Complicated Grief Treatment: What Makes It Work?

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Submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy under the Executive Committee of the Graduate School of Arts and Sciences

COLUMBIA UNIVERSITY
2013
ABSTRACT

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This dissertation is an exploration of the putative mediators of complicated grief treatment (CGT) in an effort to gain a better understanding of the mechanisms by which the treatment exerts its effects. This three-paper dissertation utilizes data from an NIMH-funded randomized controlled trial of CGT (Shear et al., 2005), which showed that CGT is more effective than Interpersonal Psychotherapy (IPT) in reducing symptoms of complicated grief (CG). The first paper examines a broad range of ancillary outcomes including symptoms of anxiety, depression, complicated grief and sleep disturbance due to bad dreams. Antidepressant use is examined as a possible moderator since half the sample was taking antidepressants and those taking antidepressants had a marginally better response rate in CGT than those not taking them (59% vs. 42% in CGT and 40% vs. 19% in IPT). CGT was more effective than IPT in reducing cognitive symptoms of anxiety, depression as measured by the Hamilton Rating Scale for Depression (HRSD), somatic symptoms of depression, guilt/self-blame, negative thoughts about the future, avoidance and poor sleep due to bad dreams. The difference in treatment effect on the HRSD for CGT over IPT was more pronounced for participants not taking antidepressants where CGT reduced depression but IPT did not. Paper two examines possible mediators specific to the model of CGT including: guilt/self-blame specific to the death or deceased; negative thoughts about the future; avoidance of reminders of the loss; anxiety and depression (intense negative emotions). Antidepressants are also examined as a potential moderator to explore whether their use affects the mediating role of the identified variables. All of these variables emerged as either full or partial mediators of CGT. Antidepressant use had no effect on the
mediating role of these variables. Paper three examines whether alliance (measured at week 4) predicts subsequent change in grief symptoms (controlling for early symptom change) and if so, whether it accounts for the difference in treatment effect between CGT and IPT (mediation). Working alliance emerged as a mediator of CGT, accounting for 28% of the treatment effect found between CGT/IPT and grief symptoms. Discussion sections for each paper summarize study findings, limitations and implications for future research.
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Acknowledgements and Dedication

I would like to thank my dissertation committee for their inspiration and guidance: Dr. Katherine Shear, Dr. Nabila El-Bassel, Dr. Robin Gearing, Dr. Melanie Wall and Dr. Anne Germain. As a pioneer in the field of complicated grief research, Dr. Shear has taught me a great deal about the complexity of complicated grief (CG) and its treatment. She has also been a role model for combining clinical research and practice in the interest of making a lasting difference in people’s lives. Dr. El-Bassel sparked my interest in mediation analysis and the value of delving into the “black box” of psychotherapy in order to better understand what creates change within treatment. Dr. Gearing was instrumental in helping me to hone in on my research interests and to identify the best way of approaching my chosen topic. Dr. Wall provided me with crucial guidance in statistical analyses and how to interpret and present my findings. And finally, Dr. Germain provided guidance on the interesting and understudied question of dreams in CG and how they might be used to gauge progress in treatment.

I would also like to thank the patients in the Complicated Grief Treatment in Older Adults (CGTOA) and Healing Grief After Loss (HEAL) studies, who gave me insight into the debilitating nature of complicated grief and the inspiration to contribute research as well as clinical practice in this field. My sincerest thanks also go to my colleague Angela Ghesquiere for her friendship, guidance and encouragement while pursuing my research assistantship and doctoral work at Columbia. Finally, I would like to thank my father and step-mother for providing ongoing support and encouragement, and to my daughter for asking me thoughtful questions about CG and how best to help people recover. This dissertation is dedicated to my mother who taught me about love and loss and who inspires me each day to live life to the fullest.
Introduction

This dissertation is an exploration of the possible mediators of complicated grief treatment (CGT) in an effort to gain a better understanding of the mechanisms by which the treatment exerts its effects. In a randomized controlled trial it was shown that CGT is more effective than Interpersonal Psychotherapy (IPT) in treating complicated grief (CG), a newly identified syndrome that causes significant impairment and is associated with a negative course without treatment (Shear et al., 2005). The response rate of the intent-to-treat sample (n=95) was 51% in CGT vs. 28% in IPT, p = .02 and among treatment completers (n=69) the response rate was 66% in CGT vs. 32% in IPT, p = .006. Among treatment completers, CGT was also more effective in reducing grief symptoms, depression and grief-related impairment in work and social functioning.

Over the past decade, several other clinical trials have examined psychotherapy interventions targeting CG and have found positive results (Wagner et al., 2006; P. Boelen et al., 2007; Rosner et al., 2011). These studies confirm that people with symptoms of complicated grief can be effectively treated with the right tools. Identifying which components are the most salient and understanding how they work to reduce CG symptoms requires further study.

Complicated grief is a debilitating condition that affects roughly 7% of bereaved people (Kersting, 2011). It is characterized by persistent symptoms of separation distress (longing and yearning for the deceased, intense sadness, preoccupation with thoughts and memories of the deceased and loss of interest in activities) and traumatic distress (disbelief and shock, difficulty comprehending the loss, feeling lost and disoriented, intrusive images and avoidance of reminders of the loss). While not currently a diagnosis in the DSM-IV, CG can be reliably
identified by administering the Inventory of Complicated Grief (ICG) more than six months after the death and using a cut-off score of 30 (Prigerson, Bierhals et al., 1995). CG has been distinguished from other disorders such as MDD, Anxiety and PTSD (Prigerson, Frank et al., 1995; P. A. Boelen & van den Bout, 2008). It has been associated with increased risk for other physical and mental health problems such as high blood pressure, cancer, hypertension, suicidal ideation and substance abuse (Prigerson et al., 2009).

CGT is the first targeted treatment for this condition that was manualized and tested in a formalized randomized controlled trial (Shear et al., 2005). The treatment is based on an attachment theory framework for understanding bereavement, grief and mourning and the complications that impede natural healing. Most typically these include counter-factual thinking around troubling aspects of the death (e.g. blaming oneself or others for how the person died) or consequence of the death (e.g. life has no purpose or meaning without the loved one); avoidance behaviors; and problems with emotion regulation. This results in the syndrome of complicated grief. CGT works to identify and resolve the complicating issues (e.g. acceptance vs. counterfactual thinking, reducing avoidance, supporting emotion regulation) in order to facilitate the natural healing process of fully acknowledging the finality and consequences of the loss and re-envisioning life with meaning and satisfaction.

This dissertation explores the possible mediators of CGT, first by looking broadly at a range of ancillary outcomes of the treatment (paper 1) and then more specifically at possible mediators related directly to the treatment model (e.g. avoidance, negative thoughts, self-blame, etc.) (paper 2). Mediation analysis is becoming increasingly more important as researchers, clinicians and funders seek to improve outcomes and efficiency of psychotherapy. Methodology
for establishing mediation has been developed and more psychotherapy studies are incorporating potential mediators into their data collection and analyses.

The primary task in establishing mediation is to demonstrate a strong association between the intervention and the mediator and between the mediator and the outcome (Baron & Kenny, 1986). It is also necessary to show that change in the mediator preceded change in the outcome (Johansson & Hoglend, 2007). Establishing temporal precedence can be difficult, as it requires measurements at multiple time points during the treatment rather than just at beginning and end. Paper 2 examines 5 potential mediators of CGT, following guidelines for establishing mediation proposed by Baron and Kenny as well as modifications by the MacArthur work group (Kraemer et al., 2008) and taking temporal precedence into account where possible.

In addition to exploring possible mediators related specifically to the model of CGT, this dissertation also examines the role of a non-specific component of the treatment, therapeutic alliance (paper 3). Most commonly defined as the agreement between therapist and patient on the goals and tasks of therapy as well as the therapeutic bond (Bordin, 1979), the alliance has largely been examined in terms of its correlation with outcome, not its role as a mediator of treatment effects.

Alliance has been identified in the literature as one of the most salient components of psychotherapy, accounting for significantly more of the variance in outcome than specific treatment techniques (Wampold, 2001). Recent studies have shown that the correlation between alliance and outcome holds true across treatment types, patient characteristics, measurement scales, raters, time of alliance (early, mid or late), outcome measures, publication source, research design, and researcher allegiance (Horvath et al., 2011; Fluckiger, 2012). Only a
handful of studies have found that alliance is not associated with treatment gains (Gaston et al., 1991; Barber et al., 1999; Feeley, 1999; Kaufman et al., 2005).

One of the critiques of alliance research has been that temporal precedence has been overlooked. Alliance, measured late in the treatment, may be associated with outcome but may reflect symptom improvement rather than the other way around (Feeley, 1999; Kazdin, 2007). To avoid this problem, researchers recommend that alliance be measured early in the treatment and that outcome reflect change that occurred after the alliance was measured (Zuroff & Blatt, 2006; Kazdin, 2007). More recent studies have used longitudinal designs to examine alliance at multiple time points, controlling for earlier symptom change (Barber et al., 2000; Kaufman et al., 2005; Zuroff & Blatt, 2006; Beckner et al., 2007). Only one study identified by this author has examined alliance as a potential mediator of outcome and found that it did not mediate change in depression among adolescents treated with CBT because alliance was not associated with treatment gains (Kaufman et al., 2005).

**Specific Aims and Hypotheses of the Three Papers**

The overall aim of the dissertation is to enhance our understanding of how CGT works to reduce grief. What are the changes within the patient or within the treatment that are associated with and account for a reduction in the symptoms of complicated grief? Do specific ingredients of the treatment matter most or do non-specific components such as therapeutic alliance matter more? This 3-paper dissertation will utilize data from an NIMH-funded randomized controlled trial of CGT (Shear et al., 2005). The first paper examines a broad range of ancillary outcomes including symptoms of anxiety, depression, complicated grief and sleep disturbance due to bad dreams. Antidepressant use is examined as a possible moderator since half the sample was taking antidepressants and those taking antidepressants had a marginally better response rate in
CGT than those not taking them (59% vs. 42% in CGT and 40% vs. 19% in IPT). Paper two examines possible mediators specific to the model of CGT including: guilt/self-blame specific to the death or deceased; negative thoughts about the future; avoidance of reminders of the loss; anxiety and depression (intense negative emotions). Antidepressants are also examined as a potential moderator to explore whether their use affects the mediating role of the identified variables. Paper three examines whether alliance (measured at week 4) predicts subsequent change in grief symptoms (controlling for early symptom change) and if so, whether it accounts for the difference in treatment effect between CGT and IPT (mediation).

**Paper 1**

**Aim 1:** To examine whether treatment type (CGT or IPT) is significantly associated with a change in ancillary outcomes including: symptoms of anxiety, depression, complicated grief and sleep-related symptoms.

Hypothesis: CGT will be more effective in reducing symptoms of anxiety, depression, complicated grief and sleep-related symptoms than IPT.

**Aim 2:** To examine whether antidepressant use moderates the relationship between treatment group and ancillary outcome.

Hypothesis: Those taking medication will have better outcomes in CGT than those not taking medication.

**Paper 2**

**Aim 1:** To examine whether change in intermediary variables (ancillary outcomes identified in paper 1) is associated with a change in grief symptoms. These include: self-blame related to the death or deceased; negative thoughts about the future; anxiety; depression; and avoidance of reminders of the loss.
Hypothesis: A reduction in each of the intermediary variables (individually) will be associated with a reduction in grief.

**Aim 2:** To identify which of the intermediary variables can be considered mediators of the treatment effect found between CGT/IPT and grief symptoms and to quantify the magnitude of their mediating effect.

Hypothesis: Each of the intermediary variables will be considered mediators of the treatment effect found between CGT/IPT and grief symptoms.

**Aim 3:** To examine whether antidepressant use affects the mediating relationship between intermediary variables and treatment outcome.

Hypothesis: The mediating role of each intermediary variable will be stronger for those not taking antidepressants than for those taking them.

**Paper 3**

**Aim 1:** To examine whether treatment type is associated with early therapeutic alliance (measured at week 4).

Hypothesis: Treatment type will not be associated with early therapeutic alliance.

**Aim 2:** To examine whether early working alliance is associated with a reduction in grief symptoms.

Hypothesis: Early working alliance will be associated with a change in grief symptoms.

**Aim 3:** To examine whether alliance can be considered a mediator of the treatment effect found between CGT/IPT and grief symptoms and to quantify the magnitude of its mediating effect.

