total DTS score.

Quality of Life

Health-related quality of life was measured using the Functional Assessment of Cancer Therapy-Breast (FACT-B), developed by Cella et al., (1997). FACT-B is a 44-item self-report measure designed to assess multidimensional quality of life (QoL) in patients with breast cancer. The scale consists of a general scale (FACT-G), and a sub-scale specific to breast cancer symptoms (BCS). FACT-G is composed of 27 items and four subscales: Physical Wellbeing (PWB), Functional Wellbeing (FWB), Social/Family Wellbeing (SFWB) and Emotional Well-being (EWB). Internal consistency for the FACT-B total score is high ($\alpha = .90$), with subscale alpha coefficients ranging from .63 to .86. This measure was administered only to women in the study.

Couples Therapy Alliance Scale

To ensure that quality of the therapeutic alliance was not a confounding factor in the event that no treatment effects were seen, each couple completed a short qualitative measure, the Couples Therapy Alliance Scale, by the third treatment session.

Statistical Plan

Treatment efficacy was evaluated using three methods; visual inspection, significance testing and assessment of clinical significance of treatment outcomes. As standard practice in single-case experimental designs visual inspection of graphic representations of clinical outcomes was initially carried out (Franklin, et al., 1996; Morely & Adams, 1991). To ensure a systematic approach across all couples, a split middle technique

procedure was used (White, 1972, 1974). This descriptive approach reveals linear trends in data, predicts future course of behavior, and permits systematic examination and comparison of trends within and across phases, respectively. To this end, a "celeration" line, described by White and Harring, (1980), was established for all baseline data per couple. This was carried out using SPSS.14, which uses a least squares method to minimize the squared distances between a line of "best fit" and individual data points during the baseline phase. The line essentially splits the data, so 50% falls above and 50% falls below the celeration line. The celeration line was then extended into the treatment phase and used to reveal an accelerating, decelerating or stationary trend. Visual analyses of treatment effects were evaluated by comparing the treatment trends to the celeration line. An increasing treatment trend, relative to the celeration line, represented clinical gain on the DAS and FACT, respectively. A decreasing treatment trend, relative to the celeration line, represented clinical gain on the POMS and DTS, respectively.

Since the split middle technique is primarily a descriptive procedure for trend estimation, the statistical significance of departures in treatment trends relative to the projected celeration line was evaluated using a binomial test, as proposed by White (1972). The null hypothesis upon which this test was based was that no change in outcome measures existed across baseline and treatment phases. In the absence of treatment effects, the celeration line was taken to be a valid estimate of clinical outcomes during the treatment phase, and data points were expected to fall above and below the projected line in equal proportions. In cases where data points fell above and below the line in unequal proportions, the binomial test was used to evaluate whether the difference in proportions was of sufficiently low probability to reject the null hypothesis.

A more stringent criterion for assessment of treatment efficacy used in this study was evaluation of the clinical significance (CS) of treatment outcomes. CS refers to more practical or meaningful differences that may not necessarily accompany statistically reliable effects (Jacobson & Truax, 1991). CS was operationalized using the reliable change index (RCI), articulated by Jacobson et al., (1984). Specifically, RCI refers to the smallest difference between pre and post treatment scores on a measure which corresponds to a real difference in clinical course or function. A conservative estimate of 'real change' was adopted, using Jacobson et al.'s (1991) most recent formulation, which takes into account both the standard error of measure, and test-retest reliability of the instrument in order to determine a threshold for chance variation. In this study, CS was conferred when the following two conditions were met: (1) difference in pre-post scores exceeded the RCI and (2) post treatment score fell within a normative range, as defined by the measure in question. Finally, clinically important changes on outcome measures were followed up by sub group analyses, using non-parametric techniques on aggregate pre-post treatment scores.

Hypotheses

It was hypothesized that:

(1) Breast cancer survivors would experience more secure attachment towards their respective partners at treatment follow-up;

(2) Compared to baseline, treatment trends observed for marital adjustment and quality of life would be significantly steeper and positive (indicating better adjustment and quality of life, respectively);

(3) Compared to baseline, treatment trends observed for overall mood disturbance (e.g. depression, anxiety) and trauma symptoms would be significantly steeper and negative (indicating less mood disturbance and trauma symptoms);

(4) The above hypothesized effects would be replicated across couples randomized to the EFT condition; but not to couples randomized to the PE condition.

(5) Treatment gains would be maintained by three months post treatment.

RESULTS

Sample Characteristics

Twenty two couples responded to recruitment efforts by participating oncologists and one community psychiatrist. Of these, seven couples were excluded for the following reasons; three had cancers other than breast or had advanced stages; one had a comorbid psychiatric illness; one was still undergoing adjuvant chemotherapy and two were not considered maritally distressed according to DAS norms and criteria. Fifteen couples met inclusion criteria and were enrolled in the study. Two couples dropped out prior or close to treatment midpoint due to medical reasons (one patient had a relapse while both mothers of the second couple became diagnosed with terminal breast cancer) and were unable to commit to therapy sessions. The male partner of one couple was unable to accompany his partner for more than 50% of treatment sessions, due to job commitments. This couple was therefore excluded from analyses due to ambiguity in the nature of the intervention (i.e. individual vs. couple therapy). The data presented in this study was based on twelve couples, 9 of which were randomized to EFT and 3 were randomized to PE. The mean age of wives was 54.8 years (range: 44-69; *S.D.* 6.6); and the mean age of husbands was 57.6 (range: 44-72; *S.D.* 8.4). Couples were all married for an average of 28.9 years (range: 14-40; S.D. 6.9) and had an average of 2.1 children (range: 1-4, S.D. 1). The average annual income was $ 94,915 (range: $ 32,000-$111,000, S.D. $ 31,046). Average age of wives at diagnosis was 48 years (range: 36-61; S.D. 6.88). The average time elapsed since diagnosis was 3.4

years (range: 1-10; S.D. 2.5). All twelve couples were Caucasian, 11 were English speaking, 1 was bilingual, and received treatment in French.

Treatment Fidelity

A checklist of therapist interventions used in previous studies was used to assess adherence to protocol in both EFT and PE conditions (Dandeneau et al., 1994; Johnson et al., 1985a; Johnson et al., 1997). The checklist consisted of eight interventions specific to EFT, and eight ones non-specific to EFT. Two graduate students were offered three hours of training consisting of reviewing the EFT manual, checklist of interventions and a practice coding session using five sessions previously coded by the principle investigator. Once an inter-rater reliability coefficient of 0.80 was reached, raters were randomly assigned five sessions from couples' treatment sessions. Raters screened a 10 minute segment twenty minutes into each taped session. Eighty five percent of therapist statements in the EFT condition were coded on the checklist as EFT interventions, while only 20% of therapist statements in the PE sessions were considered EFT interventions.

Changes in Attachment Security

Attachment security was stable during baseline for all couples. Following treatment, 2 out of 9 women (couples 2 and 6) who received EFT experienced greater attachment security towards their respective spouses. In both instances, preoccupied or anxious attachment, was endorsed at study entry, as the most habitual form of coping. No changes in attachment security emerged in dyads assigned to the PE condition.

Visual Inspection of Treatment Trends

Graphic representations of treatment effects on dyadic adjustment are illustrated in Figure 1 for each of the 12 couples. Couples 1 to 9 received EFT, while couple 10 to 12 received PE. Treatment effects on mood disturbance, trauma symptoms and quality of life are illustrated in Figures 2, 3 and 4, respectively and are included in Appendix A. For mood disturbance and trauma symptoms, separate trends were derived for each partner in a respective dyad and represented on one graph for comparative purposes.

Data collected at baseline for dyadic adjustment was fairly stable, with no indication of spontaneous improvement. Visual inspection of graphs for couples who underwent EFT treatment revealed three distinct patterns. The first pattern characterized by couples 2, 4, 6, and 8 was an overall upward treatment trend relative to the projected celeration line, indicative of improvement in dyadic adjustment. Couple 6 showed a sharp increase in DAS scores after the first session. Though such an immediate and strong effect would confer strong evidence for treatment efficacy, a latency period was expected in this type of psychotherapy research before improvements were to be seen. Such immediate effects were, therefore, taken to be likely a reflection of optimism of treatment initiation, versus a real treatment effects. The second pattern revealed by couples 1 and 7 was an upward, but shallow, trend relative to the celeration line, indicative of improvement, albeit more modest. The third pattern observed in couples 3, 5, and 9 was a flat or stationary trend close to the celeration line, indicative of no treatment response. Relative to couples treated with EFT, couples 10 and 12, assigned to the PE condition showed a stationary treatment trend close to the celeration line, indicating no improvement. Couple 11 showed an apparent deterioration. This was attributable to significant medical set-backs that this couple experienced during the course of their participation in the study, which exacerbated problems identified at pre-treatment.

Compared to dyadic adjustment, data collected at baseline for mood disturbance revealed some fluctuation in female partners of couples 1, 3, 6, 7, and 8. Some variation on this measure was expected in large part due to the nature of the construct being measured – mood, where some individuals may be more prone to normal variations inherent to mood. Couples 1, 3, and 10 showed an upward trend, indicating deterioration in mood during baseline. Couples 7 and 8 showed a downward trend, indicating improvement in mood. It has been suggested that the act of seeking and finding a source of psychotherapeutic treatment might in itself account for changes in mood (McNair, Lorr & Droppelman, 1992). Out of the 9 couples who underwent EFT, visual inspection of graphs reveals a general downward treatment trend for 7 couples, indicative of improvement in mood (couples 1, 2, 3, 4, 6, 8, and 9). A downward treatment trend was observed in the male partner of couple 5, but not the female partner. Couple 7 evidenced a stationary trend, indicative of no change. In contrast, couples 10, 11 and 12, who underwent PE evidenced a general upward treatment trend, indicative of greater mood disturbance. It is of note that couple 10 and male partner of couple 12 evidenced flat treatment trends close to the respective celeration lines, indicating floor effects.

Data collected at baseline for trauma symptoms was largely stable across couples, with the exception of some variation in female partner of couple 6 and male partner of couple 7, who evidenced a downward trend, indicative of some improvement during baseline. Visual inspection of graphs for couples who underwent EFT revealed a downward treatment trend for 4 couples (1, 7, 8 and 9), and the female partner of couple 2, indicative of improvement in trauma symptoms. Female partners of couples 4, and 6 showed the following trend: an exacerbation of trauma symptoms during treatment, which decreased by treatment termination to levels lower or close to baseline. Of the couples who received PE, couple 10 evidenced a stationary treatment trend, couple 11

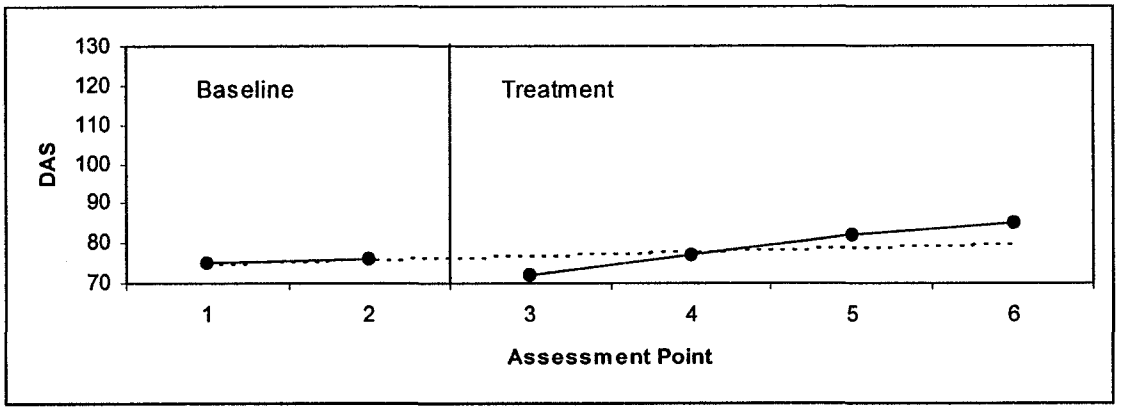
showed a downward trend, indicative of some improvement as did the female partner of couple 12.

Quality of life data collected at baseline was also fairly stable. This measure was only administered to women. Visual inspection of graphs of women who received EFT revealed an upward treatment trend for 6 women (of couples 1, 2, 4, 6, 8 and 9), indicating improvement on this measure of quality of life. A stationary trend was seen for the remaining 3 women who received EFT (couple 3, 5 and 7), indicating no changes. All three 3 women randomized to the PE condition evidenced a stationary treatment trend, indicating no changes on this measure.

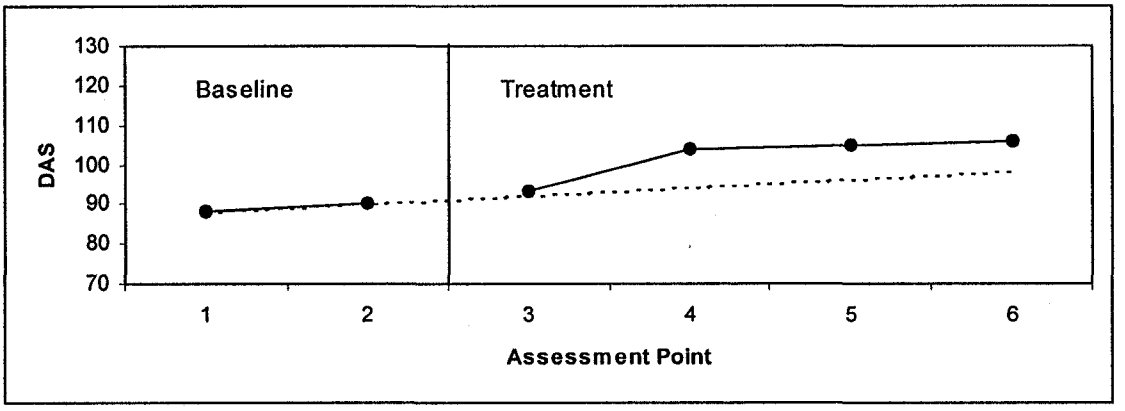
Figure 1. Combined DAS scores for each couple. Key: Baseline A couples: 3 = after first session, 4 = treatment mid-point, 5 treatment completion, 6 = 3 months follow-up, Baseline B and D couples: 4 = after first session, 5 = treatment mid-point, 6 treatment completion, 7 = 3 months follow-up, Baseline C couples: 5 = after first session, 6 = treatment mid-point, 7 treatment completion, 8 = 3 months follow-up.

Baseline A:

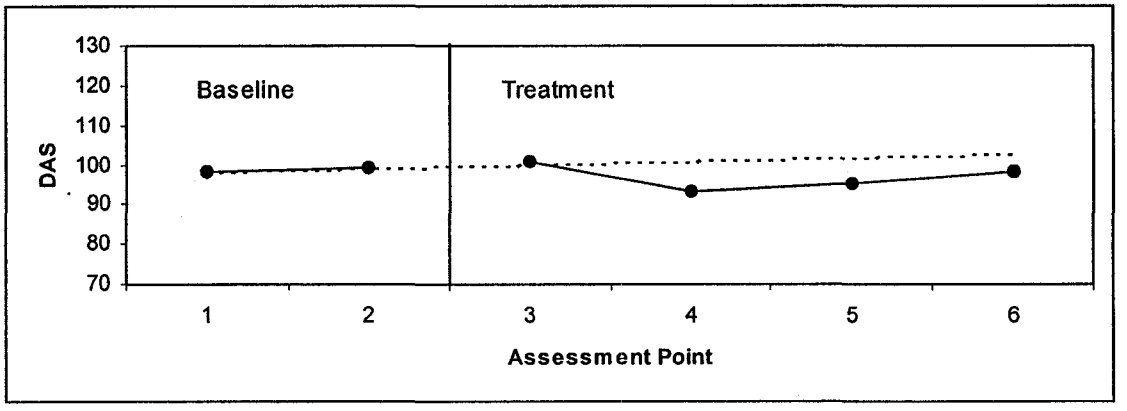
Couple 1



Couple 2

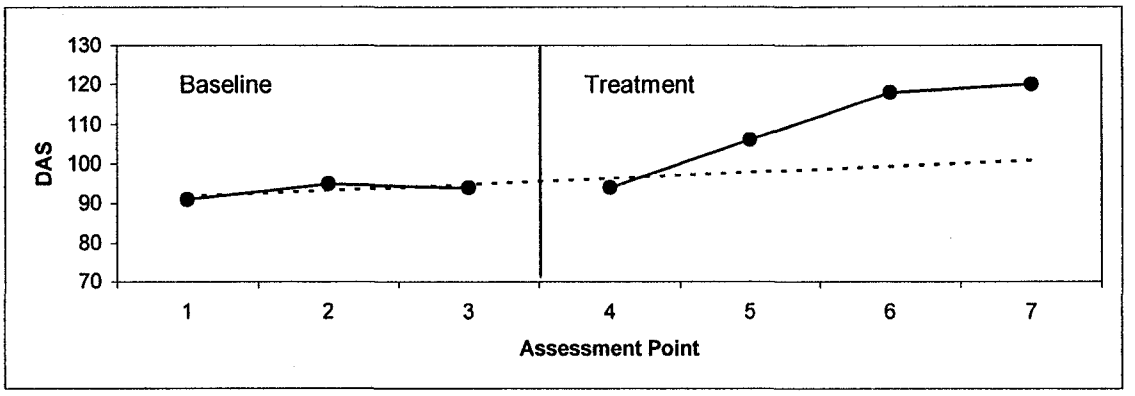


Couple 3

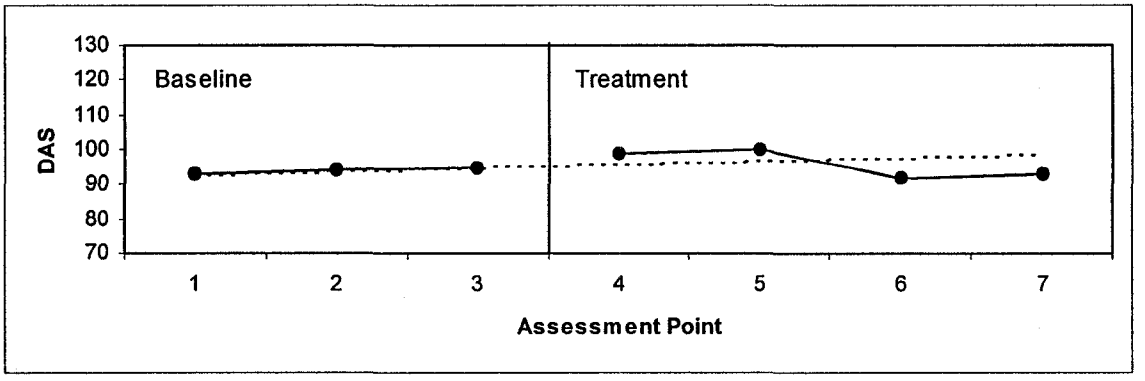


Baseline B:

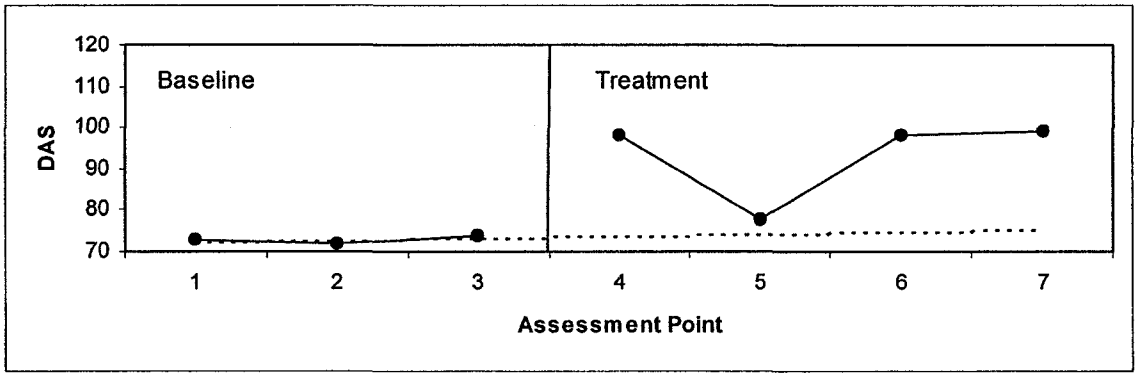
Couple 4



Couple 5

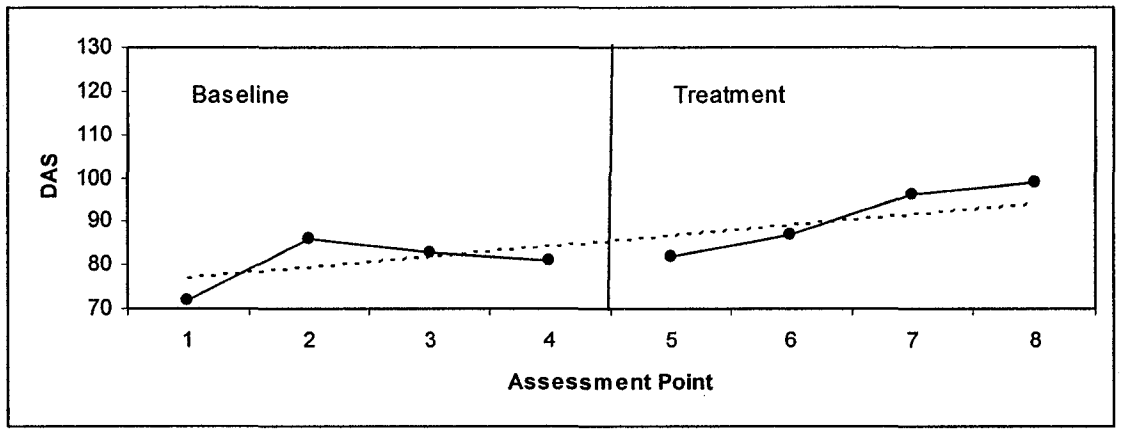


Couple 6

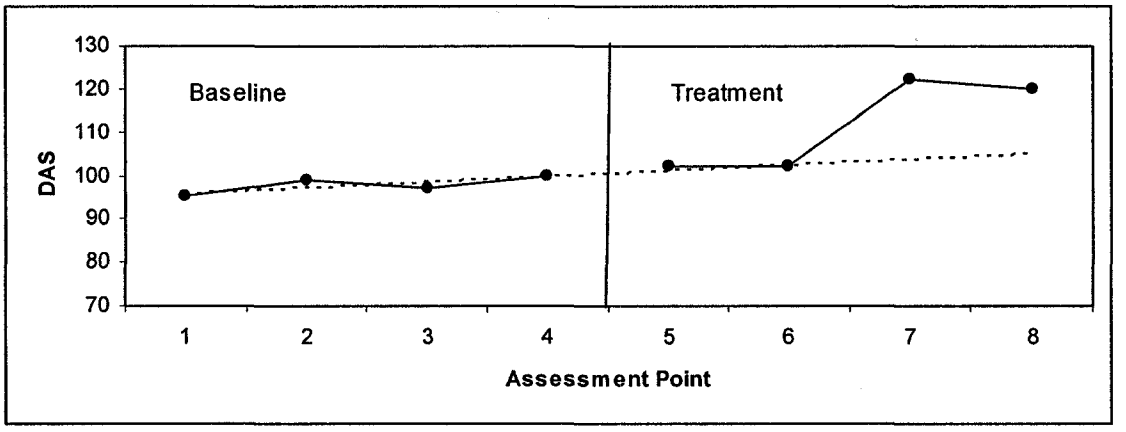


Baseline C:

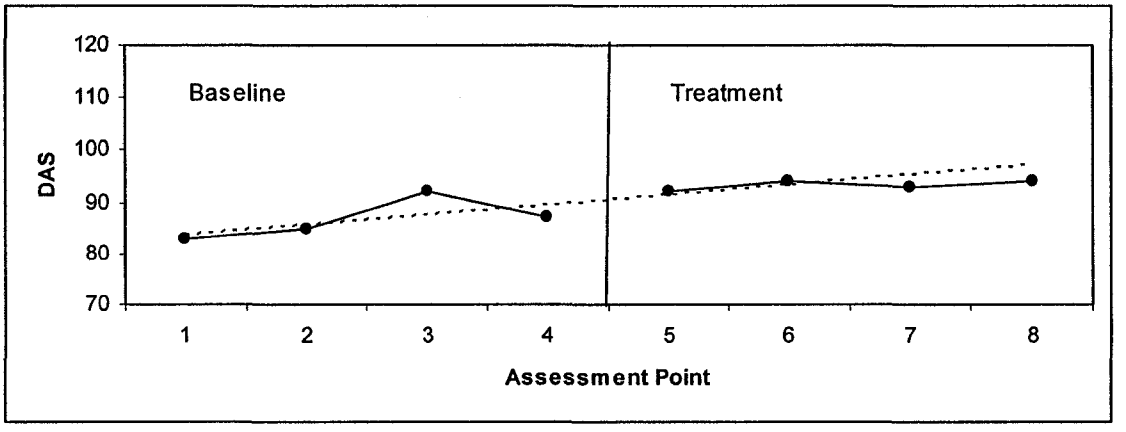
Couple 7



Couple 8

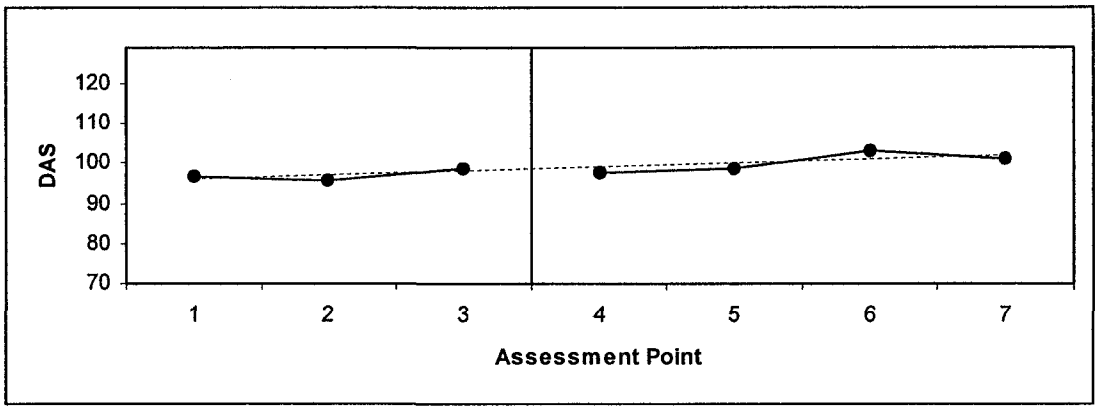


Couple 9

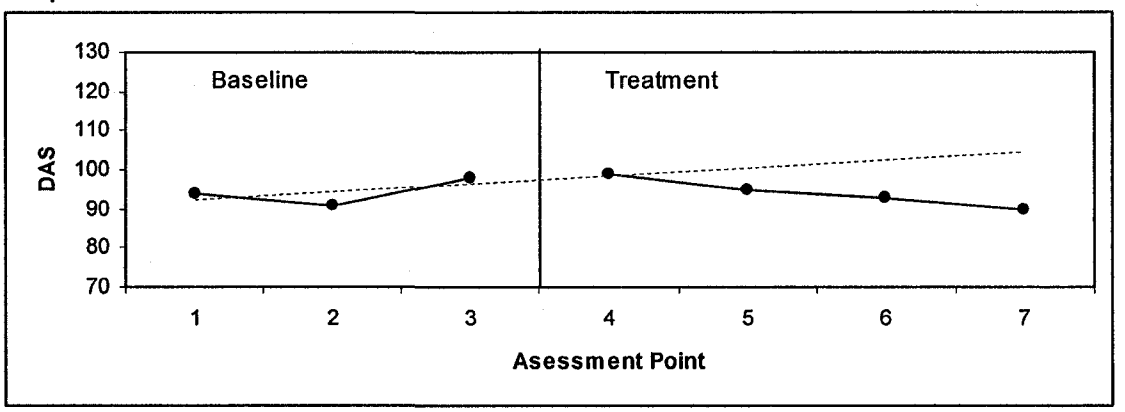


Baseline D: (Control)

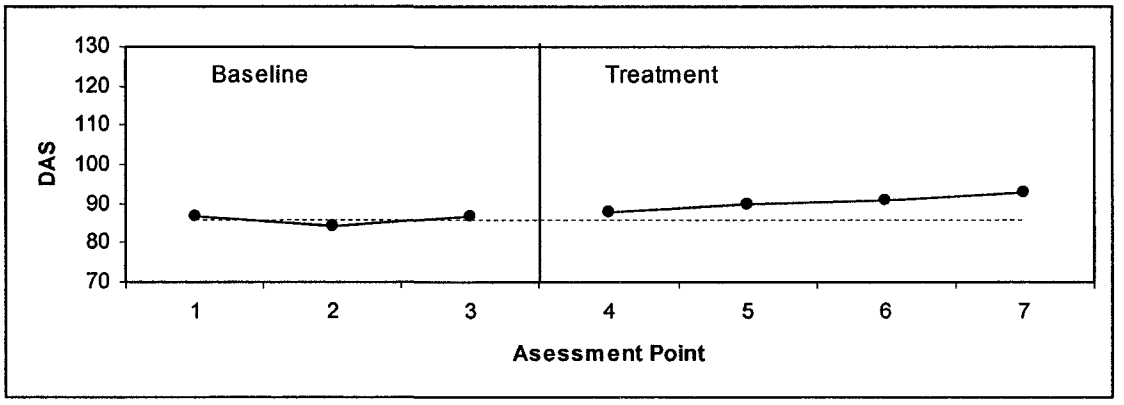
Couple 10



Couple 11



Couple 12



Statistical Significance of Treatment Trends

To corroborate visual inspection of graphic representations, a binomial test was applied to treatment trends judged to have departed from the projected celeration line, indicating a possible treatment effect. This method is fully described by White (1972) and Kazdin (1982, 1984) Statistical findings are summarized in Table 2. Out of the nine couples who received EFT, gains in dyadic adjustment reached statistical significance at $p=0.06$ for four couples (2, 4, 6, 8). The gains observed in couples 1 and 7 by visual inspection alone were not statistically different from the celeration line ($p>0.06$).

For mood disturbance, three out of the nine couples (2, 4, 6) who received EFT showed statistically significant reductions in mood disturbance, consistent with visual inspection. For couples 1, 3, and 9, only female partners showed statistically significant reductions in mood disturbance ($p=0.06$). Similarly, male partners of couples 6 and 8 showed a statistically significant reduction in mood disturbance ($p=0.06$).

Two out of the nine couples assigned to the EFT condition evidenced statistically significant reductions in trauma symptoms (couples 4 and 8), as did the male partner of couple 6 and female partners of couple 2 and 9 ($p= 0.06$).

On quality of life, seven of the female participants who received EFT evidenced statistically significant gains that were associated with treatment ($p=0.06$), while treatment trends of couples 5 and 8 did not reach statistical significance. Consistent with visual analyses, none of the three couples who received PE showed no statistically significant treatment effects on any of the four measures ($p>0.06$).

Table 2. Summary of statistical significance of treatment trends on outcome measures. Key: '=' indicates a treatment trend that did not depart from the celeration line, showing a stationary trend, '*' indicates statistically significant, 'ns' indicates a non significant finding, '↓' indicates decrements

Couple	Statistical significance of treatment trends relative to celeration lines			
	DAS	POMS	DTS	FACT-B
1 Female Male	ns	0.06* =	0.06* =	0.06*
2 Female Male	0.06*	0.06* 0.06*	0.06* 0.06*	0.06*
3 Female Male	↓ 0.06*	0.06* ns	ns ns	0.06*
4 Female Male	0.06*	0.06* 0.06*	0.06* ns	0.06*
5 Female Male	=	ns 0.06*	ns 0.06*	↓ 0.06*
6 Female Male	0.06*	0.06* 0.06*	ns 0.06*	0.06*
7 Female Male	ns	ns =	0.06* ns	0.06*
8 Female Male	0.06*	ns 0.06*	0.06* 0.06*	ns
9 Female Male	=	0.06* =	0.06* =	0.06*
10 Female Male	=	ns =	ns =	ns
11 Female Male	↓ 0.06*	ns ns	ns 0.06*	ns
12 Female Male	ns	ns ns	0.06* ↓0.06*	ns

Clinical Significance of Treatment Changes

Pre-treatment scores for each measure administered to participants were derived using the mean average score of data collected during baseline for each participant per respective measure. For the DAS, the mean average of combined scores from both partners of a dyad collected during baseline was used. The difference between pre-treatment and post treatment scores was calculated and divided by the standard error of difference, as described by Jacobson and Traux (1991). Using a 95% confidence interval, as the criterion for significant treatment effects, the following RCI's and normative cut-off points were established for the respective measures; a 7 point increase on combined DAS scores and a post treatment score above 98 points; a 40 point reduction on the POMS and post treatment score below 30 points; a 30 point reduction on DTS and posttreatment score below 40; and a 10 point increase on FACT-B. Table 3 summarizes the findings.

According to clinical significance criteria, a total of 5 couples (2, 4, 6, 7, and 8) made clinically meaningful gains on the DAS, all the female partners of which also evidenced clinically significant reductions in total mood disturbance on the POMS and total trauma symptoms on the DTS. Moreover, clinically meaningful gains were observed on the FACT-B for all these women. Out of these 5 couples, only 2 men made significant shifts on the POMS and DTS, while two had made clinical gains, post treatment scores still fell within the distressed range, indicating improvement, but not recovery. Two couples (1, 9), while still experienced marital difficulties, as measured by the DAS, evidenced clinically significant reductions on the POMS, DTS, and clinically important gains on the FACT-B. No clinically important changes were detected in two couples (3, 5) on any of the measures.

Compared to couples who received EFT, none of the couples assigned to PE showed any clinically significant gains on any of the outcome measures.

Table 3. Clinical significance of outcome measures. Key: "-" indicates non-significant findings due to floor effects on measures (indicating no distress at pre-treatment), '*' met both criteria for CS only at 3 months follow-up

Couple	Clinical significance criteria for outcome measures			
	DAS (>98 points)	POMS (<40 points)	DTS (<30 points)	FACT-B (>10 points)
1	No			
Female		No	-	Yes
Male		-	-	
2	Yes			
Female		Yes	Yes	Yes
Male		No	-	
3	No			
Female		No	No	No
Male		No	No	
4	Yes			
Female		Yes	Yes	Yes
Male		No	No	
5	No			
Female		-	No	No
Male		-	No	
6	Yes			
Female		Yes	-	Yes
Male		Yes*	Yes	
7	Yes*			
Female		-	Yes	Yes
Male		-	-	
8	Yes			
Female		Yes	Yes	Yes
Male		Yes	Yes	
9	No			
Female		Yes	Yes	Yes
Male		-	-	
10 (PE)	No			
Female		-	-	No
Male		-	-	
11 (PE)	No			
Female		No	No	No
Male		No	No	

12 (PE) Female Male	No	No -	No -	No

Sub-scale Analyses

Clinically significant treatment trends were followed up by sub-group analyses using aggregate mean scores. Wilcoxon signed rank t tests, the non-parametric equivalent of a paired t-test, were performed between aggregate score means at baseline and treatment completion for the various sub-scales comprising the POMS DTS and FACT-B, respectively. Results for the POMS, DTS and FACT-B subscales are shown in Tables 4, 5 and 6, respectively in Appendix A. Analyses indicated a significant decline in tension or anxiety ($Z = -2.35$, $p=0.02$), depression ($Z = -2.36$, $p=0.02$), anger ($Z= -2.37$, $p = 0.02$) and confusion ($Z=-2.12$, $p=0.03$). Declines on symptoms of intrusion, avoidance and hyperarousal were not statistically significant. Statistically significant gains emerged on Physical Well being ($Z = -3.02$, $p=0.043$), Social Wellbeing ($Z=-2.03$, $p= 0.043$), Emotional Well being ($Z= -2.34$, $p = 0.018$), and Functional Wellbeing ($Z=-2.37$, $p = 0.018$). No statistically significant differences were found on the symptom subscale specific to breast cancer patients (Other).

Stability of Clinical Changes

Wilkoxon signed rank tests were carried out between aggregate score means of all 9 couples in the EFT condition on each of the four outcome measures at treatment completion and three month follow-up. The mean ranks of DAS ($Z=-2.68$, $p = 0.002$) and FACT-B ($Z=-2.49$, $p = 0.01$) scores were not equivalent at these two assessment points. Inspection of mean differences on these two measures indicated that, in addition to an absence of relapse, there was continued improvement in marital adjustment and quality of life, past treatment completion. The mean ranks of POMS ($Z= -0.87$, $p=0.39$)

and DTS (Z= -0.652, p=0.51) scores from treatment completion to follow-up were equivalent, indicating no relapse and persistence of treatment gains.

DISCUSSION

This study is the first to evaluate the efficacy of Emotionally Focused Therapy (EFT) on the reduction of marital distress and improvement of psychological well-being in married couples who have faced localized breast cancer. A multiple baseline design across couples was used with the inclusion of a control group, who received psychoeducation in didactic format. Firmly rooted in attachment theory, EFT conceptualizes marital distress as stemming from unmet attachment needs in the face of crisis, which give rise to absorbing states of negative emotions and dysfunctional interaction cycles, ultimately undermining adjustment and coping. Change is brought about in EFT by promoting more secure emotional bonding within the dyadic unit, such that partners are both able to self-regulate and help the other self-soothe during vulnerable times. A reciprocally determined process was targeted simultaneously during treatment in order to promote adjustment.

Attachment styles, conceptualized as coping strategies employed in close relationships, were hypothesized to shift towards greater security, following EFT. This hypothesis was partially supported, with two of the nine couples who received EFT evidencing more secure attachment in female partners by treatment completion, a clinically relevant change which persisted to three months post treatment. In contrast, none of the couples in the control group evidenced any changes in levels of attachment security. Both women in the EFT condition who endorsed greater attachment security also evidenced recovery on all outcome measures; dyadic adjustment, mood disturbance, trauma symptoms and quality of life; a finding that is in keeping with associations coined in the literature between greater attachment security and higher

marital satisfaction (Kobak & Hazan, 1991) and more positive emotions (Collins, 1996). Interestingly, for both couples who didn't respond to treatment, dismissive attachment, was endorsed by women, as their predominant coping style.

The finding that 2 couples made shifts towards greater attachment security by treatment completion was somewhat surprising, as such changes were not expected to be obtained before three months post treatment. The evidence for EFT's success in reducing marital distress (Johnson et al., 1999) is much more robust relative to existing data supporting its role in increasing attachment security (Makinen & Johnson, 2006). This is because increases in attachment security, manifested in habitual ways of relating, would be expected to evolve over longer periods of time extending past treatment completion and involve repeated affiliative behavior and deeper levels of emotional experiences within the dyadic unit before such internalizations of secure attachment may be incorporated (Davila et al., 1999). One explanation which may account for the noted increases in attachment security observed in two women of this study relates to treatment length. Specifically, couples in this study received a total of 20 sessions; nearly double the typical treatment 'dose' offered to maritally distressed couples in the context of other outcome studies (e.g. Goldman & Greenberg; Johnson & Greenberg, 1985a, 1985b; Makinen & Johnson, 2006). Treatment length may, therefore, be a possible mediator of change in attachment security by providing greater opportunity for couples to enact positive interactions, with the guidance of a therapist, which, in turn, promotes an inner sense of felt security, facilitating internalizations of such experiences. This explanation, however, does not account for the other 3 couples who recovered on clinical measures by treatment completion, without evidence of any concomitant increase in attachment security. Such discrepancy may either be due to the existence of significant differences in variables related to therapeutic processes (e.g. therapist interventions; degree of affiliative behaviors, levels of experiencing in therapy), or may

simply be attributed to a type I error. Predominant styles of relating, which impinge directly on emotional regulation and adjustment is a relevant clinical question. The findings reported in this study with respect to increases in attachment security represent a novel finding, and require further replication in a study that links outcome to treatment process. This may bear directly on treatment implications either with respect to type of interventions employed by the EFT therapist or length of treatment requirements.