Hypothesis: Early working alliance will not be considered a mediator of the treatment effect found between CGT/IPT and grief symptoms.
Research to date has shown that treatments designed to treat CG can be successful but we do not yet know exactly how they work. This dissertation will address this gap in the literature by examining potential mediators of an efficacious treatment, CGT. Identifying the ancillary outcomes and possible mediators of CGT will provide us with valuable information that may help to explain how this treatment works to reduce the debilitating symptoms of CG. Researchers can use this information to study these variables more closely and incorporate them into future research studies designed specifically to test the mediators and mechanisms of action of CGT. Ultimately, practitioners will be able to use the findings to hone in on the most salient aspects of the treatment, thereby making therapy for CG more potent and efficient.
References


Paper 1: Ancillary Outcomes of Complicated Grief Treatment
Introduction

The loss of a loved one is one of the most difficult experiences a person can endure. While most move successfully through a normal grief process, roughly 7% of bereaved people develop a debilitating condition known as complicated grief (CG) (Kersting, 2011). CG is characterized by persistent yearning and longing for the deceased; intense sorrow and emotional pain; preoccupation with thoughts of the loved one and circumstances of the death; a sense of disbelief and shock regarding the death; anger and bitterness over the death; maladaptive appraisals (self-blame) about oneself in relation to the deceased or the death; excessive avoidance of situations and activities that serve as reminders of the loss; feelings of detachment from other people since the death; and the feeling that life is meaningless or empty without the deceased (American Psychiatric Association, 2011).

Although some of the symptoms of CG overlap with disorders sharing similar features, studies have distinguished it from major depression, anxiety and post-traumatic stress disorder (Prigerson, Frank et al., 1995; Shear et al., 2005; P. A. Boelen & van den Bout, 2008). Additionally, studies show that treatments for depression have minimal effect on symptoms of CG (Shear et al., 2011). Complicated grief has been associated with increased risk for cancer, high blood pressure, suicidal ideation, hypertension and substance abuse (Prigerson et al., 2009). Diagnostic criteria for CG have been proposed for the Diagnostic Statistical Manual of Mental Disorders (DSM-5) and will likely be included in the section on disorders requiring further study as a “complex persistent bereavement-related disorder” (American Psychiatric Association, 2011).

Over the past decade, there has been growing interest in the treatment of CG and several clinical trials that have examined psychotherapy interventions (Shear et al., 2005; Wagner et al.,
Outcomes have focused primarily on grief symptoms but have also included measures of anxiety, depression, impairments in social and work functioning, general mental and physical health, general psychopathology, negative cognitions, avoidance behavior and sleep quality. In the first large randomized controlled trial of psychotherapy targeting symptoms of CG, Shear et al. (2005) found a significant reduction in CG symptoms in those treated with Complicated Grief Treatment (CGT) compared to Interpersonal Psychotherapy (IPT). The study also found a decrease in depression and social and work impairment among treatment completers (Shear et al., 2005). Utilizing the same data, Germain et al. (2006) found that treatment responders showed modest but statistically significant improvements in sleep quality.

In a study by Boelen and colleagues comparing the effectiveness of Cognitive Behavioral Treatment (CBT) with supportive counseling for the treatment of CG, results showed a significant reduction in CG symptoms and general psychopathology in the CBT groups compared to the control (P. Boelen et al., 2007). In a subsequent study utilizing the same data, the authors found a significant reduction in loss-related negative cognitions and avoidance behavior (P. Boelen et al., 2011).

Wagner et al. (2006) investigated the effectiveness of an internet-based cognitive-behavioral therapy for people with CG and found significant improvement in symptoms of intrusion, avoidance, maladaptive behavior and general psychopathology. In a study by Rosner and colleagues comparing a CG group intervention with treatment as usual (TAU) in an inpatient setting, results showed a significant reduction in grief symptoms in the treatment group compared with the control while changes in depression and overall mental distress did not differ between the two groups (Rosner et al., 2011).
The present study is intended to add to this literature by examining ancillary outcomes from the 2005 efficacy study of CGT conducted by Shear and colleagues (Shear et al., 2005). Aim 1 was to examine symptoms that can interfere with the natural grief process such as anxiety and depression as well as the most common form of grief complications such as negative thoughts about the future, guilt-related to the death or deceased and grief-related avoidance. Poor sleep quality due to bad dreams was included as an extension of prior research on the impact of CGT on overall sleep quality and associated subgroups (Germain et al., 2005). Because CGT targets specific grief complications such as counterfactual thinking around troubling aspects of the death (e.g. self blame for how the person died), avoidance behavior and emotion regulation, it was hypothesized that the symptoms identified in this report would respond better to CGT than to IPT. Aim 2 was to examine antidepressant use as a possible moderator since nearly half the sample was taking at least one antidepressant and results from the parent study showed that people taking antidepressants had marginally better response rates in CGT than those not taking them. It was hypothesized that those taking antidepressants would have better outcomes (i.e. greater reduction in symptoms) in CGT in the present study as well.

The utility in looking at outcomes above and beyond grief symptoms is that it may provide us with more information about the types of symptoms that can be effectively treated with this therapeutic approach (with and without concomitant antidepressants). This information could be used for future intervention studies targeting CG or other related disorders.

Overview of parent study

Details of the methodology of the parent study are available in a previously published paper (Shear et al., 2005). Briefly, participants were recruited through professional referral, self-referral and media announcements between 2001 and 2004 in Pittsburgh, PA at a university-
based psychiatric clinic as well as a satellite clinic in a low-income African-American community. The randomized sample included 83 women and 12 men (age 18-85) who had lost a loved one at least 6 months prior and met criteria for complicated grief, defined as a score of 30 or higher on the Inventory of Complicated Grief (ICG) (Prigerson, Bierhals et al., 1995). Participants were randomly assigned to receive IPT, n=46, or CGT, n = 49. Randomization was stratified by and within treatment site and by violent (accident, homicide or suicide) vs. non-violent death of a loved one. Both groups were offered 16 weekly therapy sessions over a 16 to 20 week period. Medication for longer than 3 months at a stable dose for > 6 weeks was permitted as long as the medication management was transferred to the study pharmacotherapist. All therapists were either masters or doctoral level clinicians with training and certification in either IPT or CGT. Therapists received ongoing supervision and therapy sessions were audio taped for adherence, performed on a randomly selected subset of session segments. Analysis of the adherence data showed that the two treatments could be reliably distinguished from one another (Wilsey et al., 2006). Data was collected by self-report and independent evaluators blinded to treatment assignment at baseline, during treatment and posttreatment follow-up. The primary outcome measure was the Clinical Global Impression of Improvement Scale (CGI), a single Likert-type rating from 1 to 7 where 1 through 3 indicate “very much,” “much” and “minimally improved” respectively; 4 indicates “no change” and 5 through 8 indicate “minimally,” “much” and “very much worse” respectively (Guy, 1976). A CGI rating of 1 or 2 “very much” or “much improved” qualified the participant as a treatment responder. Additional outcome measures included the Inventory of Complicated Grief (ICG), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI) and Work and Social Adjustment Scale (WSAS).
The control condition, IPT, is a manualized short-term treatment that focuses on a selected problem area of grief, interpersonal disputes, role transition or interpersonal deficits. Most of the IPT treatments in this study focused on grief alone or grief and one of the other problem areas.

The treatment condition, CGT, was also delivered according to a treatment manual and had yielded positive results in a prior pilot study (Shear et al., 2001). CGT is based on an attachment theory model of grief. It integrates IPT with cognitive-behavioral techniques used to address trauma-like symptoms of CG and motivational interviewing techniques. Unlike IPT, CGT includes grief monitoring, psychoeducation about CG and the techniques used to address it; exposure techniques such as imaginal revisiting (repeated retelling of the story of the death), situational revisiting (graded exposure to avoided situations) and an imaginal conversation with the deceased; a focus on personal aspirations and goals and a focus in each session on the dual process of adjustment to the loss and restoration of a satisfying life.

Results of the RCT (Shear et al., 2005) showed the response rate was greater in CGT than IPT (51% compared to 28% for IPT (p=.02)) and time response (to a 20 point or better improvement on the ICG) was faster for CGT. Among treatment completers, 66% of CGT participants responded to treatment compared with 32% in IPT. The number needed to treat was 2.9 for completers. Among treatment completers, CGT was also significantly more effective than IPT in reducing complicated grief symptoms (ICG), depression (BDI), and improving grief-related functioning (WSAS – work, home management, social situations and leisure time).

Method

Sample
This study examined treatment completers only (n=69, 35 in CGT and 34 in IPT) in order to examine ancillary outcomes among those who completed the full course of treatment. Completers did not differ from drop-outs on any of the baseline measures. The majority of the sample was female (84%), Caucasian (74%) with a mean age of 48.4 years. Nearly half the sample was taking antidepressant medication (49%) and comorbid mood or anxiety disorders were common. Forty-six percent had current major depressive disorder (MDD), 52% current posttraumatic stress disorder (PTSD), 18% current generalized anxiety disorder (GAD), 10% current panic disorder (PD), 3% current social phobia disorder, and 6% current obsessive-compulsive disorder (OCD). See Table 1 for baseline comparison of completers by treatment group.

**Ancillary Outcome Measures**

**Anxiety Symptoms** – Anxiety symptoms were measured using two different instruments: the Beck Anxiety Inventory (BAI) and the Structured Clinical Interview for the DSM-IV (SCID).

BAI: Treatment effects on the BAI, a 21-item, well-validated instrument used to measure clinical anxiety (Beck et al., 1988) were shown in the parent study; among completers, the change in mean BAI score was 9.5 in CGT vs. 5.8 in IPT, p = .17 (Shear et al., 2005). In this analysis, this work is extended to examine whether the treatment differentially affected cognitive and somatic subscales.

Cognitive Subscale: A composite of items from the BAI (described above) was used to measure the cognitive aspects of anxiety identified by Hewitt and Norton who found two factor loadings for the BAI; cognitive and somatic (Hewitt & Norton, 1993). The items that loaded highest on the cognitive factor (and lowest on the somatic factor) include: *fear of the worst*
happening, terrified, nervous, fear of losing control, fear of dying, and scared. Internal consistency for the composite variable (using this sample) was high (Cronbach’s α = .89).

Somatic Subscale: This variable, derived from the BAI (described above), includes items that loaded highest on the somatic factor and lowest on the cognitive factor (Hewitt & Norton, 1993): face flushed, feeling hot, numbness or tingling, dizzy or lightheaded, wobbliness in legs, sweating, heart racing or pounding, unsteady, difficulty breathing, faint, indigestion, and feelings of choking. Cronbach’s α in this sample = .88.

SCID: Change in anxiety disorder diagnoses was evaluated for those disorders endorsed by more than 10% of the completer sample. This included Generalized Anxiety Disorder (GAD) and Post Traumatic Stress Disorder (PTSD), measured by the SCID (First et al., 1996).

Depressive Symptoms – Depressive symptoms were measured using 3 different instruments: the Beck Depression Inventory (BDI), the Hamilton Rating Scale for Depression (HRSD) and the SCID.

BDI: The BDI is a widely used, well-validated 21-item self-report instrument used to assess the severity of depression (Beck et al., 1979). Treatment effects on the BDI were shown in the parent study. Among treatment completers, the change in mean BDI score was 12.7 in CGT vs. 7.3 in IPT, p = .02 (Shear et al., 2005). In this analysis, this work is extended to examine whether the treatment differentially affected cognitive and somatic-affective subscales (Steer et al., 1999). All items on the BDI are scored from 0 to 3, with 3 = the most symptomatic and 0 = the least.

Cognitive Subscale: A composite of items from the BDI was used to measure cognitive aspects of depression including: pessimism, past failure, guilty feelings, punishment feelings,
self-dislike, self-criticalness, suicidal thoughts or wishes, crying and worthlessness. Cronbach’s α in this sample = .86.

Somatic-Affective Subscale: This variable, derived from the BDI (described above), includes items that loaded highest on the somatic-affective factor: loss of pleasure, loss of interest, indecisiveness, loss of energy, irritability, change in appetite, tiredness and fatigue, and loss of interest in sex. Lack of concentration also loaded high on this factor but was not included in this analysis because it is not in the 21-item version of the BDI. Cronbach’s α in this sample = .81.

Guilt/self-blame (general): This variable was derived from one item on the BDI (described above). This item asks the respondent to select the statement which best describes the way he/she has been feeling in the past week: I don’t feel particularly guilty; I feel guilt a good part of the time; I feel quite guilty most of the time; I feel guilty all of the time. This variable measures guilt in general and was moderately correlated with the grief-specific guilt measure derived from the SCI-CG (r=.53).

Negative thoughts about the future: This variable was measured by one item on the BDI (described above), which asks the respondent to select the statement that best describes the way he/she has been feeling in the past week: I am not particularly discouraged about the future; I feel discouraged about the future; I feel I have nothing to look forward to; I feel that the future is hopeless and that things cannot improve.

HRSD: The Hamilton Rating Scale for Depression (HRSD) is a widely used, well-validated 25-item interview-rated instrument used to assess the severity of depression (Hamilton, 1960). The total score was used to measure depression.