With respect to the main outcome variables; consistent with predictions; EFT had a positive impact on total mood disturbance, trauma symptoms and quality of life. Specifically, less mood disturbance and trauma symptoms and higher quality of life were reported by women who were coupled to partners, whose combined dyadic adjustment was normative following EFT. These effects were also seen in 2 out of the four couples who had not recovered on dyadic adjustment, per se. Qualitative comparisons of these four couples indicated older age and existence of family support for women in those two couples who had evidenced some shifts on mood disturbance, trauma symptoms, and quality of life without accompanying gains on dyadic adjustment. Such patterns, however, were not observed for men. An explanation for these discrepant findings across genders is offered in the literature, specifically related to the notion that men are less likely to seek external sources of support (e.g. family, friends, coworkers), whereas women typically have wider social networks outside a marriage, (Edwards et al., 1999).

Sub-group analyses further indicated a positive impact of EFT on depressive symptoms, anxiety and feelings of anger, as well as improvement in functional, emotional, physical and social wellbeing. Though a reduction in total trauma symptoms emerged in couples who underwent EFT, sub-group analyses failed to differentiate between specific symptoms (e.g. avoidance, hyperarousal, intrusion), that which may possibly be a function of limited sensitivity of the assessment measure used.

Compared to couples in the EFT condition, no clinically relevant changes were seen on any of the outcome measures of couples assigned to the control condition. The relative deterioration on mood disturbance observed in two of the three couples was attributed to medical setbacks (i.e. discovery of a new breast mass, and diagnosis of multiple myeloma) that had occurred while couples were enrolled in the study. This is relevant to mention in order to distinguish between natural reactions to medical events versus an 'adverse reaction' to conditions in the control group. In terms of maintenance of clinical gains, the impact of EFT appears to be more than just transient. Couples who had recovered on the various outcome measures at treatment completion showed no differences by three months follow-up. The same was true for couples assigned to the control condition, where no spontaneous improvement was noted.

Findings reported in this study are largely in keeping with a number of randomized clinical trials assessing the efficacy of EFT on marital distress (Johnson & Greenberg, 1985a, Goldman & Greenberg, 1991; Walker et al., 1996) and depression (Dessaules et al., 2003). More importantly, the continued improvement in dyadic adjustment observed at follow-up is consistent with previous findings by Johnson & Talitman (1997) and Walker et al., (1996), demonstrating either persistent gains or continued improvement in marital functioning post treatment. In a two year follow-up study assessing maintenance of EFT treatment gains in couples with chronically ill children yielded similar findings. This is particularly relevant in view of the similarity of the sustained stress levels faced by parents of chronically ill children and couples who have faced breast cancer.

One important difference between the current study and previous studies is the relative increase in the proportion of couples who continue to improve following treatment termination. Specifically, past outcome trials have shown clinical improvement in over 70% of couples who received EFT at three months follow-up, compared to 50%

at treatment termination (Johnson & Greenberg, 1985a, Walker et al., 1996). In the current study, just slightly over 50% of couples recovered on dyadic adjustment by three months follow-up, consistent with findings at treatment termination. The discrepancy noted between the current study and past ones was initially conjectured to have been a function of problematic dyadic adjustment endorsed by couples at study entry (pre-treatment DAS M: 87; S.D: 9; range: 73-97). More poignant was the overwhelming consensus of the treating clinicians as to the relatively high distress levels experienced by many of the study couples, as exhibited by fairly rigid interactional cycles, long-standing histories of depression, exacerbated by marital distress and the unfolding of external stressors during the course of therapy (e.g. job loss, financial strain, substance use). The small sample size inherent to this study may have further contributed to a possible selection bias rendering both the nature and degree of distress seen within this particular cohort of couples somewhat higher than has been typically the case in previous EFT outcome studies.

This study represents the first outcome study that evaluates an experientially-based treatment approach, using a research design borne out of the behavioral tradition. Multiple baseline designs incorporate several features that optimize internal validity, including each participant serving as his/her own control, replication across participants and direct inference of a treatment effect by visual inspection alone. With respect to the latter point, treatment is inferred based on immediacy, and strength of a target response following introduction of treatment. While this may be readily the case in behavioral (observable) outcomes, such immediate and dramatic changes are rarely seen in psychotherapy which targets process-oriented outcomes (e.g. dyadic adjustment) that typically evolve over time. In our research study, a latency period was expected before change was perceptible on outcome measures.

Data was analyzed using three different, but complementary approaches (visual inspection, statistical significance of treatment trends and application of RCI criteria to pre-post test scores). Findings were largely consistent across all three approaches; however some minor discrepancies did emerge. For example, visual inspection alone was associated with the most liberal findings with respect to demonstrating a treatment effect. Statistical significance, on the other hand was somewhat restrictive, but this was a direct function of the limited number of data points collected during the treatment phase (four points), which resulted in limited power to detect a treatment effect. White and Harring (1980), for example, recommends collecting at least 10 data points. Methodologically, this was not possible to implement, in view of the substantial burden it would place on patients in having to fill out lengthy assessment measures on a weekly basis, in addition to the possible practice effects/social desirability it may have induced. In order to overcome limitations inherent to the two data analytic approaches, RCI criteria were used and found to be most useful in elucidating a treatment effect.

In summary, findings from this study provide initial support for offering EFT to couples dealing with relational and emotional distress following diagnosis and treatment of early breast cancer. The present evaluation, however, is not without limitations. First, study participants were a fairly affluent, well-educated and Caucasian cohort, which may limit the generalizability of findings to minor populations and those from disadvantaged backgrounds. Secondly, women included in this study were treated for localized breast cancer and had comparatively favorable prognoses. Whether such treatment effects would replicate in a more distressed clinical population due to more serious disease requires further investigation. Thirdly, three couples randomized to the EFT condition dropped out prior to treatment mid-point, representing 25% of the treatment sample. Although there were no obvious differences between completers and non-completers on demographic characteristics, two explanations may be offered; psychotherapy may be

incompatible with ongoing acute medical events (as was the case with 2 couples who dropped out) and EFT may not be suited to all couples.

Findings from our study justify carrying out a randomized clinical trial, where treatment is replicated across a larger sample of couples dealing with varying disease stages. Elucidation of underlying mechanisms and patient characteristics associated with treatment success remains a question that requires further study. The replication of clinically significant effects seen in this study would provide an important approach to helping couples dealing with the emotional aftermath of breast cancer diagnosis and treatment.

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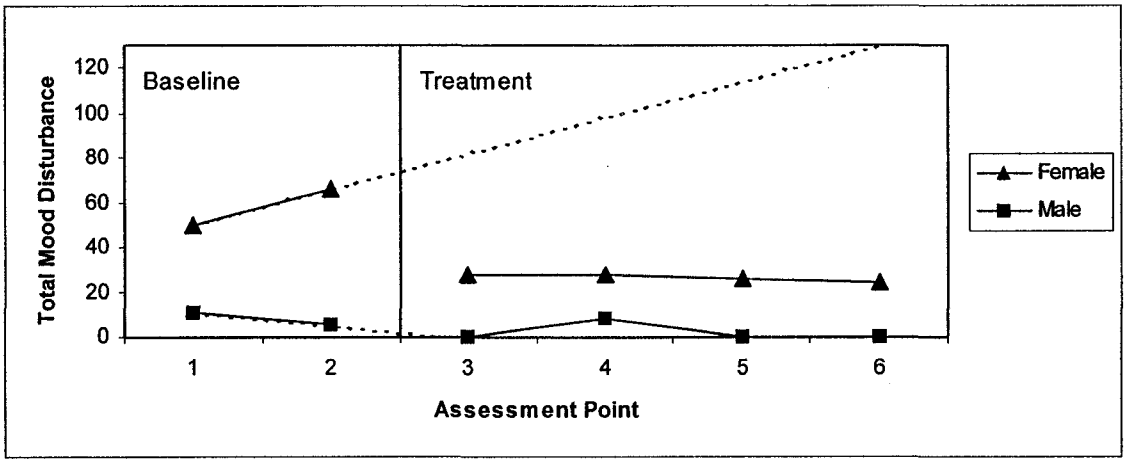
Appendix A

Figure 2. Graphic representations of treatment effects on mood disturbance

Couple 1



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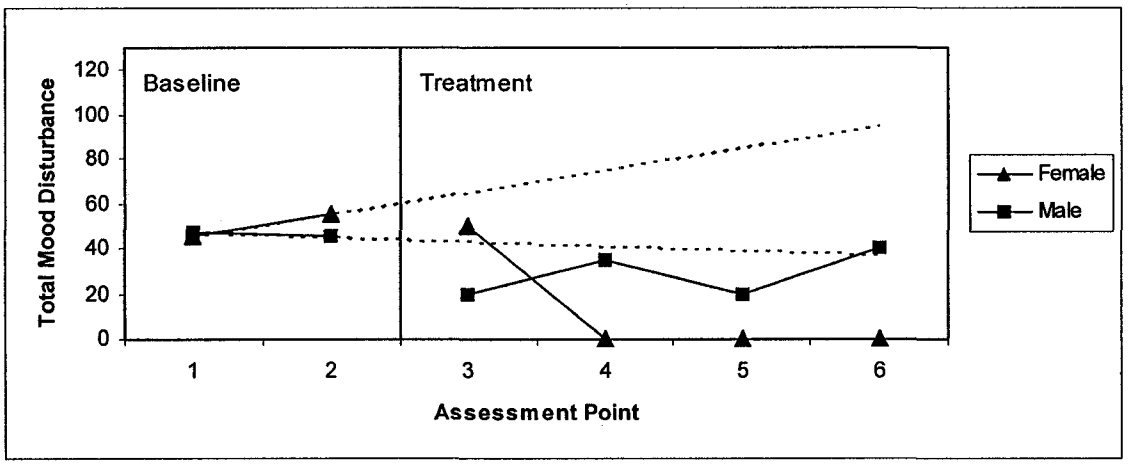

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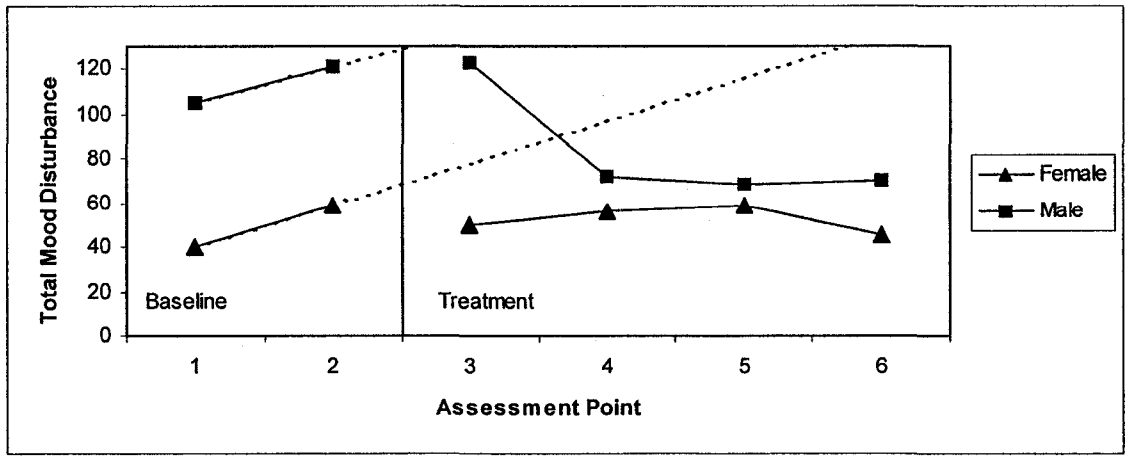

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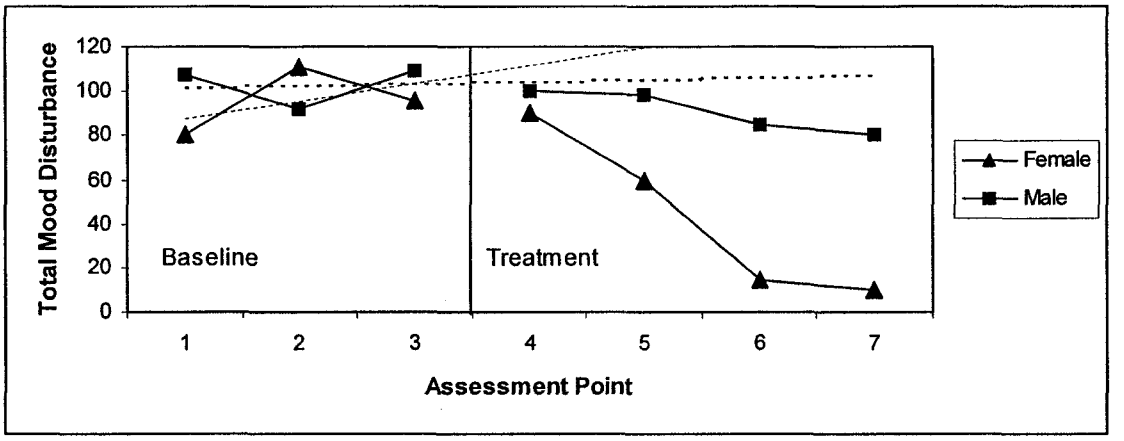

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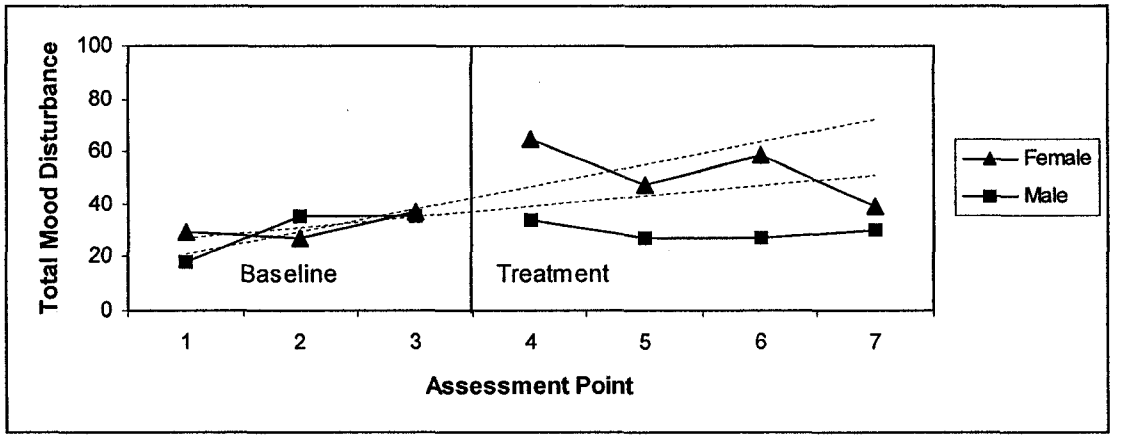

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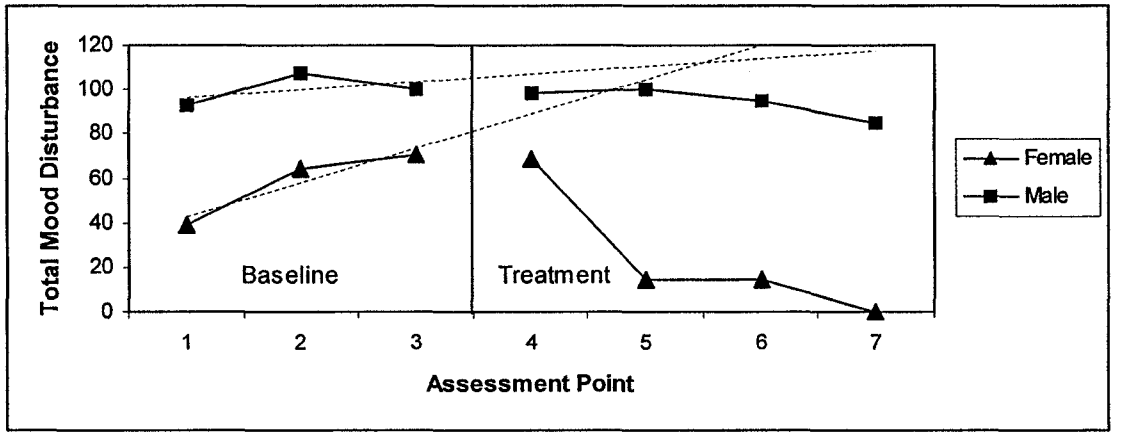

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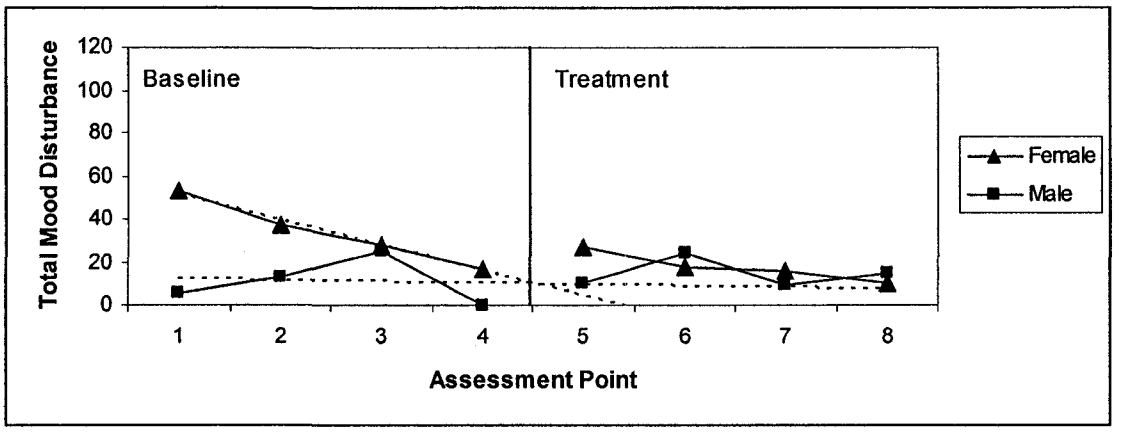