SCID: Major Depressive Disorder (MDD) was measured by the SCID (First et al., 1996).
Complicated Grief Symptoms – Symptoms of CG were measured by variables created from two different instruments: the GRAQ and the SCI-CG.

Avoidance (GRAQ): This variable was measured by the total score on the Grief Related Avoidance Questionnaire (Shear et al., 2007). This 15-item self-report questionnaire was developed and tested by Shear’s research team to assess the level of grief-related avoidance of common situations and activities following the death. Each item is scored from 0 to 4 with 0 = never, 1 = rarely, 2 = sometimes, 3 = often and 4 = always. The scale has good psychometric properties ($\alpha = .87$) and CG patients endorse a range of scores on the scale.

Avoidance of the loss subscale: This variable was derived from the GRAQ (described above), a composite of 6 items that pertain specifically to reminders of the deceased: *Do you avoid rooms or places that you associate with the person who died? Do you avoid activities around your home associated with the person who died? Do you have activities outside your home that are associated with the person who died? Do you avoid activities with family members or friends that are associated with the person who died? Do you avoid social activities with friends that are associated with the person who died? Do you avoid social activities with couples or other groups that provoke feelings of being “odd man out” or feelings of intense longing for the person who died?* In a study by Shear et al. (2007), this subscale was significantly correlated with the Work and Social Adjustment Scale, which measures functional impairment. Cronbach’s $\alpha = .87$.

Avoidance (SCI-CG): This variable was derived from the Structured Clinical Interview for Complicated Grief (SCI-CG), developed and tested by Shear et al.’s research group. A composite of two items from the SCI-CG was used to measure avoidance behavior: “Do you avoid activities, people, places, or objects that remind you of ____?” and “Do you feel reluctant
to talk about ____?” Items are rated from 0 to 2 with 0 = no, 1 = maybe 2 = yes. Cronbach’s $\alpha = .48$.

Guilt/self-blame related to the death or the deceased: This variable was derived from the SCI-CG (described above). A composite of the following items was used: Have you had guilty or self-blaming thoughts or beliefs about the death? Do you blame yourself for doing or not doing something either when _____ was alive, or at the time he/she died, that you think might have helped? Do you have the idea that you could have prevented this death, even though you know it isn’t very rational? Cronbach’s $\alpha = .86$.

Sleep-related Symptoms – In a study by Germain and colleagues examining the effects of CGT on sleep quality, no significant differences were found between treatment groups on overall sleep quality or any of the seven subscales of the Pittsburgh Sleep Quality Index (PSQI), however statistically significant but modest improvement in sleep quality was found for CGT responders (Germain et al., 2006). This work is extended to examine the effects of CGT on sleep quality due to bad dreams specifically.

Bad dreams: This variable was derived from one item on the PSQI, a 19-item self-report instrument that measures seven aspects of sleep quality (subjective sleep quality, sleep latency, duration, efficiency, disturbances, use of sleep medication and daytime dysfunction) in the past month. The item asks the respondent: During the past month, how often have you had trouble sleeping because you had bad dreams? Each item rates the frequency of symptoms from 0 to 3 with 0 = not in the past month, 1 = less than once a week, 2 = once or twice a week and 3 = 3 or more times in the past month.

Statistical analysis
Differences in baseline characteristics between treatment groups were tested using Fisher’s exact test (categorical characteristics) or two-sample t-tests (continuous characteristics). Hypothesizing that improvements in ancillary outcomes would be greater in the CGT group compared to the IPT group, one-tailed t-tests were used to test for improvements from baseline to week 16 (post-treatment) in each ancillary outcome between treatment groups. Although this method can inflate the type-1 error rate, this decision was made based on findings from the parent study that CGT was more effective than IPT in reducing symptoms of CG and depression in the completer sample and trended toward efficacy with regard to reducing anxiety (Shear et al., 2005). In addition, the model of CGT targets these variables specifically, providing further justification for the hypothesis that CGT would produce greater effects on these outcomes than IPT. Statistical significance was set at p<=0.05. Change in ancillary outcomes within treatment groups were tested with paired t-tests and mean changes within treatment groups were standardized to facilitate comparison across different outcomes (referred to in Table 2 as “standardized change” by dividing the mean change (baseline to post-treatment) by the pooled baseline standard deviation. For dichotomous outcomes McNemar’s test was used to test for changes within treatment group. Effect size (ES) for the treatment differences between groups was calculated by dividing the mean difference in outcome (baseline to post-treatment) by the pooled baseline standard deviation. The Wilks-Shapiro test was used to check change variables for large departures from normality. Where found, sensitivity analysis was done to assess the robustness of the p-values by additionally performing the Wilcoxin signed rank test.

To test for moderation of effects by antidepressant use, multiple regression analysis was used to examine the interaction between antidepressant use and treatment group as it affects
change in ancillary outcomes. For interaction tests, the more liberal p-value of 1.0 was used for statistical significance due to the difficulty of detecting interaction effects.

Results

Baseline characteristics

Table 1 includes demographic characteristics of the sample of treatment completers. The sample was 84% female, 74% Caucasian, 22% African-American, 3% Asian, with a mean age of 48.4 years. Mean ICG score was 44.8. Comorbid mood or anxiety disorders were common. Forty-six percent had current major depressive disorder (MDD), 52% current posttraumatic stress disorder (PTSD), 18% current generalized anxiety disorder (GAD), 10% current panic disorder (PD), 3% current social phobia disorder, and 6% current obsessive-compulsive disorder (OCD). Thirty-four out of 69 (49%) were taking antidepressant medication.

There were no significant differences in demographic characteristics or ancillary outcomes between the two randomized groups at baseline.

<table>
<thead>
<tr>
<th>Table 1. Baseline Comparison of Treatment Groups (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
</tr>
<tr>
<td>Sample Characteristics</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
</tr>
<tr>
<td>Medication (at least one)</td>
</tr>
<tr>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Posttraumatic Stress Disorder</td>
</tr>
<tr>
<td>Generalized Anxiety Disorder</td>
</tr>
<tr>
<td>Panic Disorder</td>
</tr>
<tr>
<td>Social Phobia</td>
</tr>
<tr>
<td>Obsessive Compulsive Disorder</td>
</tr>
<tr>
<td>Inventory of Complicated Grief, mean (SD)</td>
</tr>
<tr>
<td>Work and Social Adjustment Scale, mean (SD)</td>
</tr>
<tr>
<td>Beck Depression Inventory, mean (SD)</td>
</tr>
<tr>
<td>Beck Anxiety Inventory, mean (SD)</td>
</tr>
<tr>
<td>Hamilton Rating Scale for Dep., mean (SD)</td>
</tr>
<tr>
<td>Sleep Quality (Global)</td>
</tr>
</tbody>
</table>

A Data are expressed as No. (%) unless otherwise noted.

b n=34 due to missing data

c n=33 due to missing data

d Measured by the Pittsburgh Sleep Quality Index (PSQI) (Germain, et al. 2006), scores above 5 indicate poor sleep quality.
Changes in Psychological Symptoms Baseline to Post-Treatment

Figures 1 – 3 show standardized changes in ancillary outcomes within treatment groups. Table 2 shows pre and post treatment scores by treatment group, standardized change within groups and effect sizes for the treatment differences.

Changes in Anxiety Symptoms

Cognitive symptoms of anxiety (measured by the BAI) showed large decreases significantly in both treatment groups but the change was greater in CGT than IPT (1.01 standardized change in CGT vs. 0.55 standardized change in IPT, treatment effect size (ES) = 0.45, p = .02). Somatic symptoms of anxiety (BAI) also significantly decreased in both groups (0.42 in CGT vs. 0.43 in IPT) but there was no difference between the groups (ES = .02, p = 0.53). GAD (DSM-IV) did not significantly decrease in either group while PTSD (DSM-IV) significantly decreased by 35% in CGT and by 23% in IPT, although the difference between treatment groups was not statistically significant.

Changes in Depressive Symptoms

Depressive symptoms measured by the HRSD showed large decreases significantly in CGT compared to no significant change in IPT (1.2 standardized change in CGT vs. 0.12 standardized change in IPT, treatment ES = 0.99, p = .0002). Cognitive symptoms of depression (measured by the BDI) showed decreases significantly in both groups (0.75 in CGT vs. 0.49 in IPT) but the change was marginally greater in CGT (ES = 0.29, p = .06). Somatic-affective symptoms of depression (BDI) also decreased in both groups (.83 in CGT vs. 0.52 in IPT) but the change in CGT was greater (ES = 0.34, p = .05). MDD (DSM-IV) significantly decreased by 35% in CGT while the change of 15% in IPT was not significant.
Guilt not-related to the death (measured by the BDI) showed large decreases significantly in both groups but the change was greater in CGT than IPT (0.81 standardized change in CGT vs. 0.33 standardized change in IPT, ES = .48, p = .01). This difference became marginally significant (.06) when using the non-parametric Wilcoxin signed rank test to account for the non-normal distribution of this variable.

Negative thoughts about the future showed large decreases significantly in both treatment groups but the change was greater in CGT than IPT (1.01 standardized change in CGT vs. 0.47 standardized change in IPT, ES = 0.45, p = .01).

**Change in Complicated Grief Symptoms**

Avoidance (measured by the GRAQ) showed large decreases significantly in CGT compared to no significant change in IPT (0.72 standardized change vs. 0.25 standardized change, treatment ES = 0.47, p = .05). Both group showed decreases significantly on the avoidance of the loss subscale but the difference between the groups was not significant (.56 in CGT vs. .39 in IPT, ES = .18, p=.28). Avoidance (measured by the SCI-CG) showed large decreases significantly in both groups, with a marginally greater change in CGT compared to IPT (1.43 standardized change in CGT vs. .94 standardized change in IPT, ES = .52, p = .06).

Guilt/self-blame related to the death (measured by the SCI-CG) showed large decreases significantly in both groups but the difference between groups was not statistically significant (1.17 standardized change in CGT vs. .77 standardized change in IPT, ES = .41, p = .08).

**Change in Sleep-Related Symptoms**

The frequency of bad dreams decreased significantly in CGT while in IPT it remained the same. In CGT, the percentage of participants who had bad dreams in the past month decreased
from 56% (19/34) to 34% (11/32) while in IPT, the percentage who had bad dreams decreased from 51.5% (17/33) to 50% (16/32).

**Figure 1. Change in Anxiety Symptoms by Treatment Group**

<table>
<thead>
<tr>
<th>Ancillary Outcomes of CGT</th>
<th>CGT</th>
<th>IPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>*BAI Total</td>
<td>0.82</td>
<td>1.01</td>
</tr>
<tr>
<td>Cognitive Subscale (BAI)</td>
<td>0.51</td>
<td>0.55</td>
</tr>
<tr>
<td>Somatic Subscale (BAI)</td>
<td>0.42</td>
<td>0.43</td>
</tr>
<tr>
<td>GAD (DSM-IV)</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>PTSD (DSM-IV)</td>
<td>34%</td>
<td>24%</td>
</tr>
</tbody>
</table>

Note: Standardized change is calculated as baseline score – post-treatment score/pooled baseline standard deviation. Changes in GAD and PTSD are not standardized; they are shown as % change.
* Difference in treatment effect is statistically significant (p<.05).
Change in the BAI total score was previously published by Shear et al. (2005) and is included here for reference.