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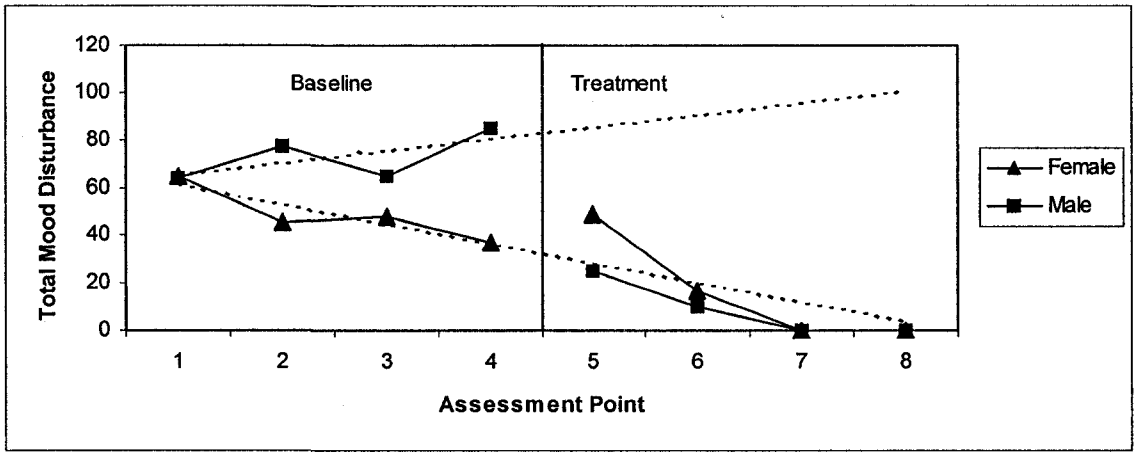
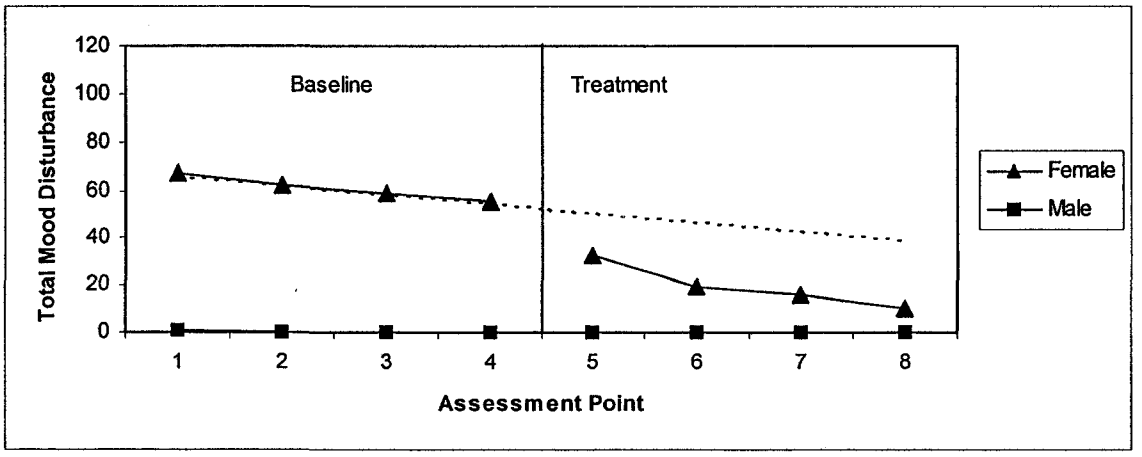
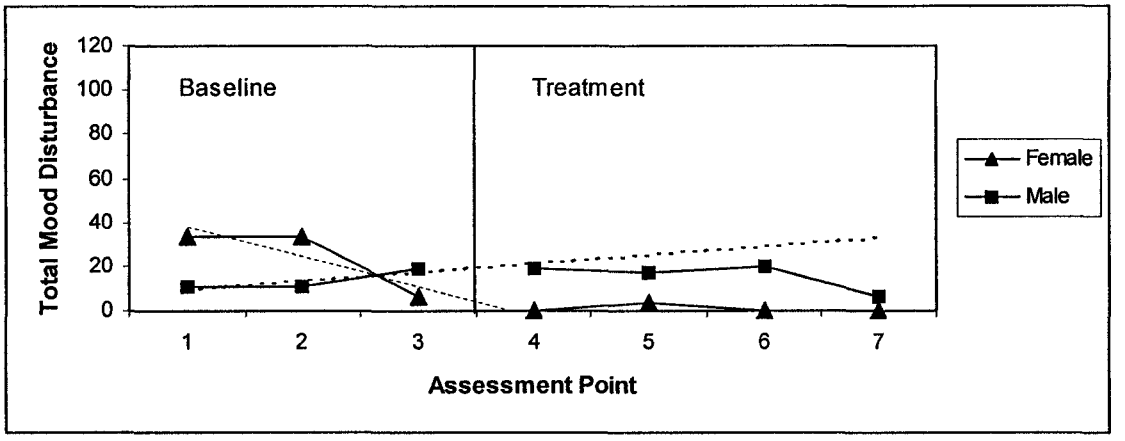


Couple 9



Couple 10 (PE)



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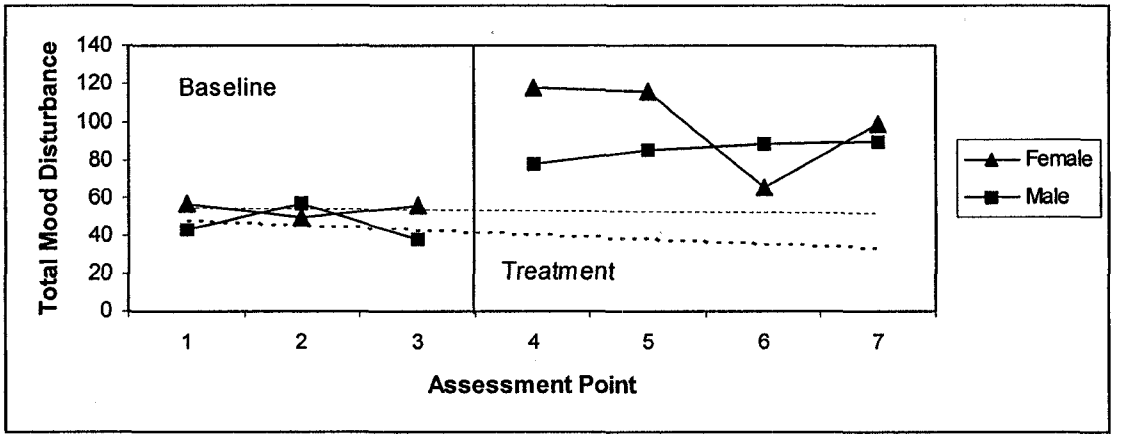


Couple 12 (PE)

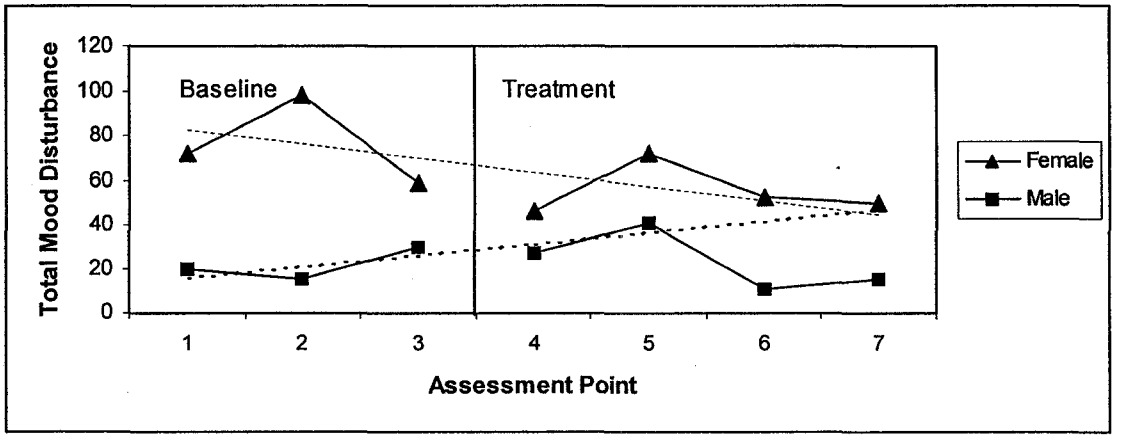
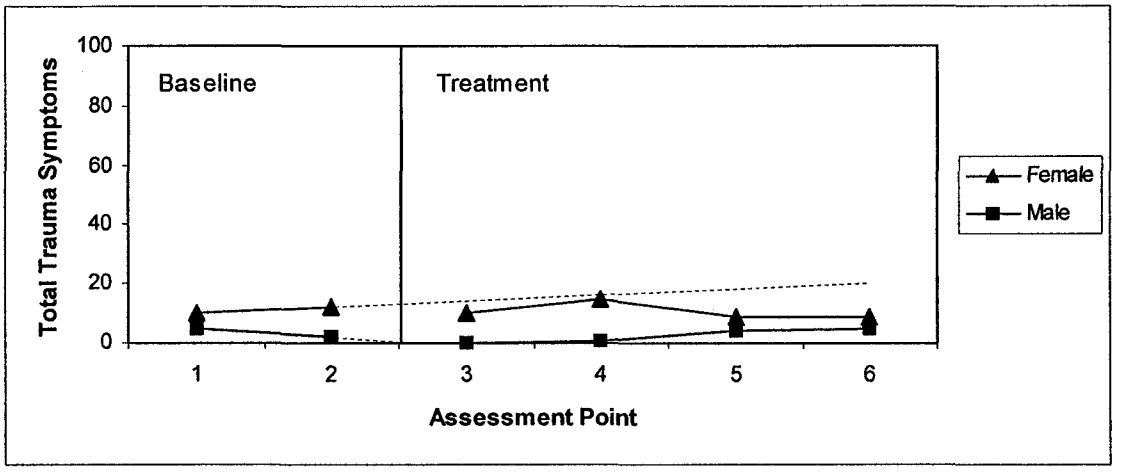
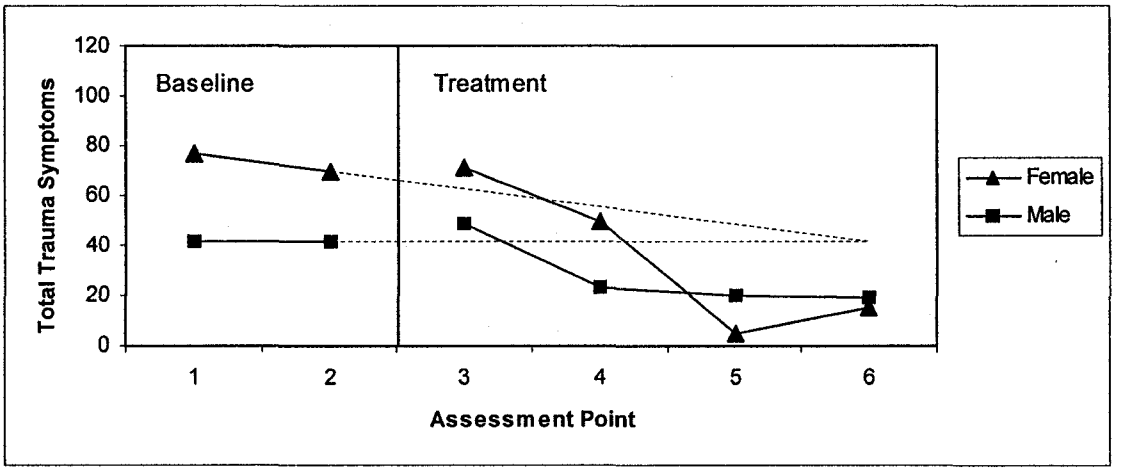


Figure 3. Graphic representations of treatment effects on trauma symptoms

Couple 1



Couple 2



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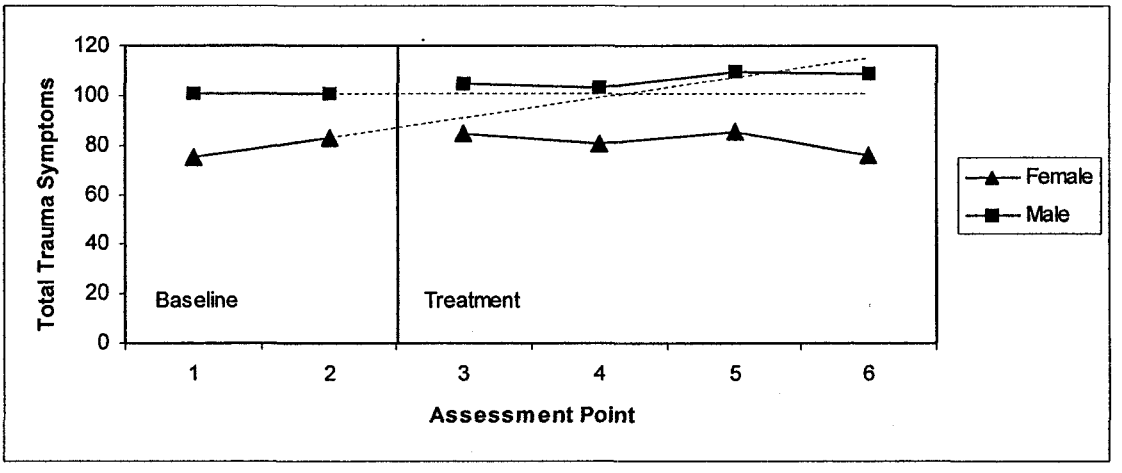

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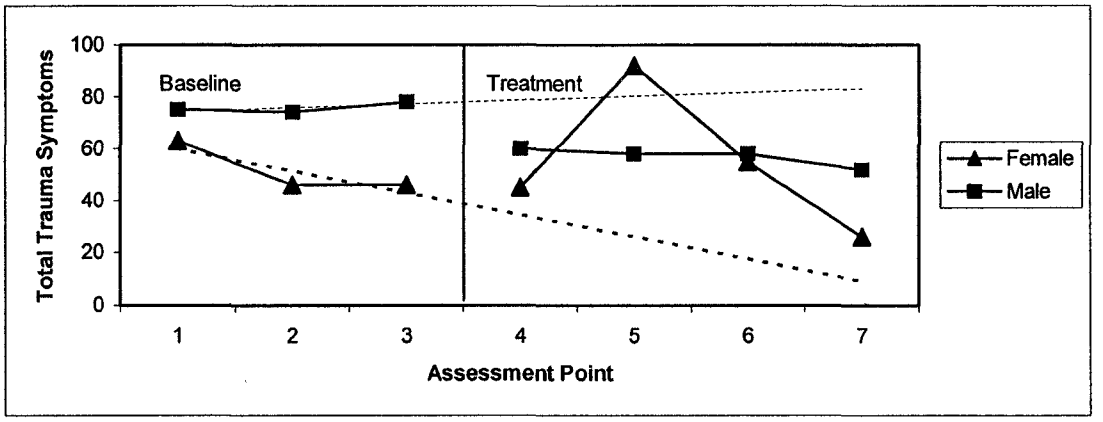

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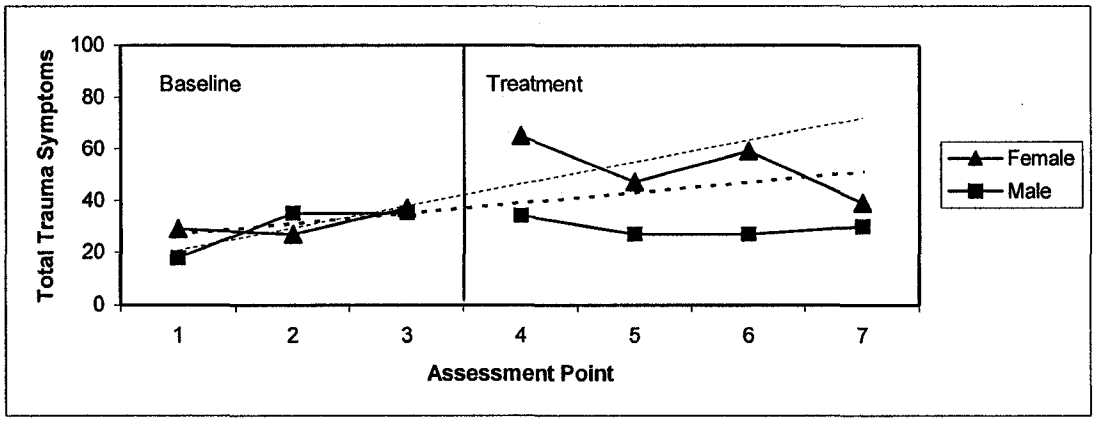

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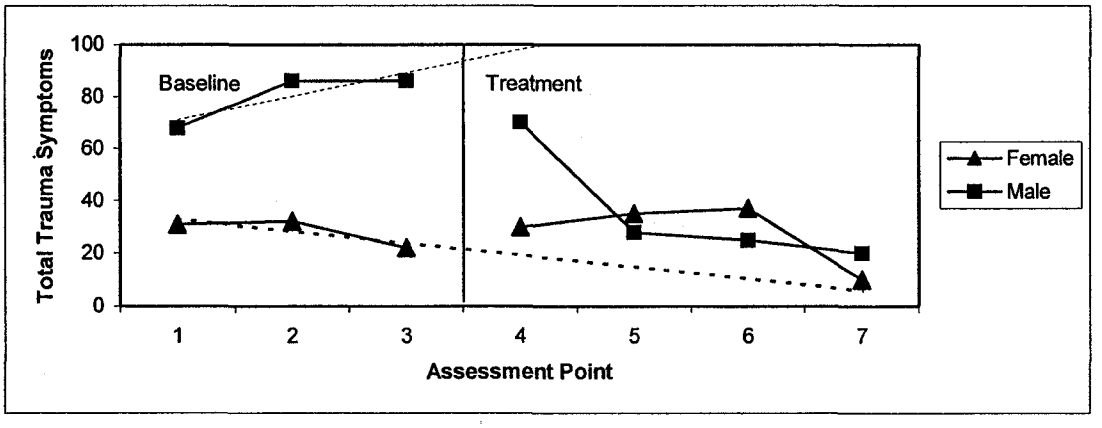

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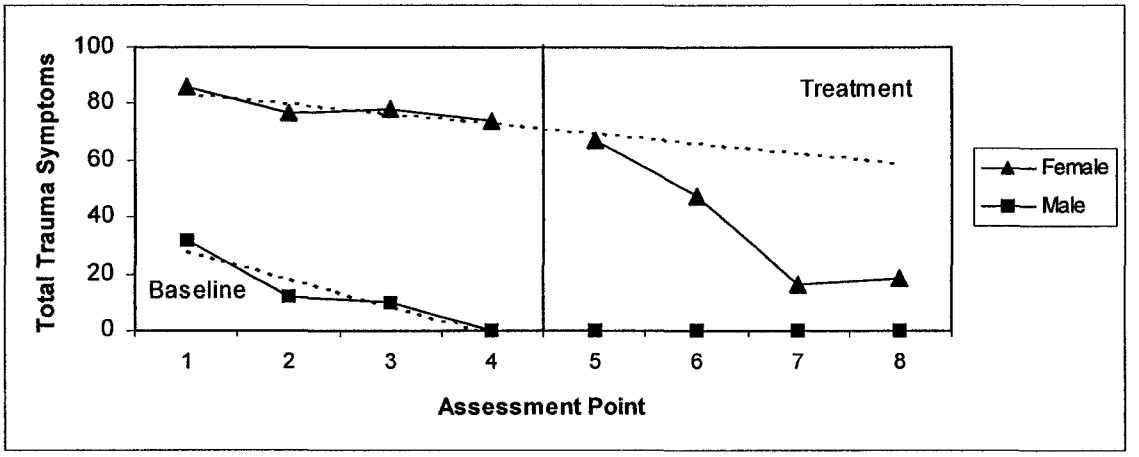

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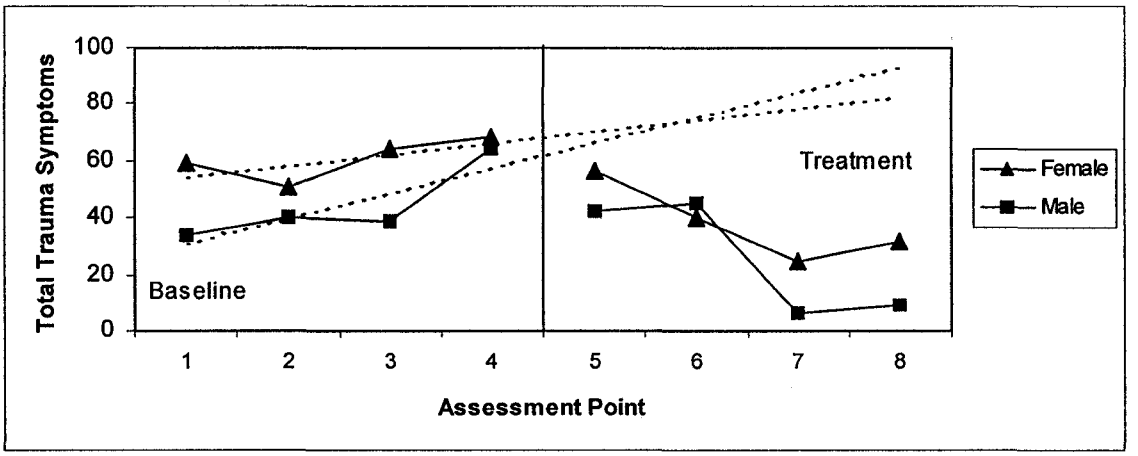