**Figure 2. Change in Depressive Symptoms by Treatment Group**

<table>
<thead>
<tr>
<th>Ancillary Outcomes of CGT</th>
<th>CGT</th>
<th>IPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>*HRSD</td>
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<td>1.21</td>
</tr>
<tr>
<td>*BDI Total</td>
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<td>0.7</td>
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<tr>
<td>Cognitive (BDI)</td>
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<td>0.67</td>
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<tr>
<td>Somatic (BDI)</td>
<td>0.82</td>
<td>0.82</td>
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<tr>
<td>*Guilt- General (BDI)</td>
<td>0.81</td>
<td>0.81</td>
</tr>
<tr>
<td>*Neg. Thoughts About Future (BDI)</td>
<td>1.01</td>
<td>0.47</td>
</tr>
<tr>
<td>MDD (DSM-IV)</td>
<td>15%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Note: Standardized change is calculated as baseline score – post-treatment score/pooled baseline standard deviation. Change in MDD is not standardized; it is shown as % change.
* Difference in treatment effect is statistically significant (p<.05).
Change in the BDI total score was previously published by Shear et al. (2005) and is included here for reference.
Figure 3. Change in Complicated Grief Symptoms by Treatment Group

Table 2. Pre and Posttreatment Scores by Group & Effect Sizes for Treatment Differences

<table>
<thead>
<tr>
<th>Variables</th>
<th>CGT Mean (SD)</th>
<th>IPT Mean (SD)</th>
<th>Effect Size</th>
<th>P-Value</th>
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<td></td>
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<td>6.4 (4.1)</td>
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<td></td>
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<td>.02</td>
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<td>n=34</td>
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<td>6.0 (5.1)</td>
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<td></td>
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<td>6/32 (19%)</td>
<td>6/34 (18%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>5/32 (16%)</td>
<td>5/34 (15%)</td>
<td></td>
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<td>1 (3%)</td>
<td>0%</td>
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<td>Pretreatment</td>
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<td>16/34 (47%)</td>
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<tr>
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<td>8/34 (24%)</td>
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<td>10.5%</td>
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<tr>
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<td>.02</td>
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<td>Posttreatment</td>
<td>Change</td>
<td>Standardized change</td>
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<td><strong>P-value of stand. change</strong></td>
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<td>.13</td>
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<td>.13</td>
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<td>n=34</td>
<td></td>
<td></td>
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<tr>
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<td><strong>Negative Thoughts</strong></td>
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<td>n=34</td>
<td></td>
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<td>Pretreatment</td>
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<td>1.1 (.83)</td>
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<td>P-value of stand. change</td>
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<tr>
<td><strong>MDD (DSM-IV)</strong></td>
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<td>n=34</td>
<td></td>
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<tr>
<td>Pretreatment</td>
<td>17/32 (53%)</td>
<td>13/34 (38%)</td>
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<td>.21</td>
</tr>
<tr>
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<td>6/32 (19%)</td>
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</tr>
<tr>
<td>Change</td>
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<td>5 (15%)</td>
<td>19%</td>
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<td>P-value of stand. change</td>
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**Grief-Related Symptoms**

<table>
<thead>
<tr>
<th></th>
<th>Pretreatment</th>
<th>Posttreatment</th>
<th>Difference</th>
<th>Standardized change</th>
<th>P-value of stand. change</th>
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<tr>
<td>Avoidance - GRAQ</td>
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<td>n=25</td>
<td>25.5 (11.1) 21.4 (12.8)</td>
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<td>.47</td>
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<tr>
<td>Avoidance of Loss Subscale</td>
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<td>n=25</td>
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<td>1.7 (1.4)</td>
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<td>Difference</td>
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<tr>
<td>Guilt/Blame - SCI-CG</td>
<td>n=25</td>
<td>n=31</td>
<td>4.5 (2.2)</td>
<td>4.4 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>1.9 (1.9)</td>
<td>2.7 (2.5)</td>
<td></td>
<td>2.6 (2.1)</td>
<td>.41</td>
</tr>
<tr>
<td>Change</td>
<td>2.6 (2.1)</td>
<td>1.7 (2.6)</td>
<td></td>
<td>2.6 (2.1)</td>
<td>.41</td>
</tr>
<tr>
<td>Standardized change</td>
<td>1.17</td>
<td>.77</td>
<td></td>
<td>1.17</td>
<td>.77</td>
</tr>
<tr>
<td>P-value of stand. change</td>
<td>.00</td>
<td>.00</td>
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<td>.00</td>
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</tr>
</tbody>
</table>

**Sleep-Related Symptoms**
### Table 3. Pre and Post Treatment Scores on HRSD by Treatment Group & Antidepressant Status

<table>
<thead>
<tr>
<th></th>
<th>No Antidepressants</th>
<th>Antidepressants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CGT (n=14)</td>
<td>IPT (n=20)</td>
</tr>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
</tr>
<tr>
<td></td>
<td>P-value</td>
<td>P-value</td>
</tr>
<tr>
<td>Pre</td>
<td>18.6 (6.1)</td>
<td>16.3 (6.2)</td>
</tr>
<tr>
<td>Post</td>
<td>8.7 (5.0)</td>
<td>16.5 (9.8)</td>
</tr>
<tr>
<td>Diff</td>
<td>9.9 (6.7)</td>
<td>-2.2 (6.6)</td>
</tr>
</tbody>
</table>

Note: n = 34 in the no-anti-depressant group and 33 in the antidepressant group rather than 35 and 34 respectively due to missing data.

### Discussion

This study extends research by Shear et al. (2005) by identifying additional outcomes of CGT including a reduction in anxiety, depression, grief-related avoidance, guilt/self-blame and negative thoughts about the future. These symptoms can be conceptualized as the complicating...
problems that prolong acute grief. Among the variables where the difference in change between groups was statistically significant, effect sizes for the difference between the treatments were in the medium to high range (.34 - .99), which is particularly striking since the control group (IPT) was an active treatment condition that has proven to be efficacious in the treatment of depression. The main finding that CGT produced significantly greater change in the range of additional outcomes reported here is important because it provides us with more information about what is changing within the patient during or as a result of treatment. These variables may in fact be mediators of CGT or just added benefits and should be explored as such.

The target symptoms assessed in this report are typical of mood and anxiety disorders, yet they had not responded to previous treatment and did respond to a targeted treatment for CG (85% of the 243 individuals seeking treatment for CG in the parent study had previously sought treatment for grief (Shear et al., 2011) and had not improved). This suggests that CGT is producing unique benefits.

The significant reduction in symptoms of anxiety, depression (including negative thoughts about the future and guilt/self-blame) and avoidance of reminders of the loss supports the theoretical model of CGT, which posits that complicating thoughts, emotions and behaviors can interfere with the normal grieving process. For example, negative emotions such as guilt, which are continuously activated in CG, can keep the person focused on the painful aspects of the death and the consequences of the loss (Shear, 2012). Negative thoughts about the future can similarly keep the patient stuck in a constant state of worry about bad things that might happen and a conviction that life can never be good again. Avoidance behavior can interfere with the emotional processing necessary for grief to proceed.
Two of the outcomes reported by Shear et al. (2005) in addition to a reduction in CG were depression, measured by the BDI and anxiety, measured by the BAI. While depression decreased more in CGT than IPT, the difference in anxiety reduction was not statistically significant\(^1\). In the present study, these measures were broken down into subscales (cognitive and somatic) in order to explore whether treatment group affected cognitive vs. somatic aspects of depression and anxiety differently. Surprisingly, results showed better outcomes for CGT than IPT on the somatic subscale of the BDI and not on the cognitive subscale where both groups saw a significant reduction. The stronger outcome on the somatic subscale may indicate that the differential impact of CGT vs. IPT on depression is more strongly related to change in the somatic components of the disorder. Given that CGT does not target somatic symptoms directly, this is an interesting finding and may signify that the physiological dysregulation experienced by people with CG is amenable to the techniques used in CGT. It is also plausible that as symptoms of CG come down (via techniques used in CGT), somatic symptoms of depression such as *loss of energy, irritability, change in appetite, loss of interest in other people* and *loss of pleasure* start to abate as well.

A seemingly contradictory finding is that the cognitive subscale of the BAI showed significantly better results for CGT while the somatic subscale of the BAI showed no difference between groups. This result is opposite that of the BDI subscales where the somatic component responded more in CGT than IPT. The cognitive subscale of the BAI included items related to worrying about the future such as *fear of the worst happening, fear of losing control, and fear of dying*. It is possible that CGT does better at addressing these symptoms than IPT whereas the

\(^1\) In this study, the analysis of the treatment effect difference of the BAI total score was significant at the .05 level.
cognitive aspects of depression, which are focused more on the past such as feeling like a failure, guilty feelings, self-criticalness and punishment feelings respond well to both treatments.

The difference in change between groups on the HRSD is also noteworthy, with a significantly greater change in CGT than IPT. This result matches that of the other depression measures (BDI and MDD) and the effect size of the difference between the groups of 1.2 is equal to that of the difference between groups on the BDI measure of depression. While the change in depression as measured by the HRSD was significant, the mean score post treatment (11.2) was still within the mild clinical range (7 – 17 is mild, 18 to 24 moderate and >25 is severe), although just barely for those in CGT not taking antidepressants (post-treatment score = 8.7). The HRSD was also the only measure where outcome differed by antidepressant use. CGT did better than IPT in lowering depression only for those not taking medication. This finding is in direct contrast to that of the parent study where antidepressant use marginally increased the response rate in CGT. The fact that antidepressant use was an added benefit to CGT participants in reducing grief symptoms but not in reducing depression supports the assertion by grief researchers that grief and depression are distinct disorders.

The inclusion of change in ‘poor sleep quality due to bad dreams’ as an ancillary outcome of CGT was based on prior research showing that the majority of CG patients exhibit clinically significant sleep disturbance (Germain et al., 2005). While CGT does not target bad dreams or nightmares, it does target cognitive schemas related to the death and the deceased that cause patients distress. That bad dreams decreased more in CGT than IPT is consistent with the hypothesis that changes in cognitive schemas that occur during CGT persist during dreaming (Germain et al., 2013). This finding may be particularly relevant for military veterans who have
CG, many of whom have related bad dreams. CGT could be particularly helpful for this population.

This study has several limitations. Using a sample of completers rather than the intent-to-treat group reduced the sample size from 95 to 69, which may have reduced the power to detect differences between the treatment groups. It also leaves open the possibility that those who dropped out of treatment were different from those who stayed in, compromising the generalizability of the findings. However, an analysis of the variables at baseline showed no difference between completers and drop-outs on any of the measures. Another limitation is that the SCI-CG and GRAQ were introduced later in the study, reducing the sample size for the variables created from these scales even further from 69 to about 55. This may have affected the results with respect to self-blame where the difference in means was marginally significant (.08) and avoidance where the difference between groups was statistically significant for only one of the three measures.

This study examined ancillary outcomes in the treatment of CG and found that CGT is effective in reducing anxiety and depressive symptoms (including negative thoughts about the future and guilt) as well as grief-related avoidance and bad dreams in addition to CG. These symptoms are manifestations of complicating problems targeted by CGT. As such, the current analyses can be considered a first step in identifying the mechanisms of action of this treatment.
References


Paper 2: Mediators of Outcome in Complicated Grief Treatment
Introduction

This study is an exploration of possible mediators in a previously reported efficacy study of Complicated Grief Treatment (CGT) (Shear et al., 2005). Complicated grief (CG) is a recently identified syndrome that is impairing and associated with a negative course without treatment. CG affects roughly 7% of bereaved people (Kersting, 2011). While not currently a diagnosis in the DSM-IV, CG can be reliably identified by administering the Inventory of Complicated Grief (ICG) (Prigerson et al., 1995) more than six months after the death of a loved one and using a cut-off score of 30. As outlined by Shear et al. (2005, 2011), CG is characterized by a sense of disbelief regarding the death; anger and bitterness over the death; intense longing and yearning for the deceased with recurrent pangs of painful emotions; preoccupation with thoughts of the loved one, often including distressing intrusive thoughts related to the death; and extensive avoidance of reminders of the loss.

CGT is the first targeted treatment for this condition that was manualized and tested in a formalized randomized controlled trial. The treatment is based on an attachment theory framework for understanding bereavement, grief and mourning and the complications that impede natural healing. The goals of CGT are to reduce grief complications and to rejuvenate the natural healing process.

In a randomized controlled trial testing the efficacy of the treatment, CGT was found to be more effective in treating complicated grief than IPT (intent-to-treat response rate: 51% vs. 28% p = .02) (Shear et al., 2005). Among treatment completers, the response rate in the CGT group was 66% vs. 32% in IPT, p = .006. The number needed to treat was 4.3 for modified intent-to-treat and 2.9 for completers. Among completers, CGT was also more effective in reducing grief symptoms (ICG), depression (BDI) and work and social functioning (WSAS).
The current paper reports results of mediation analyses carried out to explore the mechanisms of action of CGT. In a prior analysis of the completer sample (see paper 1), this author identified secondary outcomes of CGT that are hypothesized to mediate the reduction in grief symptoms: a reduction in guilt/self-blame, negative thoughts about the future, anxiety and depression (intense negative emotions) and avoidance of reminders of the loss. About half of the study participants were taking antidepressant medication and those who were had a markedly greater rate of completion in CGT (91% vs. 58%) (Simon, 2008). Therefore, analyses were conducted to determine whether the mediating process between treatment and outcome differed for those taking antidepressants (moderated mediation).

Methodology for establishing mediation has been developed and the approach advocated by Baron and Kenny is widely accepted (Baron & Kenny, 1986). The primary task is to demonstrate a strong association between the intervention and the mediator and between the mediator and the outcome. It is also necessary to establish that change in the mediator preceded change in the outcome (Johansson & Hoglend, 2007). This study examines the association between five putative mediators and the reduction in grief symptoms, using the method proposed by Baron and Kenny. It also addresses temporal precedence by examining the association between change in the mediator early in treatment and subsequent change in outcome.