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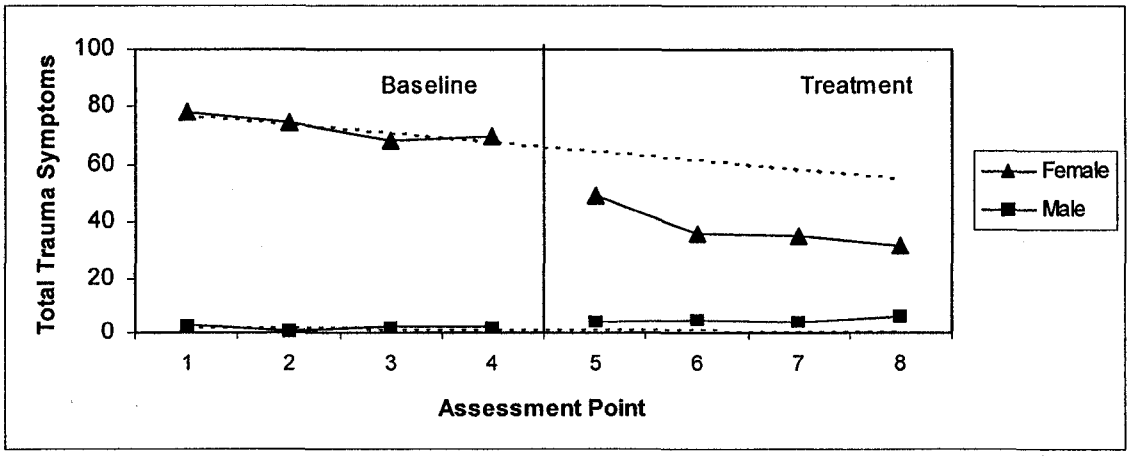

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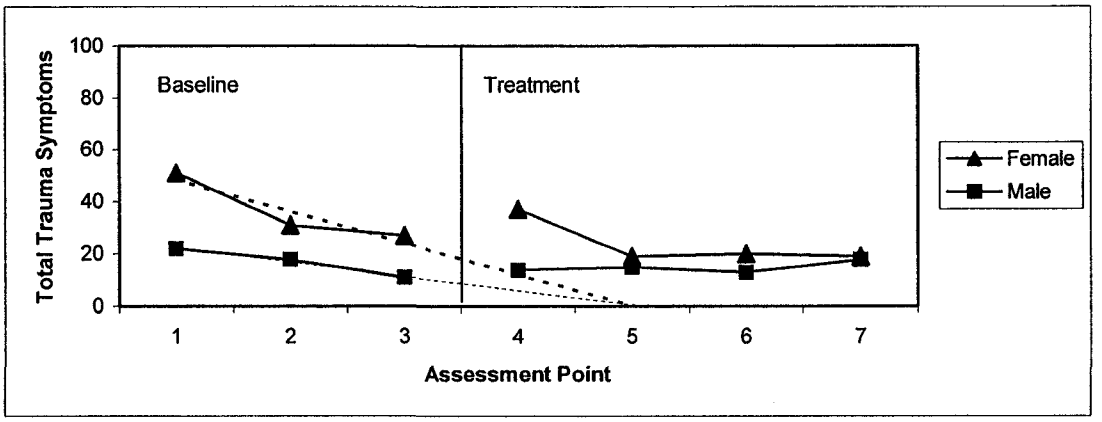

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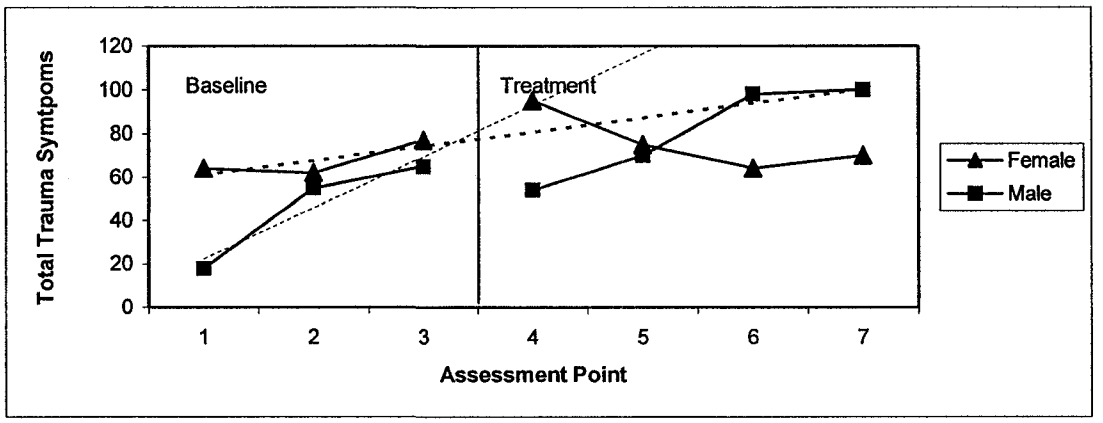

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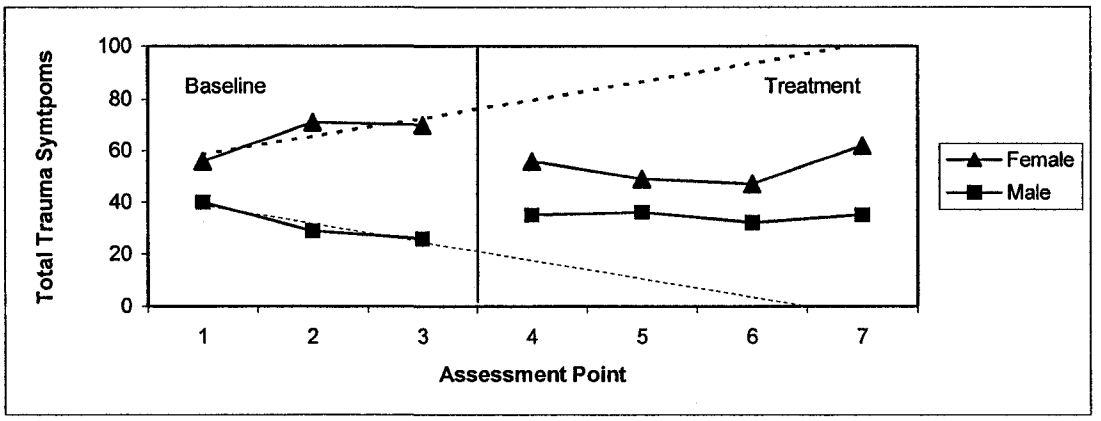
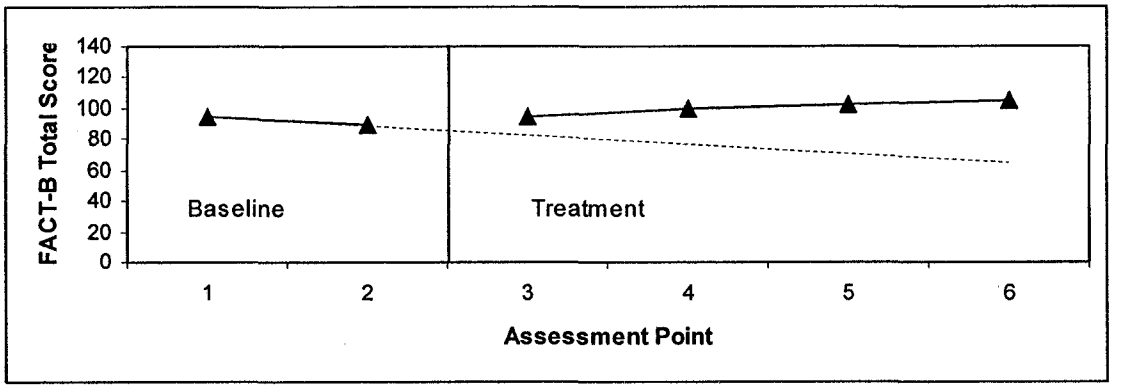


Figure 4. Graphic representations of treatment effects on Quality of life

Couple 1



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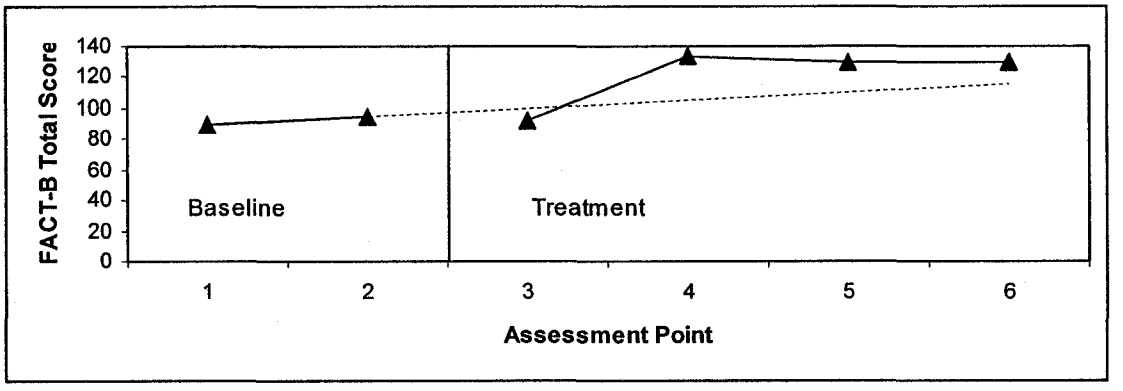

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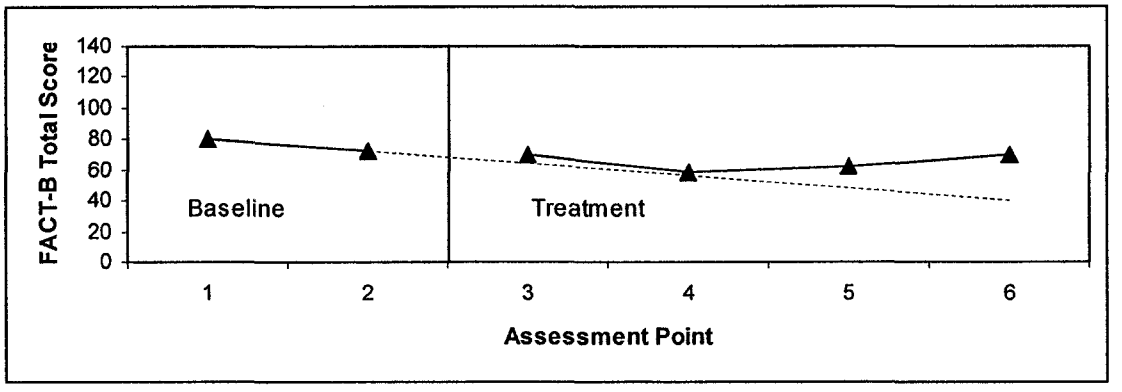

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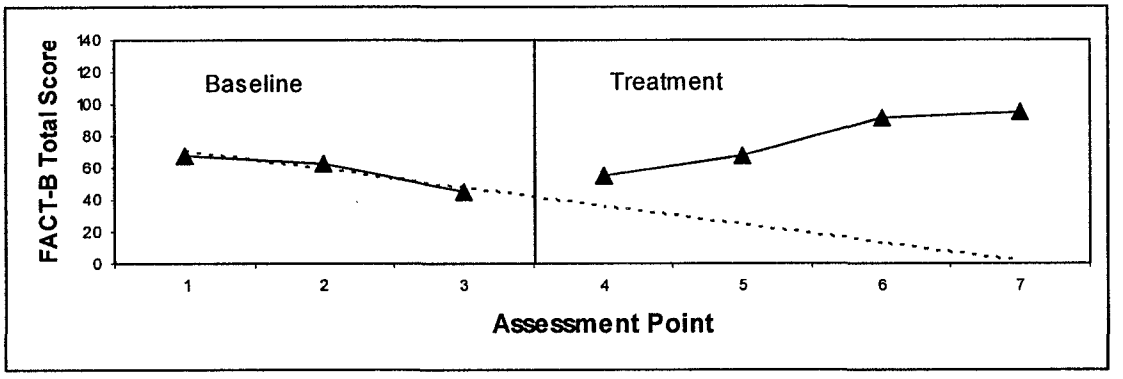

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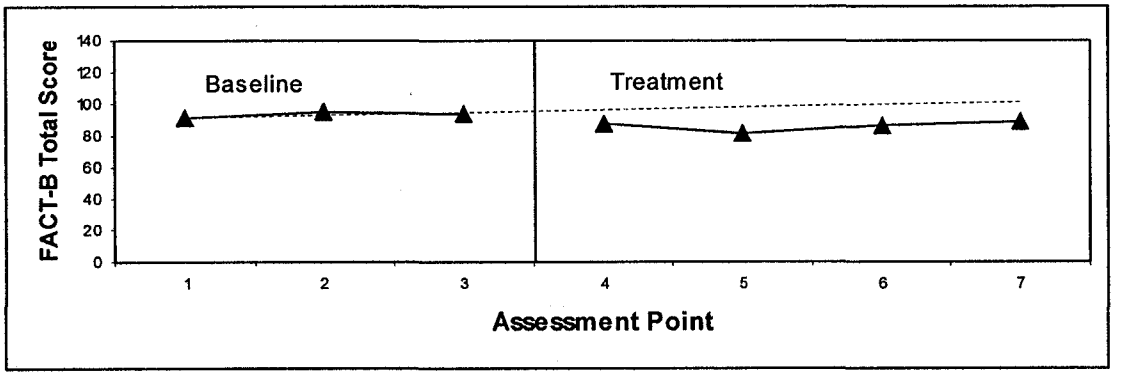

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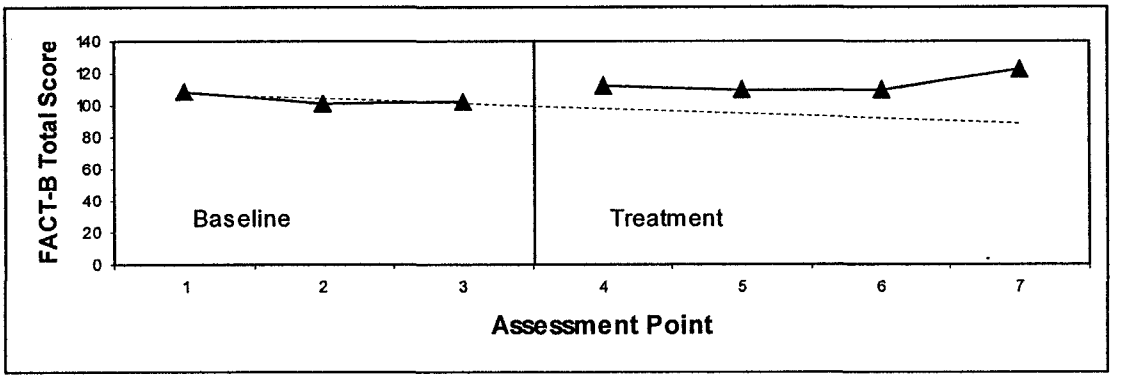

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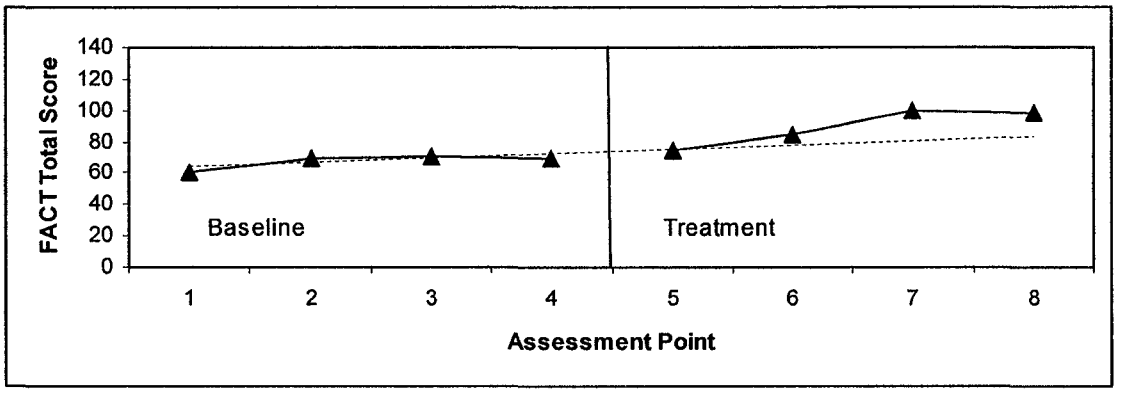

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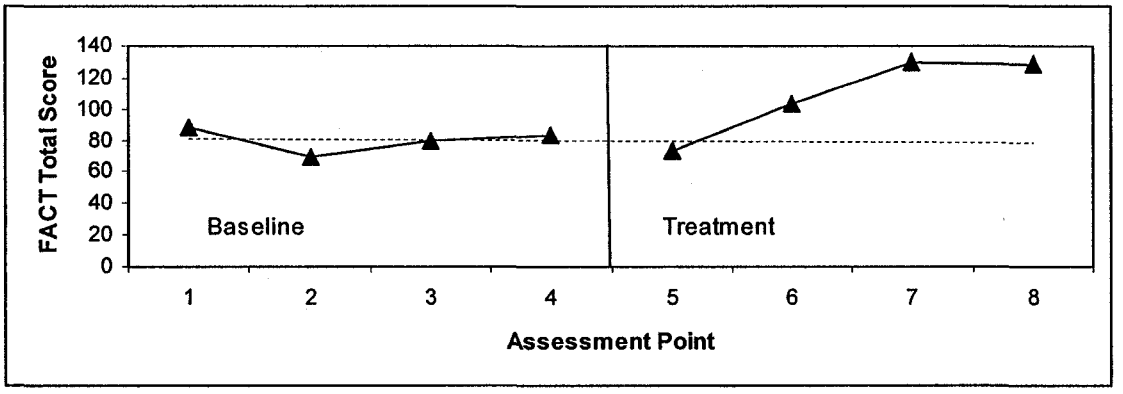

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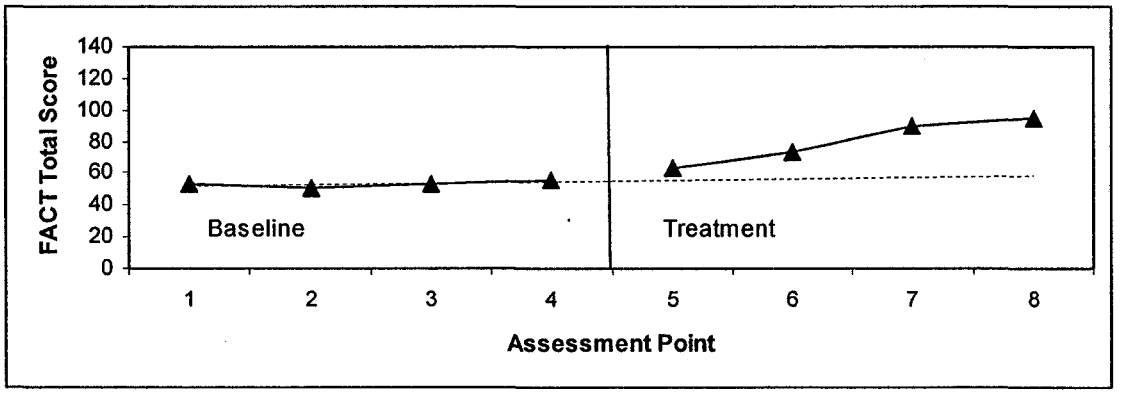
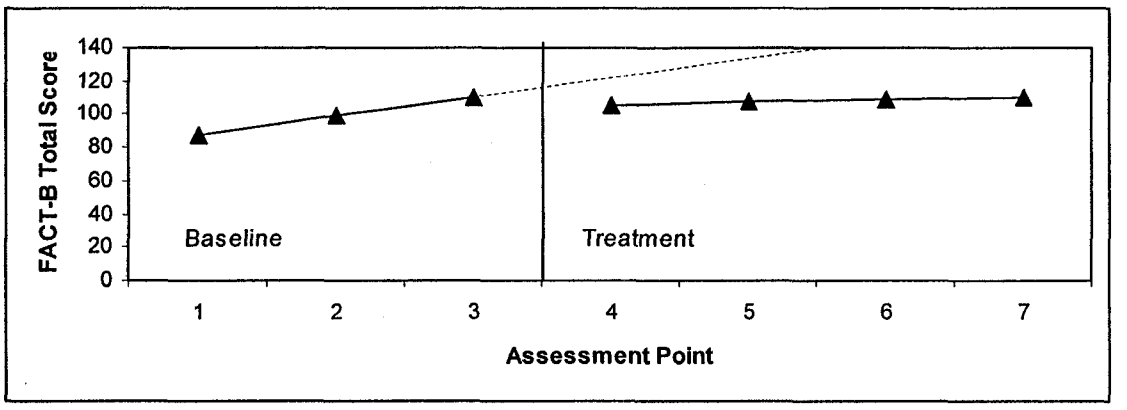


Couple 10 (PE)



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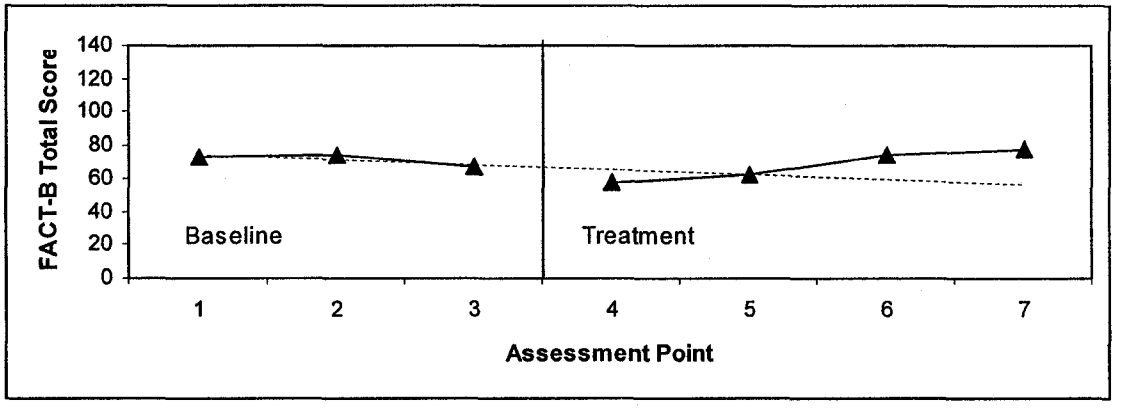


Couple 12 (PE)

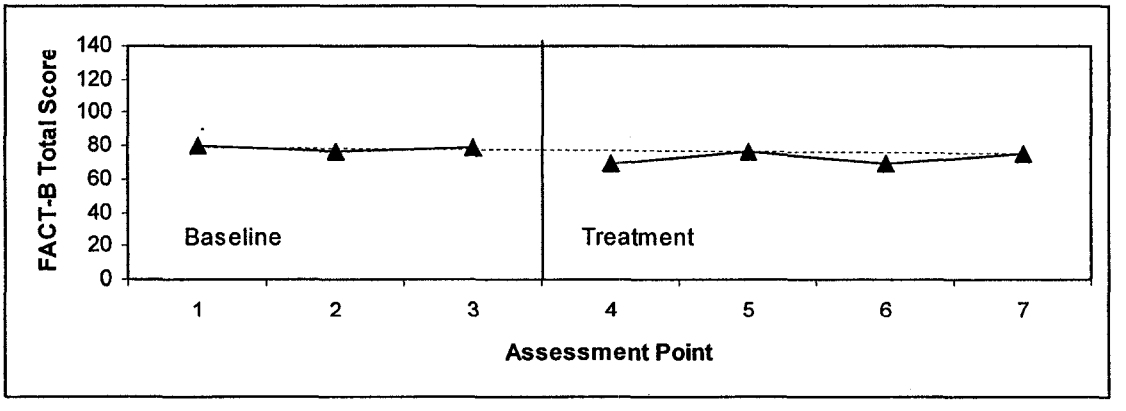


Table 4. POMS sub-scale analyses of couples randomized to EFT

Subscale	Pre-treatment	Post treatment	Z	*p*
Tension	12.27 (3.73)	4.42 (3.20)	-2.35	0.02*
Depression	16.86 (7.49)	5.00 (6.05)	-2.36	0.02*
Anger	12.43 (9.66)	2.71 (3.49)	-2.37	0.02*
Vigour	10.73 (8.67)	14.43 (8.14)	-0.81	0.42
Fatigue	12.29 (6.77)	5.71 (2.05)	-1.61	0.1
Confusion	10.71(4.30)	5.14 (2.11)	-2.12	0.03*

Table 5. DTS sub-scale analyses of couples randomized to EFT

Subscale	Pre-treatment	Post treatment	Z	*p*
Intrusion	17 (6)	5.75 (5.61)	-1.29	0.19
Avoidance	22.5 (10.34)	8.75 (6.60)	-1.46	0.14
Hyperarousal	21 (9.83)	5.25 (3.86)	-1.46	0.14

Table 6. FACT-B sub-scale analyses of survivors randomized to EFT

Subscale	Pre-treatment	Post treatment	Z	*p*
Physical Wellbeing	19.71 (6.23)	23.74 (3.59)	-3.02	0.043*
Social Wellbeing	13 (5.47)	17.85 (6.56)	-2.03	0.043*
Emotional Wellbeing	12.86 (4.22)	19.14 (4.56)	-2.34	0.018*
Functional Wellbeing	12.57 (6.07)	18.42 (6.70)	-2.37	0.018*
Other	19.57 (4.31)	22.42 (3.40)	-1.18	0.06

MANUSCRIPT 3: A PRELIMINARY INVESTIGATION OF THE CLINICAL IMPACT OF EMOTIONALLY FOCUSED THERAPY ON NATURAL KILLER CELL CYTOTOXICITY OF EARLY BREAST CANCER SURVIVORS

ABSTRACT

Purpose: Significant psychological morbidity following diagnosis and treatment for breast cancer has been shown to be of sufficient potency so as to down regulate critical immune parameters through direct and indirect pathways. The goal of the present study was to conduct a preliminary investigation of the clinical impact of a structured couple-based intervention, Emotionally Focused Therapy, on natural killer cell cytotoxicity (NKCC) in women diagnosed and treated for early breast cancer. *Methods:* Twelve couples were randomized to receive either twenty sessions of Emotionally Focused Therapy (EFT) or Psycho-education (PE). A multiple baseline experimental design across couples was used. *Results:* Women randomized to EFT evidenced more variation in response to treatment, with half of the sample experiencing small but clinically irrelevant up regulation in NKCC, while the other half showed clinically significant down-regulation in NKCC. Women receiving PE showed no changes in NKCC. More importantly, shifts in NKCC were in keeping with trajectories in dyadic adjustment and clinical events unfolding during the course of treatment. *Conclusions:* Findings provide some preliminary for small changes in NKCC following EFT. Recommendations for future psychoneuroimmunology trials are discussed.

INTRODUCTION

The diagnosis of early breast cancer and its associated treatments are often accompanied by significant psychological morbidity in the form of depression, anxiety, anger and even symptoms of post-traumatic stress (Derogatis, 1983; Alter et al., 1996; Cordova et al., 1995). Emotional support provided through the secure connection to a significant other can be an important buffer and has been linked to optimal psychological and physiological adjustment (Roberts 1994, Tatelman, 1999). In fact, the pivotal role played by the marital relationship in promoting coping and adjustment in the face of life threatening illness is becoming increasingly appreciated (e.g. Northouse, Baider, Kaplan deNour). When the marital relationship is troubled, both patients and their respective spouses continue to experience high levels of unremitting distress which, in addition to undermining psychological adjustment, can lead to down regulation of critical immune parameters, (Keicolt-Glaser et al., 1996), particularly for women (Malarkey et al., 1994). The goal of the present research was to carry out a preliminary investigation of the impact of a structured couples-based intervention, Emotionally Focused Therapy (EFT), on natural killer cell cytotoxicity (NKCC), in women diagnosed and treated for early breast cancer. NKCC represents one functional aspect of innate immunity, which is purported to bear clinical relevance to early breast cancer (Brittenden et al., 1996; Locke et al., 1984).

Natural killer (NK) cells and clinical relevance to breast cancer

Morphologically characterized by their large granular structures, NK cells comprise 5-15% of white blood cells in circulating blood of healthy individuals (Janeway, 2005). NK cells can be measured using quantitative and qualitative indices. The first index indicates the sheer number of NK cells circulating in peripheral blood, whereas the second provides an indication of their lytic or cytotoxic ability (NKCC) against a target cell (e.g. virally-infected or cancerous cell). In healthy adults, the relationship between

number of circulating NK cell numbers and their cytotoxic ability is generally positive and fairly stable over time (Whiteside & Herberman, 1994). This relationship, however, becomes readily perturbed in the context of several conditions, including autoimmune disease, HIV and cancers (Douglas et al., 2001).

Functionally, NK cells constitute an important component of the innate immune system and are relevant to the instigation of early host defense mechanisms, particularly surveillance and lysis of neoplastic cells that have freed themselves from normal cell cycle control (French et al., 2003; Moretta et al., 2002; Yokoyama et al., 2002). NK cells exert their action via two distinct mechanisms; 1) by direct cytotoxic attack on invading pathogens, also known as NKCC and 2) by secreting cytokines (a group of small glycoproteins with inherent signaling functions) to initiate the activity of adaptive immune parameters. As such, NK cells are important as a first line of defense and as mediators between the innate and adaptive immune responses (Vivier et al., 2004).

Variation in NKCC has been associated with carcinogenesis and eradication of newly formed breast cancer cells or micrometastases (Cragg et al., 1999; Brittenden et al., 1996; Malygin et al., 1993; Pross et al., 1996; Dewan et al., 2005). Others have correlated low NK cell activity with cancer onset (Imai et al., 2000), local recurrence (Brittenden, et al., 1996) and distant metastases (Malygin et al., 1993; Pross et al., 1993; Yamaguchi et al., 1994). Once formed, NKCC plays a key role resisting both progression and micro-metastatic spread of tumours (Herberman, 2001). Along similar lines, Whiteside et al. (1989) have found that recurrence free survival correlated with optimal NKCC.

Coping with Breast Cancer: An Attachment Perspective

Coping with cancer is becoming increasingly viewed as a 'family problem' where interpersonal processes affect and are affected by the disease in a circular fashion

(Baider & Kaplan De Nour, 1988, Northouse, 1993). Attachment theory provides the most cogent framework from which coping and adjustment to chronic illness may be conceptualized. Fundamentally a biobehavioral theory of affect regulation, attachment theory posits that in the face of danger, an individual will be propelled towards the comfort of an attachment figure that which has clear survival value (Bowlby, 1969, 1982, 1973). Breast cancer poses a substantial threat to a woman's being and to the attachment bond between her and her partner. In the face of such a crisis, partners typically turn towards each other as a way to emotionally self-regulate (Leiber, 1976, Friedman et al., 1988). In addition to seeking the support of an intimate partner, breast cancer survivors cite preference for emotional support over other types (vs. instrumental or informational; Manne, Alfieri, Taylor, & Dougherty, 1999). Secure emotional connections between partnered couples have, in turn, been associated with lower distress, depression (Roberts 1994, Tatelman, 1999), better role adjustment for the breast cancer survivor (Northouse et al., 1995) and more, recently, stronger NKCC (Picardi et al., 2007). Taken together, research on attachment relationships converges on the finding that secure connections are related to optimal affect regulation and adjustment. In turn, the ability to regulate psychological distress impacts underlying physiological systems, of relevance to overall health, particularly immune function.

Attachment Relationships and Immunity

The positive relationship between supportive close relationships and immune function emerges as one of the strongest clinical findings within the pychoneuroimmunology (PNI) literature (Herbert & Cohen, 1993a ; Uchino et al., 1996, 2006). Specifically, the emotional support conferred by an attachment figure appears be a salient predictor of various parameters of immune function, including NKCC (Baron et al., 1990; Levy et al., 1990a, Lutgendorf et al., 2006). For example, in their study of stage I and II breast

cancer patients, Levy et al., (1990a, b) found that perception of emotional support from a spouse or significant other accounted for one third of NKCC variance in patients followed by hormone receptor status at the tumor site.

Notwithstanding the protective role conferred by attachment relationships, the experience of breast cancer and its invasive treatments can create considerable strain on a marital relationship, particularly one that was troubled pemorbidly. In an effort to cope, partners unwittingly fall trap to dysfunctional interactional cycles (e.g. wife pursues/attacks followed by husband withdrawing/stonewalling) that are typically primed by absorbing states of negative affect (e.g. anger, hostility, and fear; Johnson, 1996). Such marital interactional cycles are well-documented both within the marital and PNI literature (Christensen, 1987; Heavey, Lane, & Christensen, 1993; Keicolt-Glaser et al., 1996) Distressed relationships are predictably associated chronic states of negative affect, in the form of depression, anxiety, and anger, which have been reliably linked to impaired NKCC (Levy et al., 1987; Herbert & Cohen, 1993a, b). Furthermore, contrary to the common view that men experience greater physiological arousal following conflict, a number of studies in fact support the finding that women tend to experience more pronounced and persistent homeostatic departures in a number of physiological measures, including parameters of immune function (Fehm-Wolfsdorf et al., 1999; Keicolt-Glaser et al., 1993; 1996 Malarkey et al., 1994; Ewart, Taylor, Kraemer, & Agras, 1991).

Mechanisms linking marital functioning to immune alterations

Anderson et al. (1994) advanced an empirically validated biobehavioural model capturing the role that psychological processes, behaviours and biologic pathways interact and determine health outcome. Two main pathways are thought to mediate the strong relationship between close relationships and immune function; a direct one though mood alterations and an indirect one via health behaviours (e.g. coping by

increasing substance use; altered sleep; Cohen & Williamson, 1991; Keicolt-Glaser & Glaser, 1988). Interestingly, the association between social support and immune regulation remains significant even after statistically controlling for health practices (Theorell, Orth-Gomer, Eneroth, 1990).

An important gateway to immune function is the endocrine system, which is sensitive to mood alterations. Chronic stress modulates functional immunity through activation of two main systems; the sympathetic-adrenomedullary (SAM) axis, and the hypothalamic-pituitary-adrenocortical (HPA) axis (Ritchie & Nemeroff, 1991). Sympathetic activation induces release of catecholamines; such as epinephrine and norepinephrine, both of which down-regulate immunity (Crary et al., 1982; Felten et al., 1987; Ader, Cohen & Felten, 1995). In a parallel fashion, stress-induced activation of the hypothalamic-pituitary-adrenal (HPA) axis triggers a chain of events; initially stimulating corticotropin-releasing factor (CRF). CRF stimulates the pituitary gland to release adrenocorticotropic hormone (ACTH), triggering the adrenal cortex to secrete corticosteroids. Considerable evidence converges on the generally immunosuppressive effects of glucocorticoids on NKCC (Claman, 1975; Dinkel et al., 2002). Such pathways have been substantiated empirically by examining the impact of conflict in married couples. Conflict, particularly when marked by hostility, has been reliably associated with alterations in both endocrine and immune function (Keicolt-Glaser et al., 1993; 1997, Malarkey et al., 1994).

Moreover, the protective role of attachment relationships has been elucidated by research on the neurobiology of attachment, which implicates endogenous opiods in re-establishing physiological deviations (caused by psychological or physical distress) to homeostasis (Panskepp, Siviy, & Normansell, 1985). Physiologically, attachment has been aptly described as a selective emotional bond (Ainsworth, 1989; Bowlby, 1969, 1973, 1980; Hennessy, 1997). Stressors trigger the need for proximity and attachment

behaviours (Simpson & Rholles, 1992). A threatening situation typically encourages return to a secure base (Bowlby, 1969; Panskepp et al., 1985). Oxytocin, released by positive social interactions, has the capacity to produce both acute and chronic reductions in HPA activity (Carter & Altemus, 1997; Uvnas Moberg, 1998). Carter (1998) posits that positive social behaviours, mediated through an oxytocinergic system may modulate hypothalamic-pituitary-adrenal and SAM activity, thereby accounting for the health benefits that are conferred by attachment.

Despite growing recognition of the key role played by the marital relationship in promoting adjustment in the breast cancer survivor, both at emotional and physiological levels, the literature is marked by a general paucity of couples-based interventions within this medical population. The current study is a preliminary investigation of the impact of Emotionally Focused Therapy (EFT), a structured and couples-based intervention, on NKCC in early breast cancer survivors. EFT emerges as one of the best articulated and empirically supported treatments for helping maritally distressed couples (Johnson et al, 1996). Resting on attachment theory, EFT views the marital relationship as a bond with an irreplaceable other, which provides a primary source of comfort and support, particularly in the face of crisis (e.g. receiving a diagnosis of life threatening illness). The salient goal of this treatment approach is to promote secure connections in partnered couples, which in turn fosters resilience when dealing with adversity. Secure connections confer a better capacity to self-regulate, which has physiological implications, particularly for immune function.

METHOD AND MATERIALS

Participants

Participants were a sub-set of female patients randomized to the treatment and control arms of a larger study assessing the efficacy of Emotionally Focused Therapy (EFT) on

psychological adjustment of couples. Approval of the research protocol was obtained by the Ottawa Hospital Ethics Research Board. This study took place at the Ottawa Regional Cancer Center, a teaching facility affiliated with the University of Ottawa Medical School. Criteria for study inclusion were the following; (a) patient had a confirmed diagnosis of early breast carcinoma of stages I (T1 N0 M0), IIA (T0 N1 M0, T1 N1 M0) or IIB (T2 N1 M0, T3 N0 M0); (b) patient was at least one year post diagnosis; (c) patient completed all adjuvant treatments (surgery, chemotherapy, radiation), and is at least 3 months post treatment, except for hormonal therapy. Tisch et al. (1998) demonstrated that T lymphocyte counts and in vitro lymphocyte stimulation responses showed a tendency towards normalization within 3 to 4 weeks after loco-regional post-operative radiation therapy (60 Gy on average) in patients with head and neck cancer. Persistence of immune down-regulation post-chemotherapy remains inconclusive, however, 3 months, as a minimum cut-off period for inclusion is usually the standard period in drug trials examining efficacy. Other inclusion criteria include (d) patient was married or cohabitating for at least two years, and partner was willing to participate for full duration of study; (e) couple was conversant in either English or French, (f) couple was experiencing significant relational distress, as measured by a combined average score of in the range of 78 to 97 points on the dyadic adjustment scale (DAS), described below.

Women meeting any of the following criteria were excluded from study entry and were referred to services in the community instead; (a) drug or alcohol dependence/abuse; (b) diagnosis of autoimmune disease (e.g. lupus, multiple sclerosis) (c) use of beta-blockers or psychotropic medication (d) existence of severe cognitive impairment; (e) history of severe and persistent mental illness (e.g. thought disorder, chronic suicidality; (d) physical violence in current relationship; and (e) concurrent psychotherapy (individual, marital or group).

Procedure

This study was carried out as part of a larger study examining the efficacy of EFT on overall psychological adjustment. Potentially eligible women were identified by participating oncologists, who obtained verbal consent from patients to be approached by a research associate either immediately following a routine out-patient visit or by telephone. During this initial contact the nature and purpose of study were explained in detail. Couples indicating interest were invited to attend an in depth clinical interview at the Ottawa Couples and Family Institute conducted by a doctoral candidate. All couples signed a written patient information and consent form approved by the Ottawa Hospital Ethics Review Board. The clinical interview served to ensure that couples met all eligibility criteria, including clinically relevant levels of marital distress, using the DAS measure.

Following the initial interview, couples were randomly assigned to one of two treatment conditions; Emotionally Focused Therapy (EFT) or a Psycho-Education (PE), using flip of a coin. The latter condition essentially served as a control condition. Couples assigned to the EFT condition were further stratified to one of three series; according to specific cancer staging information available in their medical charts. The study design was an A-B multiple baseline design across couples (Barlow & Hersen, 1984; Kazdin, 1992).

Each participant had her blood taken at the chemotherapy treatment unit of the ORCC by a registered phlebotomist. Depending on the treatment condition to which a participant was assigned, 2-3 samples of 8cc's of blood were taken during the baseline period, at the rate of one blood draw per week. Following each baseline period, 3 samples of 8cc's of blood were drawn, following the first treatment session, at treatment mid-point (following 10-12 sessions), and treatment completion (following 20-22 sessions), respectively. Blood samples were taken between 9:00am and 3:00pm for the

entire study sample. Each participant was assigned a specific time depending on availability. In order to control for diurnal variation, participants were requested to present at the same time across respective blood draws. Test tubes were identified by unique numbers assigned to respective participants.