*Conceptual underpinnings of CGT*

Normal grief is an instinctual psychobiological response to the death of a loved one (Bowlby, 1980). When a loved one dies, the attachment system is activated, causing an acute grief response characterized by intense separation distress (yearning and longing for the deceased, intense sadness, preoccupation with thoughts and memories of the deceased and loss of interest in activities) and traumatic distress (disbelief and shock, difficulty comprehending the
loss, feeling lost and disoriented, intrusive images and avoidance of reminders). The loss also triggers a mourning process in which the bereaved slowly comes to terms with the death and restores his/her interest in life. Healing usually proceeds in fits and starts, as a person confronts the finality and consequences of the loss and begins to redefine her/his life so that it has purpose and meaning and the possibility for joy and satisfaction. Over time, grief is transformed from an acute, dominant form to one that resides in the background, no longer interfering with daily life.

Psychological issues can complicate and derail the healing process. Most typically these include counter-factual thinking around troubling aspects of the death (e.g. blaming oneself or others for how the person died) or consequence of the death (e.g. life has no purpose or meaning without the loved one); avoidance behaviors; and problems with emotion regulation. This results in the syndrome of complicated grief. CGT works to identify and resolve the complicating issues (e.g. acceptance vs. counterfactual thinking, reducing avoidance, supporting emotion regulation) in order to facilitate the natural healing process of fully acknowledging the finality and consequences of the loss and re-envisioning life with meaning and satisfaction.

Overview of parent study

For a detailed description of methodology, see Shear et al. (2005). Recruitment of participants was carried out between 2001 and 2004 in Pittsburgh, PA. Participants were included if they had a loss at least 6 months prior, a score of >30 on the Inventory of Complicated Grief (ICG) (Prigerson et al., 1995) and identified grief as their most important problem. Participants were randomly assigned to receive 16 sessions of CGT or IPT. Medication was permitted as long as the participant had been on it for 3 months and at a stable dose for greater than 6 weeks. Therapists (either masters or doctoral level) were trained in either CGT or IPT and received ongoing supervision. Therapy sessions were audio taped for adherence. An
analysis of a randomly selected subset of session segments showed that the two treatments could be distinguished (Wilsey et al., 2006). Self-report measures and questionnaires administered by independent evaluators (blinded to treatment assignment) were used to collect data at baseline, during treatment and post-treatment follow-up. The primary outcome measure was the Clinical Global Impression of Improvement Scale (CGI). Response to treatment was defined as a rating of 1 or 2 (very much or much improved). Additional outcome measures included the Inventory of Complicated Grief (ICG), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI) and Work and Social Adjustment Scale (WSAS).

The control condition, IPT, is a short-term manualized treatment (Weissman et al., 2000) that focuses on work in one or more of four interpersonal problem areas that are thought to be associated with mood symptoms; these include grief, interpersonal disputes, role transition and interpersonal deficits. Most of the IPT treatments focused on grief alone or with one of the other problem areas.

The treatment condition, CGT, was also delivered according to a treatment manual and had yielded positive results in a prior pilot study (Shear et al., 2001). Its beginning phase included psycho-education about the difference between normal and complicated grief as well as the dual process model of adaptive coping, which includes a focus on both adaptation to loss and restoration of a satisfying life (Stroebe & Schut, 1999). Personal goals were also introduced in this early phase. The middle phase of CGT continued the focus on both loss and restoration in tandem. Setting it apart from IPT, CGT employs specific techniques to address CG symptoms. An “imaginal revisiting” exercise is used where the patient is asked to visualize and recount the story of when s/he first learned of the death (in the present tense) while being audio-taped and then listen to the story between sessions while recording distress levels. Other loss-focused
procedures include an “imaginal conversation” with the deceased, working with memories and pictures and “situational revisiting” (graded exposure to avoided situations). Restoration-focused procedures include working with aspirations and goals, rewards and self-care and situational revisiting. These components help the patient to envision a life with meaning and purpose and the possibility for joy and satisfaction.

**Method**

**Sample**

The current study examined treatment completers only (n=69) in order to test preliminary hypotheses about mechanisms of action of CGT among those who complete the full course of treatment. Completers did not differ from drop-outs on any of the baseline measures.

**Dependent Variables**

**Clinical Global Improvement (CGI):** The CGI scale (Guy, 1976) is a single Likert-type rating from 1 to 7 where 1 through 3 indicate *very much, much* and *minimally* improved respectively; 4 indicates *no change* and 5 through 8 indicate *minimally, much* and *very much worse* respectively. The independent evaluator derived the CGI score from the therapist report of global improvement, a brief narrative justifying the therapist rating and self-report assessments from the final session. A CGI rating of 1 or 2 (*very much or much* improved) qualified the participant as a treatment responder.

**Inventory of Complicated Grief (ICG):** The 19-item Inventory of Complicated Grief assesses symptoms of CG. This scale has been utilized in various studies of CG and has good internal validity and reliability (alpha = .94) and six-month test-retest reliability (r = .80). A score of 25 or higher is associated with significant impairment in functioning (Prigerson et al.,
This measure was administered at baseline, weeks 1 – 16, post treatment and 6-month follow-up.

**Work and Social Adjustment Scale (WSAS):** The WSAS is a modification of a scale developed by Hafner and Marks, consisting of 0 to 8 point ratings of the extent to which grief symptoms interfere in five areas of daily functioning: work, home management, private leisure, social leisure, and family relationships. It is a well-validated and widely used measure (Mundt et al., 2002). This measure was administered at baseline, weeks 1 – 16, post treatment and 6-month follow-up.

**Putative Mediators**

Selection of putative mediators was based on the theoretical model of CGT (see above), which posits that grief complications need to be addressed in order for the natural healing process to take place. These complications include dysfunctional thoughts, ineffective emotion regulation and excessive avoidance. Assessment instruments from the parent study were reviewed to identify candidate mediators that might be operating in CGT. These included change in self-blame/guilt related to the death or the deceased, negative thoughts about the future, anxiety, depression and avoidance behavior. In a prior analysis by this author, described in paper 1, at least one variable measuring each of these constructs was associated with treatment group at the p<=.05 level or if marginally significant, with a treatment difference effect size =>.30.

**Guilt/self-blame about the death or the deceased:** This variable was derived from the Structured Clinical Interview for Complicated Grief (SCI-CG). This SCID-like interview was developed for the parent study and has been utilized in several studies of CG by Shear et al.’s research group. A composite of the following items was used: *Have you had guilty or self-blaming thoughts or beliefs about the death? Do you blame yourself for doing or not doing...*
something either when _____ was alive, or at the time he/she died, that you think might have helped? Do you have the idea that you could have prevented this death, even though you know it isn’t very rational? Internal consistency for this composite variable was high (Cronbach’s α = .86).

Negative thoughts about the future: This variable was measured by one item on the Beck Depression Inventory (BDI), a widely used, well-validated 21-item self-report instrument used to assess the severity of depression (Beck et al., 1979). This item asks the respondent to select the statement that best describes the way he/she has been feeling in the past week: *I am not particularly discouraged about the future; I feel discouraged about the future; I feel I have nothing to look forward to; I feel that the future is hopeless and that things cannot improve.*

Anxiety: Two variables were used to measure anxiety. The first was the total score on the Beck Anxiety Inventory (BAI), a 21-item, well-validated instrument used to measure clinical anxiety (Beck et al., 1988). This measure has good internal consistency and test-retest reliability.

The second variable was derived from a composite of items used to measure the cognitive aspects of anxiety identified by Hewitt and Norton who found two factor loadings for the BAI; cognitive and somatic (Hewitt & Norton, 1993). The items that loaded highest on the cognitive factor (and low on the somatic factor) include: *fear of the worst happening, terrified, nervous, fear of losing control, fear of dying,* and *scared.* Internal consistency for the composite variable (in this sample) was high (Cronbach’s α = .89). The somatic subscale, which included items related to bodily sensations associated with anxiety such as *dizziness, sweating* and *racing heart,* was not included in this study since there was no association between somatic anxiety and treatment group (see paper 1).
Depression: Three variables were used to measure depression. The first was the total score on the Beck Depression Inventory (BDI), a widely used, well-validated 21-item self-report instrument used to assess the severity of depression (Beck et al., 1979).

The second variable was derived from a composite of items used to measure the cognitive aspects of depression identified by Steer et al., who found two factor loadings for the BDI; cognitive and somatic-affective (Steer et al., 1999). Cognitive aspects of depression include: pessimism, past failure, guilty feelings, punishment feelings, self-dislike, self-criticalness, suicidal thoughts or wishes, crying and worthlessness. Internal consistency for the composite variable (in this sample) was high (Cronbach’s $\alpha = .86$).

The third variable was derived from the somatic-subscale of the BDI and includes: loss of pleasure, loss of interest, indecisiveness, loss of energy, irritability, change in appetite, tiredness and fatigue, and loss of interest in sex. Lack of concentration also loaded high on this factor but was not included in this analysis because it is not in the 21-item version of the BDI. Internal consistency for the composite variable (in this sample) was high (Cronbach’s $\alpha = .81$).

Avoidance: Two variables were used to measure change in avoidance. The first was the total score on the Grief Related Avoidance Questionnaire (GRAQ) (Shear et al., 2007). This 15-item self-report questionnaire was developed and tested by Shear’s research team to assess the level of avoidance of common situations and activities following the death. The scale has good psychometric properties ($\alpha = .87$) and CG patients endorse a range of scores on the scale.

The second variable was derived from the SCI-CG (described above). A composite of two items from the SCI-CG was used to measure avoidance behavior: Do you avoid activities, people, places, or objects that remind you of ____? and Do you feel reluctant to talk about ____? Internal consistency for this composite variable was moderate (Cronbach’s $\alpha = .48$).
Statistical analysis

The Fisher’s exact test was used to compare baseline characteristics of categorical variables and two-tailed t-tests were used to compare baseline characteristics for continuous variables. Correlations between potential mediators were examined with pairwise correlations of mediators at baseline as well as correlations between their change scores.

Mediation analysis was performed according to the Baron and Kenny (1986) method of testing mediation (see Figure 1). The method consists of the following four components:

1. There is a main effect of treatment (Path A). This analysis was performed by the parent study (Shear et al., 2005) and was repeated in the present study by using logistic and multiple regression analyses of CGI, ICG and WSAS on a dichotomous treatment indicator.

2. Treatment is related to change in the mediator (Path B). This analysis was performed in a previous study by this author (see paper 1). Change in the mediators was operationalized by creating a change variable equal to the score at baseline – the score at post-treatment (week 16), with higher scores reflecting greater symptomatology.

3. Change in the mediator is related to change in outcome (Path C) controlling for treatment assignment. Change in outcome is equal to the score at baseline – score at post treatment (week 16). This analysis was performed using logistic and multiple regression analyses. A test for interaction between treatment group and mediators was also done to examine whether the relationship between mediator and outcome differed by treatment group. To test for moderated mediation, multiple regression analysis was used to examine the interaction between putative mediators and antidepressant use as it affects grief symptoms.

4. Effect of treatment on outcome is significantly weakened when statistically controlling for the mediator (Path D). This analysis was performed using multiple and logistic regression,
controlling for the putative mediators (same model as step 3). Each mediator was tested in a separate regression rather than testing them all together in one model. Percentage of treatment effect explained by the mediator was calculated as the original coefficient – the new coefficient / original coefficient. Examining each mediator separately was done in order to explore whether each variable alone appears to play a role in the treatment effect found between CGT and IPT. The goal was to point the way for future research to investigate whether these variables emerge as mediators in a subsequent RCT, rather than to examine which mediator was the most salient.

Further analysis was conducted to test for temporal precedence. An *early change* variable was created for each mediator equal to the score at week 1 – the score at week 8. A *subsequent change* variable was created for each outcome equal to the score at week 9 – the score at post treatment. This analysis could not be done for the variables using the SCI-CG since this measure was only collected at baseline and post treatment. For the avoidance variables measured by the GRAQ, *early change* is equal to the score at week 1 – the score at week 10 since this measure was not collected at week 8. Multiple regression analysis was used to test whether *early change* in the mediator (week 1 through 8) predicted *subsequent change* in the outcome (week 9 through post treatment), controlling for treatment group.

All analyses were performed using STATA version 11 software and statistical significance was set at p<=0.05.
Results

Baseline characteristics

The sample was 84% female, 74% Caucasian, 22% African-American, 3% Asian, with a mean age of 48.4 years. Mean ICG score was 44.8. Comorbid mood or anxiety disorders were common. Forty-six percent had current major depressive disorder (MDD), 52% current posttraumatic stress disorder (PTSD), 8.8% current panic disorder (PD), 6% current obsessive-compulsive disorder (OCD) and 3% current social phobia disorder. Thirty-four out of 69 (49%) were on at least one antidepressant medication. There were no significant differences in demographic characteristics or putative mediator variables between the two randomized groups at baseline.

Correlations between potential mediators

Correlations between potential mediators at baseline showed that depression was highly correlated with negative thoughts about the future ($r=.72$) and anxiety ($r=.66$). Anxiety was
moderately correlated with negative thoughts about the future (r=.42) and avoidance-GRAQ (r=.33). Correlations between mediator change scores revealed that change in depression was moderately correlated with change in all of the other variables, guilt (r=.31), negative thoughts about the future (r=.55), anxiety (r=.36) and avoidance-GRAQ (r=.37). Change in avoidance was moderately correlated with guilt (r=.29) and negative thoughts about the future (r=.30). See Tables 1 and 2.

**Table 1. Correlations Between Mediators at Baseline**

<table>
<thead>
<tr>
<th></th>
<th>Guilt</th>
<th>Negative Thoughts About Future</th>
<th>Anxiety (BAI Total)</th>
<th>Depression (BDI Total)</th>
<th>Avoidance (GRAQ)</th>
<th>Avoidance (SCI-CG)</th>
</tr>
</thead>
<tbody>
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<td>Guilt</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Thoughts About Future</td>
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<td>1.0</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety (BAI Total)</td>
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<td>.42</td>
<td>1.0</td>
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</tr>
<tr>
<td>Depression (BDI Total)</td>
<td>.16</td>
<td>.72</td>
<td>.66</td>
<td>1.0</td>
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<td></td>
</tr>
<tr>
<td>Avoidance-GRAQ</td>
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<td>.07</td>
<td>.33</td>
<td>.36</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Avoidance (SCI-CG)</td>
<td>.14</td>
<td>-.01</td>
<td>.11</td>
<td>.15</td>
<td>.60</td>
<td>1.0</td>
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</table>

**Table 2. Correlations Between Mediator Change Scores**

<table>
<thead>
<tr>
<th></th>
<th>Guilt</th>
<th>Negative Thoughts About Future</th>
<th>Anxiety (BAI Total)</th>
<th>Depression (BDI Total)</th>
<th>Avoidance (GRAQ)</th>
<th>Avoidance (SCI-CG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guilt</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Thoughts About Future</td>
<td>.15</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety (BAI Total)</td>
<td>-.01</td>
<td>.23</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression (BDI Total)</td>
<td>.31</td>
<td>.55</td>
<td>.36</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoidance (GRAQ)</td>
<td>.29</td>
<td>.30</td>
<td>.03</td>
<td>.37</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Avoidance (SCI-CG)</td>
<td>.20</td>
<td>.14</td>
<td>.03</td>
<td>.20</td>
<td>.55</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**Main Treatment Effect (Path A)**

As reported by Shear et al. (2005), the main treatment effect among completers of CGT on outcome was statistically significant (CGI: OR=4.01 (2.05), p=.01 (95% confidence interval (CI), 1.5 – 10.9); ICG: B=8.34 (.3.1), p=.01 (95% CI, 2.13 – 14.55); WSAS: B=5.08 (2.4), p=.04 (95% CI, .21 – 9.95)).

**Association Between Treatment Group and Change in Putative Mediators (Path B)**

For at least one variable of each construct (e.g. guilt, avoidance, depression), the association between treatment group and change in the mediator was statistically significant. For a detailed summary of the t-test results and the effect sizes for the treatment differences, see
paper 1. Variables were selected if they had an effect size => .3 and were related to the conceptual model of CGT.

**Association Between Change in Putative Mediators and Change in Outcome (Path C)**

A summary of the regression results for the three outcomes is in Table 3. For at least one variable of each construct (e.g. guilt, avoidance, depression), there was a significant association between change in the mediator and a reduction in grief (on either the CGI, ICG or WSAS). A test for interaction between treatment group & putative mediator yielded no significant results with the exception of Anxiety – Cognitive Subscale on the WSAS. With regard to this variable, there was an additional positive relationship between change in anxiety and outcome for the CGT group, B=1.65, p = .01.

**Table 3. Regression Results: Assoc. Between Change in Mediators and Grief Outcomes (Path C)**

<table>
<thead>
<tr>
<th>Mediator Variables</th>
<th>CGI OR(SE)</th>
<th>Unstandardized B(SE)</th>
<th>Standardized B(SE)</th>
<th>ICG OR(SE)</th>
<th>Unstandardized B(SE)</th>
<th>Standardized B(SE)</th>
<th>WSAS OR(SE)</th>
<th>Unstandardized B(SE)</th>
<th>Standardized B(SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Guilt/Self-Blame</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCI-CG (n=56)</td>
<td>1.2 (.15)</td>
<td>1.7 (.69)*</td>
<td>.31 (.12)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.1 (.52)*</td>
<td>.25 (.12)*</td>
</tr>
<tr>
<td><strong>Neg. Thoughts About the Future</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI (n=69)</td>
<td>2.3 (.92)*</td>
<td>6.6 (2.1)**</td>
<td>.36 (.11)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4.7 (1.6)**</td>
<td>.33 (.12)**</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAI total (n=69)</td>
<td>1.1 (.03)</td>
<td>.23 (.18)</td>
<td>.15 (.12)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.04 (.14)</td>
<td>.04 (.12)</td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>1.1 (.08)</td>
<td>1.1 (.38)**</td>
<td>.32 (.11)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.32 (.32)</td>
<td>.13 (.12)</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI total (n=69)</td>
<td>1.2 (.05)**</td>
<td>.87 (.18)**</td>
<td>.52 (.11)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.76 (.13)**</td>
<td>.59 (.10)**</td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>1.3 (.12)**</td>
<td>1.3 (.43)**</td>
<td>.33 (.11)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.99 (.33)**</td>
<td>.34 (.11)**</td>
</tr>
<tr>
<td>Somatic-Affective Subscale</td>
<td>1.3 (.12)**</td>
<td>1.6 (.36)**</td>
<td>.46 (.11)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.4 (.27)**</td>
<td>.53 (.10)**</td>
</tr>
<tr>
<td><strong>Avoidance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRAQ (n=54)</td>
<td>1.1 (.04)**</td>
<td>.53 (.12)**</td>
<td>.50 (.12)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.48 (.09)**</td>
<td>.59 (.11)**</td>
</tr>
<tr>
<td>SCI-CG (n=56)</td>
<td>2.1 (.52)**</td>
<td>3.4 (1.2)**</td>
<td>.34 (.12)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.4 (.82)**</td>
<td>.45 (.11)**</td>
</tr>
</tbody>
</table>

Note. p* <= .05, p** <= .01, p*** <= .001

*Controlling for treatment group

Change variables were standardized before running regressions calculated as change variable – mean / SD.

**Effect of Treatment on Outcome When Controlling for the Mediator (Path D)**

As predicted, the treatment effect of CGT on outcome was significantly weakened when controlling for the putative mediators (see Table 4). Full mediation was demonstrated for guilt, negative thoughts about the future, depression and avoidance. Partial mediation was
demonstrated for negative thoughts about the future, cognitive aspects of anxiety and depression (cognitive and somatic-affective) (see Table 5).

Table 4. Regression Results: Treatment Effect When Controlling for Putative Mediators (Path D)

<table>
<thead>
<tr>
<th>Variables</th>
<th>CGI OR=4, p=.007</th>
<th>ICG B=8.34, p=.009</th>
<th>WSAS B=5.08, p=.04</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New TE OR (SE)</td>
<td>Mediator OR (SE)</td>
<td>% expl. by M^</td>
</tr>
<tr>
<td>Guilt/Self Blame SCI-CG (n=56)</td>
<td>4.0 (2.4)*</td>
<td>1.2 (.15)</td>
<td>0%</td>
</tr>
<tr>
<td>Negative Thoughts About the Future</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI (n=69)</td>
<td>3.2 (1.7)*</td>
<td>2.3 (.92)*</td>
<td>16%</td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAI total (n=69)</td>
<td>3.59 (1.9)*</td>
<td>1.1 (.03)</td>
<td>8%</td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>3.4 (1.8)*</td>
<td>1.1 (.04)</td>
<td>12%</td>
</tr>
<tr>
<td>Depressed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI total (n=69)</td>
<td>2.7 (1.5)</td>
<td>1.2 (.05)**</td>
<td>28%</td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>4.1 (2.3)**</td>
<td>1.3 (.12)**</td>
<td>2%</td>
</tr>
<tr>
<td>Somatic Subscale</td>
<td>3.4 (1.9)*</td>
<td>1.3 (.20)**</td>
<td>12%</td>
</tr>
<tr>
<td>Avoidance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRAQ Total (n=54)</td>
<td>2.7 (1.8)</td>
<td>1.1 (.04)**</td>
<td>28%</td>
</tr>
<tr>
<td>SCI-CG (n=56)</td>
<td>2.9 (1.7)</td>
<td>2.1 (.52)**</td>
<td>23%</td>
</tr>
</tbody>
</table>

Note. p* <= .05, p** <= .01, p*** <= .001
B=unstandardized coefficient
M=putative mediator
^Calculated as log original OR – log new OR / log original OR
^Calculated as original Coef – new Coef / original Coef

Table 5. Mediators of Outcome in CGT

<table>
<thead>
<tr>
<th></th>
<th>Full Mediation</th>
<th>Partial Mediation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CGI</td>
<td>ICG</td>
</tr>
<tr>
<td>Guilt/Self-Blame SCI-CG</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Negative thoughts about</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>the future BDI (n=69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>BAI total (n=69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>BDI total (n=69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Somatic-Affective Subsc</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Avoidance</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>GRAQ Total (n=54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCI-CG (n=56)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

^Note: Full mediation is established when the effect of treatment on outcome is no longer statistically significant when controlling for the mediator. Partial mediation is established when the treatment effect is still significant but significantly weakened.
Temporal Precedence

Summary of regression results are in Table 6. Temporal precedence was established for 2 of the 5 mediators (avoidance and depression) when regressing early change in the mediator (weeks 1 - 8) on subsequent change in grief (weeks 9 - post treatment). An early reduction in avoidance predicted subsequent reduction in grief (WSAS), $B = .30 (.12)$, $p = .015$ compared with the overall association between change in avoidance and change in grief of $.48 (.09)$, $p = .000$. An early reduction in depression predicted subsequent change in grief (ICG), $B = .36 (.15)$, $p = .017$, compared with the overall association between change in depression and change in grief of $.87 (.18)$, $p = .000$. Additionally, an early reduction in the cognitive aspects of depression predicted subsequent change in grief (ICG), $B = 1.0 (.33)$, $p = .003$, compared with the overall association between change in cognitive – depression and change in grief of $1.3 (.43)$, $p = .005$.

Table 6. Regression Results$^A$: Early Change$^B$ in Mediator Predicts Subsequent Change$^C$ in Outcome

<table>
<thead>
<tr>
<th></th>
<th>ICG</th>
<th>WSAS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$B^D$ (SE)</td>
<td>$B^D$ (SE)</td>
</tr>
<tr>
<td>Negative Thoughts About the Future</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI (n=69)</td>
<td>1.18 (1.4)</td>
<td>.21 (1.2)</td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAI Cognitive Subscale (n=69)</td>
<td>.31 (.27)</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BDI total (n=69)</td>
<td>.36 (.15)$^*$</td>
<td>.17 (.13)</td>
</tr>
<tr>
<td>Cognitive Subscale</td>
<td>1.0 (.33)$^{**}$</td>
<td>.37 (.29)</td>
</tr>
<tr>
<td>Somatic - Affective Subscale</td>
<td>.60 (.39)</td>
<td>.28 (.33)</td>
</tr>
<tr>
<td>Avoidance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRAQ total$^E$ (n=54)</td>
<td>.18 (.15)</td>
<td>.30 (.12)$^*$</td>
</tr>
</tbody>
</table>

Note. $p^*_* <= .05, p^{**} <= .01, p^{***} <= .001$

$^A$ Only mediators that were statistically significant in the mediator analyses are included. Guilt (SCI-CG) and Avoidance (SCI-CG) were not included because the SCI-CG was only collected at baseline and post treatment. CGI as an outcome was not included because this measure was only collected at post treatment. Regressions controlled for treatment group.

$^B$ Early change in mediator = score at week 1 – score at week 8 except for the Avoidance (GRAQ) variable which = score at week 1 – score at week 10.

$^C$ Subsequent change in outcome = score at week 9 – score at post treatment.

$^D$ B = unstandardized coefficient

$^E$ Avoidance (GRAQ) was measured at week 10 in the CGT group only (n=27).

Moderated Mediation

There was an interaction between antidepressant use and the cognitive aspects of anxiety on outcome (CGI), $OR = .64 (.13)$, $p = .03$. The mediating role of anxiety reduction on outcome
(response to treatment) was stronger for those not taking antidepressants than for those taking antidepressants.