Table 1 Stratification of cancer staging and treatment allocation by baseline

Baseline	Cancer Stage	Baseline Period	Treatment Condition
A	Stage I	2	EFT
B	Stage IIa	3	EFT
C	Stage IIb	4	EFT
D	Stages I, IIa, IIb	3	PE

Treatment Conditions

Emotionally Focused Therapy (EFT). Treatment consisted of up to 20 weekly 45-60 minutes of psychotherapy sessions. EFT entails three steps, which encompass nine therapeutic tasks, which are formally manualized (Johnson, 1996).

Psychoeducation (PE). To ensure equivalence in treatment 'dose' or exposure to a therapist, couples assigned to the psychoeducation treatment condition met with a clinician for 20 weekly 45 minute workshops. The workshops were conducted in a structured and didactic format. Couples were provided with an outline of topics covered; epidemiology of breast cancer, medical treatment approaches, effects on psychological health and marital relationships, clinical trials, complementary and alternative medicine, financial and practical support. Couples randomized to this condition were given the option to be treated with EFT following their participation in the PE condition. All treatment sessions were audiotaped with couples' consent.

Clinicians and Setting

Clinicians were psychologists or Master's level clinicians with at least 7 years of experience in treating couples using the EFT model. All clinicians attended weekly supervision meetings with Dr. Susan Johnson, a licensed clinical psychologist who is also the originator of EFT. Treatments were offered at the Ottawa Couples and Family Institute.

Measures

Demographic questionnaire

A demographic questionnaire was given to each couple admitted to the study. This included information about patient and spouses ages, ethnicity, educational level, income range, employment; number of children, age at diagnosis, since diagnosis and completion of treatment, drinking history, familial history of breast cancer and current medications.

Health behaviours

A clinician administered qualitative questionnaire was given prior to each blood draw. This included 3 questions concerning health behaviours know to interfere with aspects of immune function, including changes in sleep patterns, exercise regimens and alcohol consumption. This information was collected for qualitative purposes.

Marital Adjustment

Marital adjustment was assessed using the Dyadic Adjustment Scale (DAS) (Spanier, 1976). The DAS is a 32-item self-report rating scale designed to measure the quality of adjustment between married or cohabiting couples. Psychometric properties are fully described in a companion report. Only change scores from baseline to treatment mid-

point are reported in this study and were used as an explanatory framework for patients' NKCC trajectories during treatment.

Natural Killer Cell Cytotoxicity (NKCC)

All assays were carried out by an immunologist, who is one of the co-investigators of this study. Preparation of natural killer to function as effector cells was carried out according to procedures described by Parato et al., (2002). Specifically, white blood cells were separated from whole blood. PBMC was washed, resuspended in cryopreservation media at $3x10^6$ cells/ml. Media consisted of fetal calf serum combined with 20% dimethyl sulphoxide. Samples were subsequently preserved in liquid nitrogen. At the end of the study, samples were thawed, reconsistuted with 5% RPMI/10 (RPMI 1640 and 10% fetal calf serum, 100 U/ml penicillin, 100 µg/ml streptomycin; Life Technologies,Burlington, ON, Canada). Cells were pelleted (400 xg for 10 min) and then resuspended to achieve a concentration of 1×10^6 cells/ml in RPMI/10. Cells were then incubated for 5 hours at 37° C and 5% carbon dioxide. Following this step, cells were used in a cytotoxicity assay, as effectors. Target cells used were K562 human erythroleukemic cells (American Type Culture Collection, Rockville, MA, USA).

NKCC was determined using flow cytometric procedures described by Chang et al, 1993. These require staining characteristics of 3, 39-dioctadecyloxacarbocyanine perchlorate (Molecular Probes, Eugene, OR, USA). In this study, effector to target ratios ranged from 50:1 to 3.125 to 1.

Analytic Plan

As customary with multiple baseline designs, treatment impact was initially evaluated by visual inspection of graphic representations of NKCC across baseline and treatment phases. Linear trends in baseline data were revealed using the split-middle technique described by White (1972). This descriptive approach also predicts future course of

clinical phenomena and permits systematic comparison of trends between and across phases. Celeration lines for all baseline data for each patient were carried out using SPSS.14, which uses a least squares method to minimize the squared distances between a line of "best fit" and individual data points during the baseline phase. The line essentially splits the data, so 50% falls above and 50% falls below the celeration line. The celeration line was then extended into the treatment phase and used to reveal an accelerating, decelerating or stationary trend. Treatment impact on NKCC was evaluated by comparing treatment trends to the trend established by the celeration line.

A more rigorous criterion for evaluating treatment impact used in this study was determining the clinical significance (CS) of changes in NKCC from baseline to treatment. CS refers to the smallest difference in a biologic response that may correspond to an actual change in clinical course (Eton et al., 2003). In view of the wide variation inherent in NK function both across and within individuals, a minimal criterion of a two fold increase (100%) in NKCC from baseline to treatment was adopted a priori to denote a clinically meaningful change.

It was hypothesized that patients randomized to EFT would evidence upward and clinically meaningful trends in NKCC compared to baseline. Such trends were not expected to be seen in patients randomized to the control condition.

RESULTS

Patient Characteristics

Twenty two couples responded to recruitment efforts by participating oncologists and one community psychiatrist. Of these, seven couples were excluded for the following reasons; three had cancers other than breast or had advanced stages; one had a comorbid psychiatric illness; one was still undergoing adjuvant chemotherapy and two were not considered maritally distressed according to DAS norms and criteria.

Fifteen couples met inclusion criteria and were enrolled in the study. Two couples dropped out prior or close to treatment midpoint due to medical reasons (one patient had a relapse while both mothers of the second couple became diagnosed with terminal breast cancer) and were unable to commit to therapy sessions. The male partner of one couple was unable to accompany his partner for more than 50% of treatment sessions, due to job commitments. This couple was therefore excluded from analyses due to ambiguity in the nature of the intervention (i.e. individual vs. couple therapy).

Due to low survival rates of cells following cryopreservation, blood samples from only nine women were included this report. Furthermore, treatment effects were based on 10 sessions of EFT. Out of the nine women included in the study, 6 were randomized to the EFT condition and 3 were randomized to PE. The mean age of patients was 52. years (range: 48-69; *S.D.* 5.6); and the mean age of husbands was 55.56 (range: 46-72; *S.D.* 7.2). Couples were all married for an average of 28.9 years (range: 14-40; S.D. 6.9) and had an average of 2.1 children (range: 1-4, S.D. 1). The average annual income was $ 94,915 (range: $ 32,000-$111,000, S.D. $ 31,046). Average age of wives at diagnosis was 48 years (range: 36-61; S.D. 6.88). The average time elapsed since diagnosis was 3.4 years (range: 1-10; S.D. 2.5). All 9 patients were Caucasian, 8 were English speaking, 1 was bilingual, and received treatment in French.

Baseline NKCC levels

NKCC distributions at baseline were not equivalent across patients randomized to the two experimental conditions. As illustrated in figure 1, patients in the EFT condition showed a relatively stronger and wider NKCC response at pre treatment (M: 21.08; range: 3.55-68.20; S.D.24.09), compared to patients in PE (M: 3.79; range: 1.86-5.96; S.D. 2.06). This disparity was likely due to sampling bias, given the small and unequal number of participants assigned to each condition.

The large standard deviation noted in the EFT participants, however, is in keeping with known biological behaviour of NKCC. Specifically, considerably wide variations in NKCC have been observed in healthy individuals, (Whiteside & Herberman, 1989; Pross & Baines, 1982) as well as breast cancer patients; the latter of which have a documented range of weak NKCC (less than 5% inhibition) to full NKCC (determined at 50% inhibition or higher; Ogmundsdottir, 1992).

Medical treatment variables, which likely moderated basal NKCC at study entry include time since last treatment administration (i.e. chemotherapy and radiation), in addition to concurrent endocrine treatment, which are generally associated with down regulation of NKCC (e.g. Lukac et al., 1994). Table 1 summarizes this data. Specifically, patients in the EFT condition ranged from 9 months to 6 years since their last adjuvant treatment administration, while patients in the PE condition ranged from 6 months to 2 years. There was no clear pattern between time to last adjuvant treatment and basal NKCC level. Furthermore, 4 patients receiving EFT and 2 patients receiving PE were receiving hormone therapy (Tamoxifen; nonsteroidal antiestrogen drug) during their participation in the study. One patient in the control group received Trastazumab (Herceptin), for the full duration of her participation. Heceptin is associated with an up regulation of NKCC.

Figure 1.

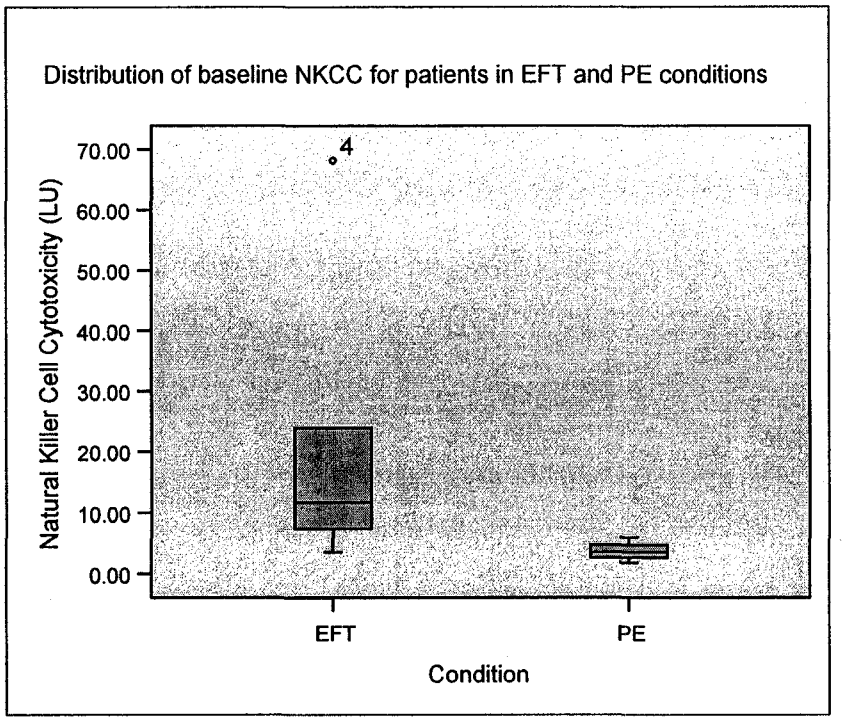


Table 2. Summary table of adjuvant treatments, basal NKCC and hormone treatment status across patients randomized to EFT and PE conditions. Key: 1 = EFT; 2= PE (Control), * Patient was on Trastazumab (Herceptin),

Patient	Condition	Time since last treatment administration (years)	Hormone Treatment	Mean Average Baseline NKCC
1	1	3.5		23.9
2	1	3		12.9
3	1	2	✓	7.45
4	1	6	✓	68.2
5	1	5	✓	10.46
6	1	0.8	✓	3.55
7	2	2	✓	5.98
8	2	0.5	✓	1.86
9	2	0.8 *		4.33

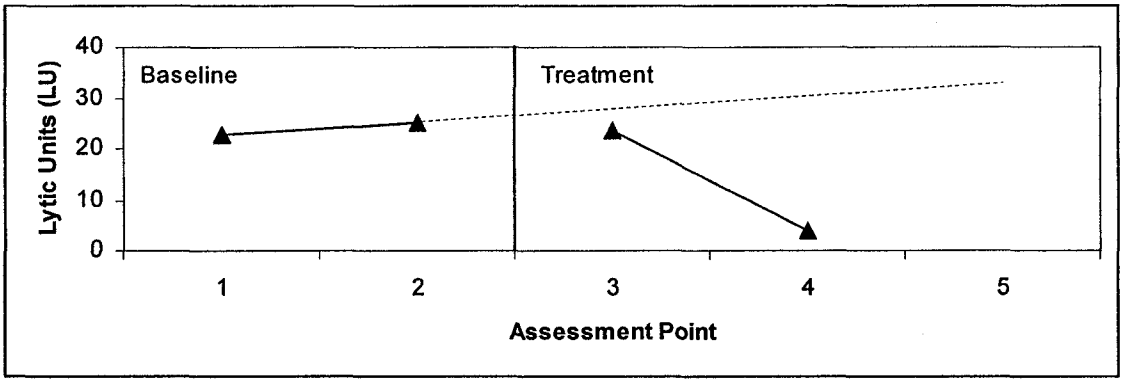
Visual Inspection of Treatment Trends

Graphic representations of treatment effects on NKCC for each patient, are illustrated in Figure 2. Patients 1 to 6 received EFT, while patients 7, 8 and 9 were in the PE condition. The behavioural course of NKCC during baseline was generally stable across all nine patients, showing no indication of spontaneous improvement. Interestingly, during baseline one patient awaiting to receive EFT and two patients in the control condition showed significant increases in NKCC ranging from two to four fold the lowest value. While these represent clinically relevant changes, they could not be reliably associated with any concomitant physical events (e.g. alterations in exercise regimens, sleep cycle, alcohol consumption) that took place during the study. In a review by Miller, Cohen, & Herbert, (1999), however, NKCC assays of depressed individuals were associated with variation as high as 75% across a one week interval. Psychological measures, collected as part of an earlier study on the same group of patients were reviewed and in 2 out of 3 patients clinically significant levels of depressive symptoms were found thereby accounting for these transient changes.

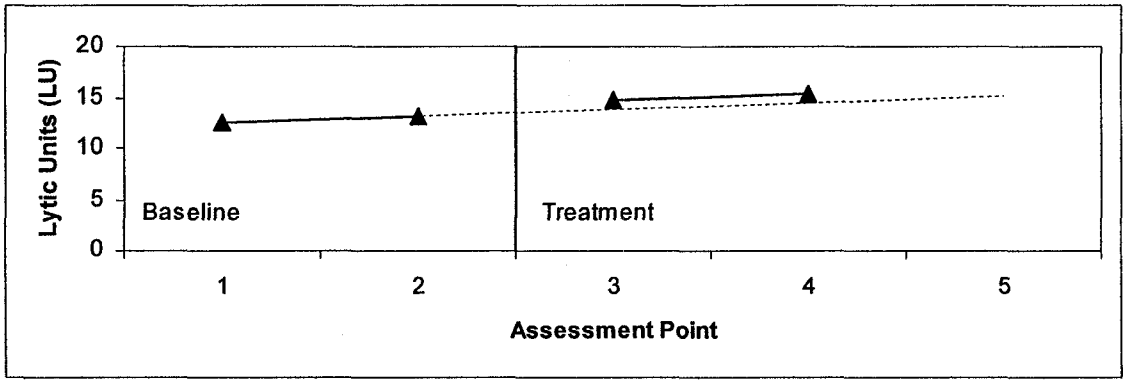
Visual inspection of graphs for patients who received EFT showed varied NKCC response to treatment. Out of the 3 couples stratified to baseline A, Patients 2 and 3 showed a clear upward trend, indicative of improved NKCC relative to baseline. Patient 1 evidenced a marked downward trend. Patients stratified to baseline B showed similar variation with respect to NKCC response. Specifically, Patients 4 and 5 evidenced a downward trend, signifying impairment in NKCC, whereas patient 6 showed a steady upward trend, indicative of improvement. In contrast, Patient 7, 8 and 9 evidenced downward treatment trends which were either close to or below the celeration line indicative of a poorer ability to mount an NK response.