**Discussion**

This study extends the efficacy findings of CGT by examining the putative mediators and mechanisms of action of the treatment. Building on the Shear et al. study, which found a main effect of CGT over IPT in reducing grief, this study tested five putative mediators of CGT and found all to be statistically significant. The finding that a reduction in guilt/self-blame related to the death or the deceased, negative thoughts about the future, cognitive aspects of anxiety, depression and avoidance behavior mediate the relationship between treatment group and outcome supports the model of CGT, which posits that complications in thoughts, emotions and behavior interrupt the normal grief process and need to be targeted in order for healing to occur.

The strongest mediator to emerge in this study is avoidance, whose role in reducing symptoms of complicated grief cannot be overstated. Both avoidance variables were significant for full mediation and accounted for a very high percentage of the treatment effect (54% and 60% on the ICG and 90% and 84% on the WSAS). While early reduction in avoidance (GRAQ) predicted subsequent change in the WSAS (grief impairment scale), it did not predict change on the ICG. It is possible that change in avoidance occurred before change in the ICG but that both changed earlier than week 10. It also possible that because this variable was only measured at week 10 in the CGT group and not in the control, the sample size was too small to detect a significant relationship between early change in avoidance and subsequent change in outcome. It should be noted that the temporal relationship between the change in avoidance and change in grief was not measured in IPT and therefore cannot definitively be attributed to the treatment.
Since overall change in avoidance did differ by treatment group, it is plausible that early change in avoidance also differed by treatment group but this requires further testing.

Reducing cognitive and behavioral avoidance is one of the key objectives of CGT as these coping strategies, if used in excess, can become a significant impediment to the healing process (Shear, 2010). Cognitive avoidance is addressed in CGT through exposure-like techniques such as imaginal revisiting (retelling the story of the death) and situational revisiting, which help the patient to confront painful emotions connected to the loss and to reflect on the finality and consequences of the death.

Behavioral avoidance is addressed through situational revisiting exercises that focus on identifying and confronting situations that the patient has been avoiding since the death. In doing this work, the patient learns to monitor the amount of distress associated with exposure to a particular situation and to gradually confront the avoided situation until the intensity of distress is reduced.

The finding that avoidance reduction (via exposure-like techniques) mediates outcome is also consistent with the findings of prior studies. Boelen and colleagues found that exposure therapy alone was more effective than cognitive restructuring alone in treating CG and that adding exposure therapy to cognitive restructuring led to more improvement than adding cognitive restructuring to exposure therapy (Boelen et al., 2007). In a further analysis of this data, the authors found that stronger reduction in CG severity was significantly associated with reductions in negative cognitions and avoidance (Boelen et al., 2011). Bryant tested CBT with and without exposure (to memories of the death and loss) in a sample of 79 patients with prolonged grief disorder (PGD) and found that the CGT/Exposure treatment resulted in superior improvement in grief, depression and PTSD symptoms at post-treatment and 6-month follow-up
(Bryant, 2012). While change in avoidance was not measured in this study, it is plausible that the exposure techniques, which focused on memories of the death and the loss, reduced symptoms via a reduction in avoidance.

Negative thoughts about the future also emerged as a strong mediator (fully mediating outcome on the ICG and WSAS and partially mediating outcome on the CGI). This finding supports the restoration focus of CGT. Helping the patient to envision a future that feels satisfying and joyful without the deceased is a main element of the treatment. There was no evidence in this analysis, however, that a reduction in negative thoughts between weeks 1 and 8 predicted subsequent reduction in grief, leaving open the question about temporal precedence. It is possible that a reduction in grief preceded the reduction in negative thoughts. It is also possible that the change in negative thoughts about the future occurred within the first few sessions, which was not captured in this analysis. Identifying the directionality of this relationship requires further testing.

Self-blame/guilt specific to the death or the deceased fully mediated outcome on both the grief (ICG) and impairment (WSAS) scales and accounted for 48% and 59% of the treatment effect on the ICG and WSAS respectively. Guilt specific to the death or the deceased, conceptualized in the CGT model as maladaptive self-blaming counterfactual thoughts, is directly targeted in the treatment. This variable was not measured for temporal precedence because the SCI-CG was only collected at baseline and post treatment. Interestingly, change in generic guilt (as measured by one item on the BDI) also differed by treatment group and was associated with a reduction in grief. It is possible that targeting grief-specific guilt reduced more generic depressive guilt feelings as well. However, we cannot be certain of the directionality of this relationship since grief-specific guilt was not measured mid-treatment.
The reduction of depression as a mediator of CGT is an interesting finding. It could be argued that both CGT and IPT have antidepressant effects, however these results showed the reduction of depression to be greater in CGT and to account for a large percentage of the treatment effect: 28%, 56% and 80% on the CGI, ICG and WSAS respectively. While depression and CG are distinct disorders, some of the symptoms overlap. It is possible that the BDI is capturing CG symptoms, accounting for its strong showing as a mediator. The cognitive and somatic-affective subscales were equally strong, suggesting that change in both categories of depressive symptoms are associated with the change in grief and may contribute to the success of CGT. The temporal precedence analysis showed that early change in depression (both the total score and the cognitive subscale) predicted subsequent change in grief, supporting the hypothesis that a reduction in depressive symptoms (particularly cognitive aspects) contributes to the reduction in grief. It should also be noted that correlations between the mediator change scores revealed that change in depression was moderately to highly correlated with all of the other variables. This suggests that there is overlap between them, which makes it difficult to determine which mediator had the strongest effect.

Of the anxiety variables, only the cognitive subscale emerged as a mediator of outcome (ICG). This variable included: fear of the worst happening, terrified, nervous, fear of losing control, fear of dying and scared. (When examined separately, fear of dying emerged as the only item that differed by treatment group.) Cognitive anxiety was a partial mediator of outcome, accounting for 25% of the treatment effect. There was no evidence that the cognitive aspects of anxiety predicted subsequent change in grief. It is therefore possible that the change in grief occurred first and that this reduced anxiety or as stated above, the change in anxiety occurred very early in treatment and was not captured in this analysis. Given that anxiety is a future-
oriented emotion (whereas depression is past oriented), the finding that anxiety may have changed subsequent to a reduction in grief would be consistent with that of negative thoughts about the future.

Regarding moderated mediation, the findings indicate that antidepressant use affects the mediating role of anxiety (cognitive) on outcome in CGT. For those taking antidepressants, the reduction in cognitive anxiety played less of a role in grief reduction than for those not taking antidepressants. This suggests that the antidepressants may have played more of a role in reducing anxiety in CGT than the psychotherapy and supports the hypothesis put forward by Simon et al. (2008) that antidepressants dampen the amygdala. In their secondary analysis of the parent study examining the role of medication in CGT, Simon et al. speculated that antidepressants may have helped CGT patients cope with some of the more activating components of CGT, allowing them to stay in treatment longer.

The main limitation of this study is that mediation was an exploratory aim in the parent study and did not include prospectively defined assessments for the putative mediators. As such, this analysis employs measures that may not adequately capture the specific constructs identified in this paper. One of the main targets of CGT is emotion regulation and this was not measured by any of the instruments. An examination of changes in anxiety and depression may reflect changes in emotion regulation but this is merely speculative. Future research on mediation in CGT should include a measure for emotion-regulation that captures the patient’s ability to tolerate difficult emotions or manage behavior in the context of emotional distress.

As an exploratory study, each mediator was examined separately. While this allows for closer scrutiny of each construct in order to detect potential mediating effects, it also has the potential for confounding between mediators that are correlated. Results should therefore be
interpreted as hypothesis generating rather than hypothesis testing. Future research should incorporate putative mediators into one statistical model in order to determine which variables mediate outcome when controlling for all the others.

Another limitation is that the sample size for some of the measures may have been too small to detect differences. The SCI-CG and GRAQ were introduced later in the study, reducing the sample size on these measures from 69 to about 55. An analysis of the participants missing these measures compared to the rest of the sample showed no differences, minimizing the possibility that the smaller sample was skewed. However, the small sample size on these measures, may have affected the results with respect to the avoidance and guilt variables in particular. It is striking that the avoidance and guilt/self-blame variables, despite the small sample size, were strong mediators of outcome. This supports the theory that addressing complicating thoughts and behaviors are important to reducing complicated grief (Shear et al., 2007; Shear, 2012).

Another limitation is that temporal precedence was addressed by examining scores at only three time points (baseline, mid-treatment and post-treatment). It is very possible that change in the mediator within the first few weeks predicted subsequent change in grief and this would not have been captured in these analyses. Additionally, the SCI-CG was only administered at baseline and post treatment, which prevented the temporal precedence analysis for the guilt and avoidance variables measured by the SCI-CG. Finally, the results of this study are only applicable to those who complete CGT since the analyses did not include the entire intent-to-treat sample.

This study identified five putative mediators of outcome in a randomized controlled trial comparing CGT to an active control condition, IPT. Mediation analysis followed the Baron and
Kenny method of identifying mediators and also took into account temporal precedence, which is rare in mediation studies of psychotherapy. These results can be used to further test the mediating role of these variables by manipulating them in a subsequent RCT, thereby yielding valuable information for clinicians treating patients with complicated grief.
References


Paper 3: Working Alliance and Outcome in Complicated Grief Treatment
Introduction

Therapeutic alliance is most commonly defined as the agreement between patient and therapist on therapeutic goals, consensus on treatment tasks and the relationship bond (Bordin, 1979). It has also been referred to as the “quality and strength of the collaborative relationship between client and therapist” (Horvath & Bedi, 2002).

The role of the alliance in psychotherapy has been debated for decades. Zuroff & Blatt (2006) identified four prevailing arguments about the contribution of the therapeutic relationship to psychotherapy outcome. The first view, endorsed by cognitive-behavioral therapists (Beck, 1983), is that a positive alliance is necessary for the effectiveness of any therapy but does not drive therapeutic change as much as specific techniques. The second view, endorsed by humanistic therapists such as Carl Rogers, is that a positive alliance is the driving force behind therapeutic change, irrespective of any specific type of treatment. The third view is that the alliance is causally related to change in outcome but its effects depend on a specific set of techniques such as transference interpretation, which operate through the alliance in psychoanalytic psychotherapy. The fourth position is that the alliance is neither a necessary ingredient nor a causal factor in outcome and that outcome is due solely to specific therapeutic techniques.

In order to show that any component of psychotherapy accounts for symptom change, whether the variable is common to all treatments such as therapeutic alliance or specific to a particular treatment type such as cognitive restructuring in cognitive therapy, mediation analysis must be performed (within the context of a randomized controlled study). This entails showing that there is a main effect of treatment, that treatment is related to an intermediary variable (mediator), that the mediator is related to outcome and that the main treatment effect is
diminished when controlling for the mediator (Kazdin, 2007). From this analysis, we can
determine how much of the treatment effect is accounted for by the variable in question.

Alliance has largely been examined in terms of its correlation with outcome, not its role
as a mediator of treatment effects. It has been identified in the psychotherapy literature as one of
the most salient components of treatment, accounting for significantly more of the variability in
outcome (5 to 7%) than specific ingredients such as treatment techniques (1%) (Wampold,
2001). This view is supported by studies that examine the correlation between alliance (as
measured by one of several standard instruments) and the primary treatment outcome using
either simple correlation or cross-sectional regression (Horvath & Symonds, 1991; Martin, 2000;
Horvath & Bedi, 2002; Horvath et al., 2011; McLeod, 2011) More recently, researchers have
used longitudinal designs to examine alliance at different time points, controlling for earlier
symptom change (Barber et al., 2000; Kaufman et al., 2005; Zuroff & Blatt, 2006; Beckner et al.,
2007).

The most recent meta-analysis of alliance in individual psychotherapy by Horvath et al.
(2011) included 201 studies and found an aggregate correlation between alliance and outcome of
.275, accounting for 5 to 7% of the variance. Recent studies have also shown that the correlation
between alliance and outcome holds true across treatment types, patient characteristics,
measurement scales, raters, time of alliance (early, mid or late), outcome measures, publication
source, research design, and researcher allegiance (Horvath et al., 2011; Fluckiger, 2012).
Horvath et al. (2011) investigated the impact of six potential moderators of alliance and outcome
and found the aggregate alliance-outcome correlations in each category to be statistically
significant beyond p<.001. The authors concluded that the impact of alliance on outcome is
“ubiquitous, irrespective of how the alliance is measured, from whose perspective it is evaluated,
when it is assessed, the way the outcome is evaluated and the type of therapy involved.” In a nutshell, alliance matters.

Only a handful of published studies on the alliance-outcome relationship have failed to confirm these results. Alliance did not predict outcome, when controlling for early change, in a sample of 54 elderly depressed patients treated in behavioral, cognitive or brief dynamic psychotherapy (Gaston et al., 1991). No relationship was found between alliance and outcome in a sample of 252 cocaine-dependent outpatients treated in cognitive, dynamic or drug counseling, also controlling for early change in outcome (Barber et al., 1999). Alliance did not predict outcome in a sample of 25 depressed outpatients treated with cognitive therapy (Feeley, 1999). This research group did find, however, that a concrete set of therapist actions, measured early in treatment by the Collaborative Study Psychotherapy Rating Scale (CSPRS), did predict subsequent change in depression, suggesting that specific ingredients drive outcomes more than common factors such as alliance. The view that specific ingredients drive outcome is also supported by numerous studies in the literature (DeRubeis & Feeley, 1990; Piper et al., 1991; Barber et al., 1996; DeRubeis & Crits-Christoph, 1998; Shear et al., 2005; Mark et al., 2011).