Figure 2. NKCC trends across patients

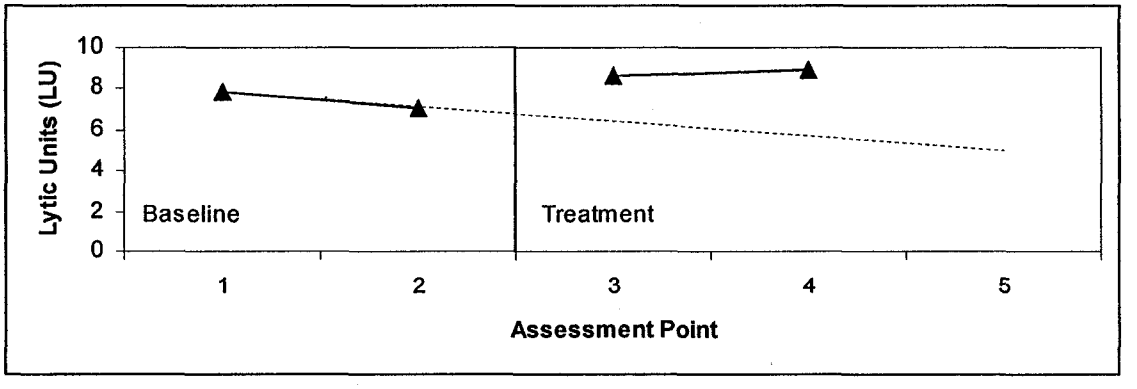
Patient 1



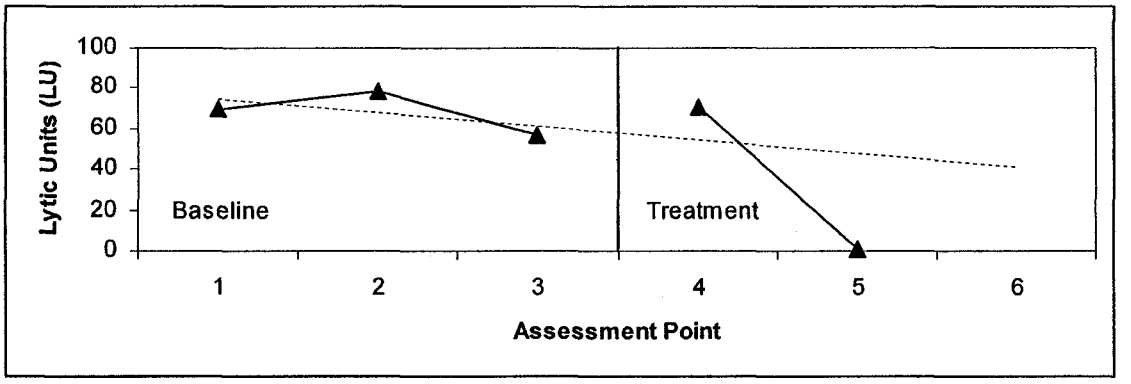
Patient 2



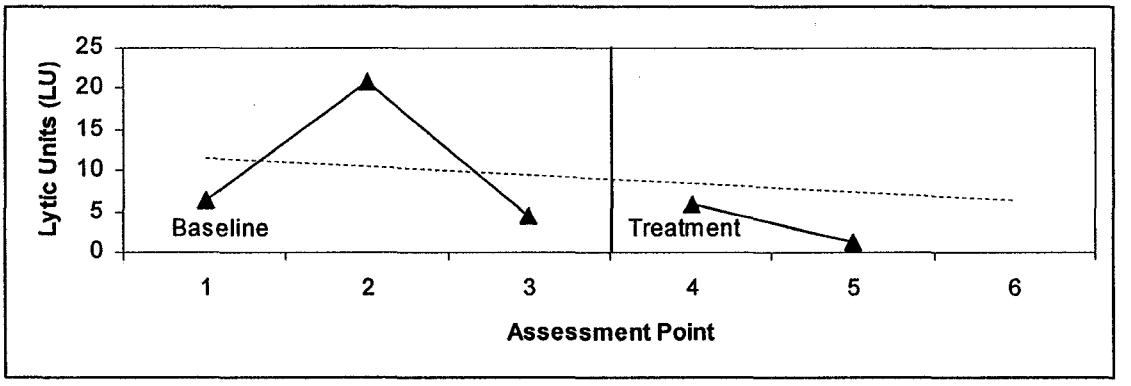
Patient 3



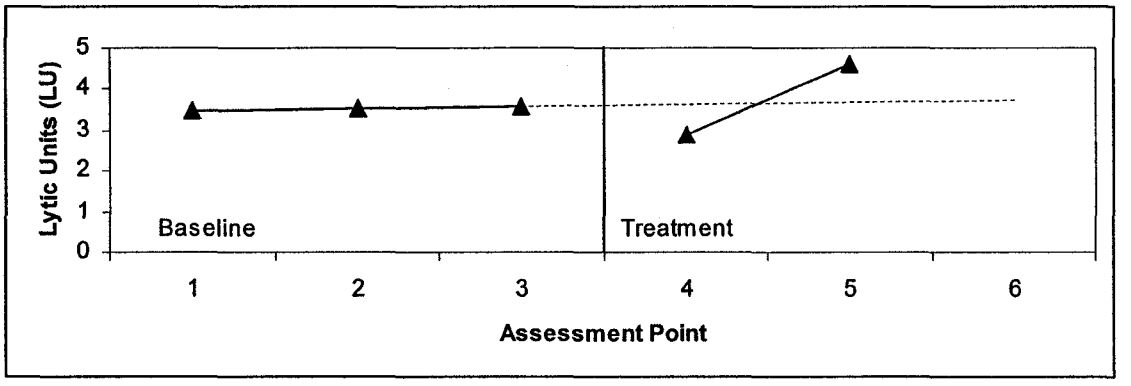
Patient 4



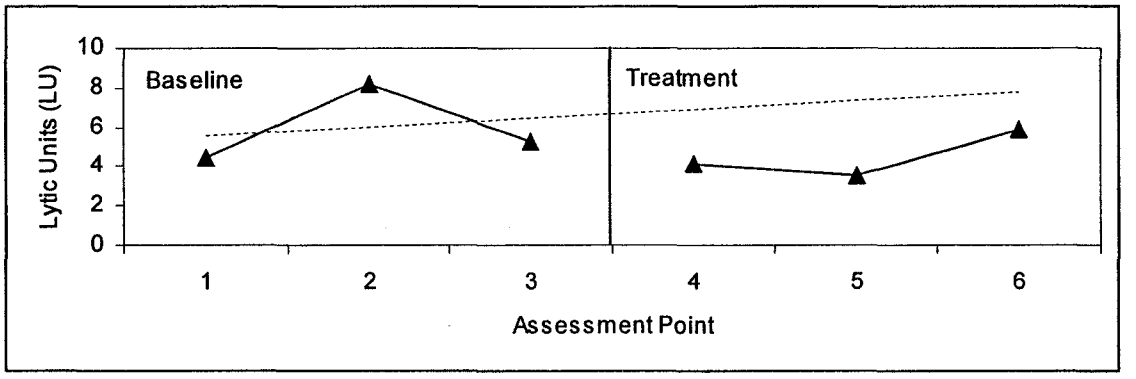
Patient 5



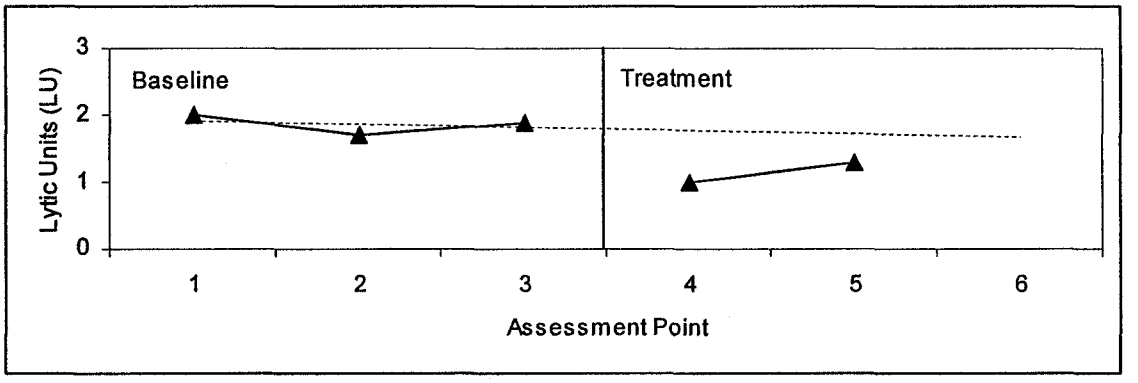
Patient 6



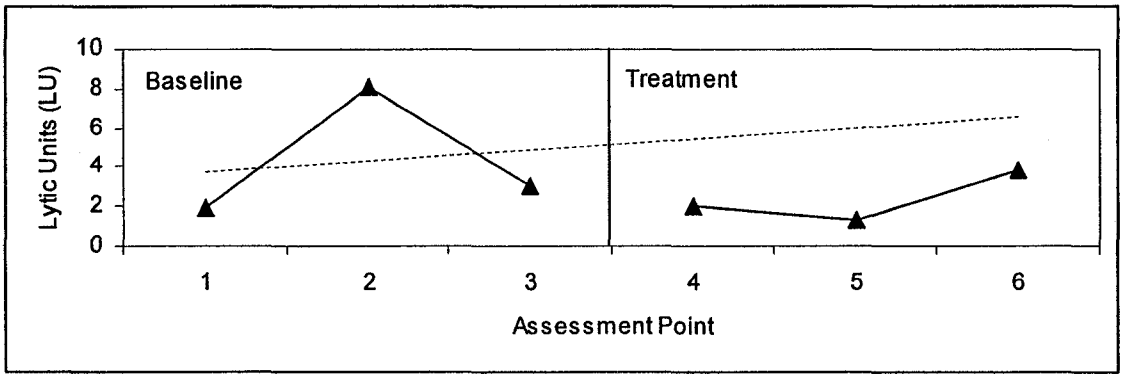
Patient 7 (PE)



Patient 8 (PE)



Patient 9 (PE)



Clinical significance of changes in NKCC

Table 3 summarizes changes in NKCC from baseline to treatment across all patients. Although 3 out of the 6 patients randomized to the EFT condition evidenced

upward treatment trends consistent with a seeming up regulation of NKCC, these changes were in fact not of sufficient magnitude to be considered of clinical relevance. Specifically, improvement in NKCC ranged from 19-30% compared to baseline levels. In contrast, patients receiving EFT who showed reductions in NKCC relative to baseline appeared to evidence more dramatic and possibly clinically relevant changes that ranged from 82-98%. In contrast, patients in the PE condition evidenced marginally lower decrements in NKCC relative to baseline, which ranged from 1-30% and were not considered to be of clinical importance.

Changes on the DAS from baseline to the tenth session, collected as part of a companion study, were categorized as weak, moderate and strong. A weak change denoted less than 1 standard deviation; moderate was 1-2 standard deviations and large was more than 2 standard deviations. Out of the three patients in the EFT condition who evidenced positive shifts in NKCC, two reported moderate changes on the DAS by the end of 10 sessions. Interestingly, the remaining 3 patients who received EFT reported only weak changes on the DAS, but evidenced significant worsening of NKCC. In contrast, patients in the control condition all reported weak changes on the DAS, which were associated with unimportant changes in NKCC levels.

Table 3. Summary table of NKCC at baseline and following 10 sessions across patients randomized to EFT and PE conditions. Key: 1 = EFT; 2= PE (Control), * Patient was on Trastazumab (Herceptin) when blood was drawn; Weak change on DAS corresponds to less than 1 SD, Moderate change corresponds to 1-2 S.D

Patient	Condition	Mean Average Baseline NKCC	NKCC following 10 sessions	Change across 10 sessions	Clinical significance of change	Change on DAS following 10 sessions
1	1	23.9	4.1	↓	Yes	Weak
2	1	12.9	15.3	↑	No	Moderate
3	1	7.45	8.9	↑	No	Weak
4	1	68.2	1.2	↓	Yes	Weak
5	1	10.46	1.17	↓	Yes	Weak
6	1	3.55	4.6	↑	No	Moderate
7	2	5.98	5.9	↓	No	Weak
8	2	1.86	1.3	↓	No	Weak
9	2	4.33*	3.8*	↓	No	Weak

DISCUSION

The primary goal if this preliminary investigation was to evaluate the impact of couples-based EFT on NKCC in women diagnosed and treated for early breast disease. The main impetus for carrying out this study is the strong positive link between attachment relationships, adjustment and aspects of functional immunity, including NKCC (Uchino et al., 1996), as well as the clinical relevance for immunocompetence in the context of breast cancer (Herbert & Cohen, 1993a). A multiple baseline design across participants was used, with the inclusion of a control group who received psychoeducation over a 10 week period. The following patterns emerged; 1) women in the EFT condition evidenced more varied NKCC activity in response to treatment; with half of patients evidencing increased, albeit clinically non-relevant, upregulation in NKCC, and the other half showing clinically relevant deterioration in NKCC; 2) women in

the control condition showed clinically insignificant down regulation in NKCC and 3) NKCC trajectories were generally in keeping with changes in dyadic adjustment, as measured by the DAS.

While the stationary NKCC trends observed in women assigned to the control group were in keeping with predictions, the seemingly bimodal trends demonstrated by women in the EFT condition was somewhat surprising, on initial inspection. Notwithstanding, variation in treatment response across patients is actually consistent with a growing empirical literature on individual differences in both stress response (Segerstrom, 2003) and treatment impact (Andersen et al., 2004; Manne et al., 2005). The degree of impact of EFT on psychological adjustment, reported in a companion report, was certainly variable across participants, and this variation was expected to carry over to immunological measures to some degree.

The clinically irrelevant gains made by half the sample versus the clinically significant deterioration evidenced by the other half of patients in the EFT condition was a puzzling finding at first. Ostensibly, EFT appears to be associated not only with zero differences, but an apparent 'adverse effect' for some patients. This conclusion, however, is argued to be rather premature, in light of a number of methodological limitations inherent to the study, which may have largely accounted for these observed patterns. Firstly, analysis of NKCC trends were based on 10 sessions of EFT, which is half of the treatment 'dose' prescribed in the research protocol. Many cell samples did not survive the cryopreservation process; a common pitfall in psycho-immunological studies that is often remedied by enrolling a sufficiently large sample size to accommodate for any data loss. The preliminary nature of this study precluded this option. There was also no follow up assessment available. This is a salient issue, because previous studies have shown that significant immune changes may only become evident several weeks following treatment completion (e.g. Andersen et al.,

2004; Larson et al., 2000). For example, following a 6 week structured psychiatric intervention, significant up-regulation in NKCC did not emerge until 6 months follow-up (Fawzy et al., 1990). The data reported in this study is, therefore, based on a modest 10 week window of psychotherapy treatment, which is argued not to have been sufficient time frame to produce clinically significant NKCC up-regulation.

Another salient factor possibly accounting for the small positive shifts in NKCC reported here may relate to the nature of the relationship between distress and depressed NKCC. While it is generally accepted that chronic negative states of affect correspond to down regulation across several immune parameters (e.g. Ironson et al., 1997; Herbert & Cohen, 1993; Valdimarsdottir & Bovberg, 1997), amelioration of mood does not necessarily correspond to a linear up-regulation of the same parameters. In a recent empirical study examining individual differences in stress trajectories and their concordance with NKCC, Thornton et al., (2007) maintain that for modest upregulation in NKCC to result, a large reduction in distress levels would first need to occur. Much smaller reductions in distress along the disease trajectory are often accompanied by more modest levels of NKCC upregulation. Dyadic adjustment, as measured by the DAS, was used in this study as a proxy for experienced distressed. Of the three patients who evidenced some upregulation in NKCC, only modest improvement was noted on the DAS for two women, while the third only showed weak levels of improvements. That NKCC upregulation levels did not reach clinically significant level is, therefore, not a surprising finding, since patients had not completed the full course of their psychological treatments.

While the narrow assessment time frame may have accounted for the lack of clinical significance in NKCC up-regulation evidenced by 3 patients in the EFT condition, it doesn't account for the potentially relevant down-regulation in NKCC seen in the other 3 patients. In order to parse out whether such significant dips were a function of transient

changes (related to external life events) or an actual adverse effect of treatment, an in-depth investigation of the first 10 sessions was carried out for these three patients, in addition to consulting with their respective therapists for clinical impressions. The following clinically relevant events were extracted: the first patient evidenced significant increases in systolic blood pressure, and expressed difficulty with having to deal with her spouse's 'withdrawn attitude'; the second patient reported concern with respect to an increase in her husband's drinking behaviour; a behaviour which had ceased for a number of years until their study entry; and the third patient described treatment as 'uncovering a bandaid on a relationship that she had given up on'. In all three cases, an interactional cycle characterized by a pursuing wife/withdrawing husband was uncovered. Dubbed as a 'signature pattern' for distressed marriages (Keicolt-Glaser at al.,1996, pg 325), pursue-withdraw cycles of interaction are reliably associated with significant endocrinological and immunological changes in women, including elevations in norepinephrine and cortisol, both of which down-regulation NKCC (Keicolt-Glaser et al., 1997;Mayne, O'Leary, McCardy et al., 1997; Dinkel et al., 2002). Common to a couples treatment facility, such interactional cycles may require up to 16 sessions before the are replaced with healthier ways of relating (Johnson, 1996). Indeed one of the three patients reported here did recover, along wither partner, by the end of twenty sessions of treatment, (as reported in a companion study). Unfortunately, no immune assay was available to track whether this change corresponded to any physiological shift.

This is the first study to examine the impact of a theoretically informed treatment approach to helping couples recover from distress either stemming from or exacerbated by diagnosis and treatment of early breast cancer. Two distinct advantages set this study apart from previous ones. Along with less than a handful of trials (e.g. Manne et al., 2005, Christensen, 1983), this study capitalized on a woman's most significant relationship in order to mobilize both her internal resources, as well as those of her

partner's to promote adjustment and coping to a chronic condition. Armed with a theoretical framework to inform treatment, outcomes can be readily explained in terms of mechanisms. Consistent with hypotheses, women assigned to the control condition showed no changes in NKCC, whereas those in EFT showed individual variation, a finding that is in keeping with previous research. The small degree of upregulation in NKCC was concordant with the moderate changes noted in dyadic adjustment by the end of ten sessions.

A number of methodological limitations merit further discussion. First, the large number of cell samples lost to cryopreservation limited the power of the study, such that statistical testing of treatment trends relative to celeration lines was precluded due to the small number of data points available for analysis. Another concern is the stability of NKCC levels prior to treatment initiation. NKCC is described by some researchers as a volatile parameter showing stability as low as 25% over a 1 week interval, particularly in individuals experiencing psychopathology (Miller, Cohen, & Herbert, 1999). Though patients in this study were not sampled from a psychiatric population, there was a significant degree of distress at study entry, which may interacted with treatment effects, producing some of the treatment variation observed. This hypothesis will need to pursued further in future trials employing large sample sizes, where NKCC levels at study entry can be controlled statistically. The present study may have also benefited from inclusion of a an age-matched group of healthy women, in order to provide a normative range against which NKCC levels of study patients could have been compared. This is particularly relevant, since all nine women, prior to study entry, had undergone a combination of cytotoxic adjuvant treatments (chemotherapy and radiation therapy), known to impair immune function. While it is generally held that immune function recovers within a few months following treatment cessation, some women do show persistent effects on immune function for much longer periods of time. This is an

important issue to recognize, since a strong biological impact may in fact be masking small to moderate treatment effects associated with psychological interventions. In the absence of statistical control, such findings may be dismissed as a type II error.

A final concern relates to the nature of the immune assay carried out. While changes in NKCC levels in this study were largely explained in terms of psychological processes, such pathways are in fact tentative, since no data was collected with respect to the endocrinological and immunological environment. Specifically, future research will need to incorporate measures of glucorticoids e.g. cortisol, in addition to enumerative indices of NK cells (using CD56 and CD57 markers) and cytokine profiles. These additional measures will provide a clearer indication as to where a disruption in the mechanism may have occurred (i.e. low cell numbers versus predominant release of certain cytokines impairing NKCC). Use of purified NK cells, as opposed to whole PBMC, may also be an important consideration in deriving a more exact index of NKCC. Since NK cells comprise a relatively small and variable proportion of lymphocytes, along with other subsets of cell populations, the observed low NKCC may in fact be a function of low cell counts.

At present, data reported in this study provides some preliminary support of small changes in NKCC in breast cancer survivors following couples-based EFT treatment. Of more importance was the concordance observed between changes in NKCC and dyadic adjustment, a relationship that is consistent with recent research describing the nature of the association between distress and NKCC. Methodological challenges were highlighted to provide guidance for future trials examining the efficacy couples-based treatments on immunological status of breast cancer survivors.

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SUMMARY AND CONCLUSIONS

The present study evaluated the clinical efficacy of Emotionally Focused Therapy (EFT) on the psychological adjustment of couples who were one year post early breast cancer diagnosis. Furthermore, a preliminary investigation of the impact of EFT on women's NKCC was carried out using a subset of the total patient sample. A multiple baseline methodology across couples, including a control group was adopted.

Comparison of treatment trends relative to baseline indicated that twenty sessions of EFT were effective in improving dyadic adjustment and quality of life, in addition to decreasing total mood disturbance and trauma symptomatology consistently across more than 50% of the couples. Even in couples where dyadic adjustment had not shifted significantly, EFT was associated with attenuation of mood disturbance, trauma symptoms and improvement in quality of life. This finding was observed more consistently across women than men, and was explained in terms of a propensity for women, when mobilized, to form supportive relationships outside a marriage (Edwards et al., 1999). Out of 9 couples, only two did not appear to respond to treatment on any of the psychological outcome variables. Follow-up assessment at three months post treatment indicated that maintenance of treatment gains with respect to mood and trauma symptoms, but a continued improvement in dyadic adjustment and quality of life. A more tentative finding was a change in attachment security in female partners of two couples by the end of twenty sessions. Such changes were surprising in view of the limited evidence supporting EFT's role in increasing attachment security, particularly following a relatively brief period of time (Makinen & Johnson, 2006). Consistent with hypotheses, no changes were noted in couples assigned to the control condition.

EFT's impact on survivors' NKCC was less clear. Notwithstanding wider variation in basal NKCC compared to the control group, women who received EFT evidenced an apparent bimodal distribution in NKCC following ten sessions of EFT. Specifically, half of

patients showed an increased, albeit clinically non-relevant, upregulation in NKCC, whereas the other half evidenced clinically relevant deterioration in NKCC. Clinically insignificant down regulation in NKCC was noted in women assigned to the control condition. Deterioration noted in the three women assigned to the EFT condition was consistent with clinical events, which transpired in the context of treatment, associated with marital distress. Of more relevance was the general concordance between NKCC trajectories and changes in dyadic adjustment. Specifically, clinical changes, measured on the dyadic adjustment scale (DAS), from baseline to the tenth session were categorized as weak, moderate and strong. Out of the three patients in the EFT condition who evidenced positive shifts in NKCC, two reported moderate changes on the DAS by the end of 10 sessions. Interestingly, the remaining 3 patients who received EFT reported only weak changes on the DAS, but evidenced significant worsening of NKCC. In contrast, patients in the control condition all reported weak shifts on the DAS, which were associated with unimportant changes in NKCC levels. The pattern of findings which emerged in this study, though preliminary in nature due to the relatively small sample size, converges with previous research describing the non-linear relationship between distress and NKCC (Thornton et al., 2007). Moreover, several research studies support that relatively longer periods of time are required to have elapsed before a change in NKCC becomes perceptible on immune assays (Andersen et al., 2004; Larson et al., 2000; Fawzy et al., 1990), a possible issue in the present study, since assays were taken following ten sessions, which was half the standard treatment dose, with no follow up.

In closing, EFT appears to be associated with a clear therapeutic effect in helping couples dealing with relational distress that is either exacerbated or maintained by various form of psychological morbidity (e.g. depression, anxiety) following early breast cancer. The evidence in favor of effectuating changes at an immunological level is more

tentative in nature, in view of the relatively small sample size. However, the pattern of findings with respect to changes in dyadic adjustment and NKCC trajectories are consistent with recent research documenting the non-linear relation between this immune parameter and perceived distress. As such, the findings are argued to merit further investigation using a well sampled randomized clinical trial, which controls for various confounding variables, including basal NKCC levels and interactions with cytotoxic regimens.

Several limitations were noted across both studies including the potential limited generalizability of findings in view of the relative affluence of the study sample and couples being exclusively of Caucasian background. Furthermore, studying a biological response as complex as NKCC requires additional measures to capture the underlying endocrinological and immunological environment in order to elucidate mechanisms of action and to be able to reliably link them to psychological processes.