As noted by Kazdin (2007), the correlation between alliance and outcome does not by itself show that alliance plays a causal role in symptom improvement. Feeley and colleagues have suggested that alliance may in fact be caused by early symptom improvement rather than the other way around (Feeley, 1999). DeRubies and Feeley (1990) found that alliance measured later in treatment was predicted by prior symptom reduction. In a subsequent study by Feely et al. (1999), this finding was not replicated. Nonetheless, researchers argue that when examining the relationship between alliance and outcome, directionality must be assessed (Johansson & Hoglund, 2007; Kazdin, 2007; Murphy, 2009). They also note that alliance research has often
ignored temporal precedence. Alliance has been measured mid-treatment and correlated with symptom change from beginning to end (Castonguay et al., 1996; Gaston et al., 1998; Beckner et al., 2007). Or alliance is averaged across the duration of treatment and related to overall symptom change (Krupnick et al., 1996; Gaston et al., 1998; Abouguendia et al., 2004). Change early in treatment and subsequent change are thus confounded because the predicted outcome incorporated symptom change that occurred before the alliance was measured.

Zuroff & Blatt (2006) took temporal precedence into account by evaluating the relationship between two components of the therapeutic relationship (perceived positive relationship with the therapist (measured at session 2) and patient contribution to the alliance (measured at session 3)) and subsequent symptom change while controlling for any potential confounding of early clinical improvement (Zuroff & Blatt, 2006). They also examined a wide range of patient characteristics that could account for the positive effects of the therapeutic relationship on outcome. In this study, 191 depressed outpatients were randomly assigned to 12 sessions of CBT, IPT, medication treatment or placebo. Data was collected at intake, weeks 4, 8, 12 and 16 and at follow-up. Few significant differences were found among the three active treatment conditions (Elkin et al., 1989), however the perceived positive relationship with the therapist predicted positive therapeutic outcome. The authors concluded that the therapeutic relationship contributes directly to positive therapeutic change, irrespective of specific technique.

While this study comes closer to demonstrating a causal relationship between alliance and outcome based on the study design, it still falls short of a full mediation analysis where the superiority of one treatment over another is explained at least in part by the alliance.

Many variables contribute to alliance including patient factors (e.g. age, race, gender, type of disorder, attachment style), therapist factors (e.g. interpersonal skills, empathy,
experience and training) and treatment factors (e.g. type of treatment, specific techniques, frequency of sessions) as well as interactions between them. For example, one treatment approach might work better for patients with a particular disorder than another. In addition to addressing the issue of causality, the examination of alliance as a mediator of treatment outcome also helps to parse out treatment factors (how the treatment is delivered) from the overall alliance affect. A prospective randomized controlled study controls for patient-related variables though it does not address therapist-related variables or interactions of patient, therapist and treatment variables.

This author identified one study where alliance (in addition to five other variables) was examined as a potential mediator of treatment outcome (Kaufman et al., 2005). In an RTC comparing CBT to a life skills control condition for adolescents with depression and conduct disorder, alliance (measured at week 3) was found to be statistically higher in the life CBT group but was not related to treatment outcome. Alliance was therefore not found to mediate the treatment effect of CBT while another mediator, negative thoughts, was.

The present study examines the role of alliance in the treatment of complicated grief (CG). Data was utilized from completers of a randomized controlled trial (RCT), which found that complicated grief treatment (CGT) is more effective than Interpersonal Psychotherapy (IPT) in reducing symptoms of CG (Shear et al., 2005). In examining the role of alliance as a contributor to post-treatment outcome, the present study sought to address the following questions: 1) Does early working alliance (measured at week 4 by the WAI) predict greater subsequent improvement in CG symptoms or associated impairment at post treatment (controlling for earlier symptom change)? And 2) Does alliance fully explain the improvement in grief symptoms found for CGT over IPT, i.e. does alliance mediate outcomes in CGT? I
hypothesized that the working alliance would be associated with symptom reduction (outcome) but would not fully account for the treatment difference in outcome in CGT (mediation).

**Overview of parent study**

A detailed description of methodology is available in a previously published paper (Shear et al., 2005). Briefly, recruitment of participants was carried out through media advertisement, professional and self-referral. Participants were included if they had a loss at least 6 months prior, a score of >30 on the Inventory of Complicated Grief (ICG) (Prigerson et al., 1995) and identified grief as their most important problem. Medication was permitted as long as the participant had been on it for 3 months and at a stable dose for greater than 6 weeks. Participants were randomly assigned to receive 16 sessions of CGT or IPT. Therapists (either masters or doctoral level) were trained in either CGT or IPT and received ongoing supervision. Therapy sessions were audio taped for adherence. Self-report measures and questionnaires administered by independent evaluators (blinded to treatment assignment) were used to collect data at baseline, during treatment and post-treatment follow-up. Response to treatment was defined as a rating of 1 or 2 (very much or much improved) on the Clinical Global Impression of Improvement Scale (CGI). Additional outcome measures included the Inventory of Complicated Grief (ICG), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI) and Work and Social Adjustment Scale (WSAS). Therapeutic alliance was measured by the Working Alliance Inventory (WAI).

For a detailed description of each treatment, see Shear et al. (2005). Briefly, IPT treatment is based on a model that postulates a bidirectional relationship between interpersonal problems and mood. The therapist and patient collaborate to select one or two of four interpersonal problem areas that are thought to be associated with mood symptoms including
include grief, interpersonal disputes, role transition and interpersonal deficits. Most of the IPT treatments focused on grief alone or with one of the other problem areas.

CGT used an attachment theory model of grief and mourning. It specifically targeted relief of complicating problems and facilitation of the natural healing process. CGT focused on both loss and restoration in tandem. Loss-related procedures included an “imaginal revisiting” exercise in which the patient tells the story of when s/he first learned of the death in the present tense and then listens to an audiotape of this at home in between sessions. Other loss-focused procedures included an “imaginal conversation” with the deceased, working with memories and pictures and “situational revisiting.” Restoration-focused procedures included working with aspirations and goals, rewards and self-care and situational revisiting. Both treatments were administered in 16 individual weekly sessions.

Method

Sample

The current study examined treatment completers only (n=69; n=35 for CGT and n=34 for IPT) in order to test hypotheses about the alliance-outcome relationship among those who complete the full course of treatment. Completers did not differ from drop-outs on any of the baseline measures. For CGT, 13/49 (27%) dropped out of treatment and for IPT, 12/46 (26%) dropped out of treatment.

Dependent Variables

Clinical Global Improvement (CGI): The CGI scale (Guy, 1976) is a single Likert-type rating from 1 to 7 where 1 through 3 indicate very much, much and minimally improved respectively; 4 indicates no change and 5 through 8 indicate minimally, much and very much worse respectively. The independent evaluator derived the CGI score from the therapist report
of global improvement, a brief narrative justifying the therapist rating and self-report assessments from the final session. A CGI rating of 1 or 2 (very much or much improved) qualified the participant as a treatment responder.

**Inventory of Complicated Grief (ICG):** The 19-item Inventory of Complicated Grief assesses symptoms of CG. This scale has been utilized in various studies of CG and has good internal validity and reliability (alpha = .94) and six-month test-retest reliability (r = .80). In the initial study, a score of 25 defined the upper quartile of scores and was associated with significant impairment in functioning (Prigerson et al., 1995). This measure was administered at baseline, weeks 1 – 16, post treatment and 6-month follow-up.

**Work and Social Adjustment Scale (WSAS):** The WSAS is a modification of a scale developed by Hafner and Marks, consisting of 0 to 8 point ratings of the extent to which grief symptoms interfere in five areas of daily functioning: work, home management, private leisure, social leisure, and family relationships. It is a well-validated and widely used measure (Mundt et al., 2002). This measure was administered at baseline, weeks 1 – 16, post treatment and 6-month follow-up.

**Independent Variable**

**Working Alliance:** Alliance was measured by the Working Alliance Inventory (WAI), a 12-item self-report instrument that measures three aspects of the therapeutic relationship: 1) agreement between client and therapist on therapy goals (e.g. *my therapist and I are working towards mutually agreed upon goals*); 2) agreement between client and therapist on the tasks of therapy (e.g. *my therapist and I agree about the things I will need to do in therapy to help improve my situation*); and 3) the interpersonal bond between client and therapist (e.g. *my therapist and I trust one another*). Each item is rated on a seven-point scale with response
choices ranging from *never* to *always*. This measure is widely used and has good internal validity and reliability ($\alpha = .92$) (Byrd et al., 2010). The WAI was collected at weeks 4, 8 and 12. The week 4 alliance score was used in this study as a measure of early alliance in order to avoid possible confound of early symptom change.

*Statistical analysis*

Comparison between completers in each treatment group on baseline characteristics used Fisher’s exact test for categorical variables and two-tailed t-tests for continuous variables. Two-tailed t-tests were used to examine the association between treatment group and alliance at week 4. Statistical significance was set at $p<=0.05$. Effect size (ES) for the difference in alliance between groups was calculated by dividing the mean difference between groups by the pooled standard deviation.

The relationships between alliance and outcomes were first analyzed using simple correlations in order to allow comparisons with results reported in the literature (Horvath et al., 2011). These tested the relationship between early alliance (week 4) and subsequent change in outcome (week 5 to 16) on the ICG and WSAS as well as the CGI at week 16.

Logistic and multiple regression analyses were then performed to examine whether early alliance (week 4) predicted subsequent change in outcome (week 5 to 16), controlling for early change in outcome (week 1 to 3) and treatment group. Subsequent change in outcome was measured in three ways: ICG change from week 5 to week 16, WSAS change from week 5 to 16, and simply the CGI at week 16. When CGI was the outcome, no control for early change in outcome was possible.

A test for interaction between treatment group and alliance was also done to examine whether the relationship between alliance and outcome differed by treatment group.
Mediation analysis was performed according to guidelines proposed by Baron and Kenny (1986) and modified by a MacArthur Foundation Network subgroup (Kraemer et al., 2008) utilizing the alliance score at week 4 as the potential mediator. The following components must be present (see Figure 1):

1. There is a main effect of treatment (Path A).
2. Treatment is related to change in the mediator (Path B).
3. Change in the mediator is related to change in outcome (Path C).
4. Change in the mediator must precede change in the outcome.

Kraemer et al. (2002) proposed a revision to step 3 so that change in the mediator can but does not have to be directly related to the outcome (Path C). If there is no direct relation but an interaction between treatment and mediator on outcome, mediation can still be established. This would mean that the relation between mediator and outcome is different depending on the treatment group, implying that the treatments work through different mechanisms (i.e. moderated mediation). In the presence of moderated mediation, differential indirect effects are estimated depending on whether treatment is CGT or IPT since Path C depends on CGT or IPT (Preacher et al., 2007). The mediation effect is quantified by taking the beta from Path B and multiplying it by one of the estimates for Path C that are obtained under each of the two treatment groups (i.e. from the interaction model). The ratio of this indirect effect (in each treatment group) can then be compared to the overall treatment effect (Path A) to measure the percentage of treatment effect explained by the working alliance.

All analyses were performed using STATA version 11 software.
Results

Baseline characteristics

The completer sample was 84% female, 74% Caucasian, 22% African-American, 3% Asian, with a mean age of 48.4 years. Mean ICG score was 44.8. Mean WSAS score was 21.2. Comorbid mood or anxiety disorders were common. Forty-six percent had current major depressive disorder (MDD), 52% current posttraumatic stress disorder (PTSD), 10% current panic disorder (PD), 3% current social phobia disorder, and 6% current obsessive-compulsive disorder (OCD). Thirty-four out of 69 (49%) were taking antidepressant medication. There were no significant differences in demographic or clinical baseline characteristics between the two randomized groups at baseline.

Association Between Treatment Group and Alliance (Path B)

Alliance at week 4 was significantly higher in the CGT group than in IPT (M = 70.4, SD = 9.5 in CGT vs. M = 65.5, SD = 11.6, p=.05). See Figure 2. The effect size of the difference between the groups was .46.
Figure 2. Alliance by Treatment Group

Association Between Alliance and Outcome

Simple correlations revealed an overall correlation between alliance and outcome of .24 (p = .04) on the CGI, .20 (p = .10) on the ICG and .24 on the WSAS (p = .05). While the correlations between alliance and outcome were significant on the CGI and WSAS for the whole sample, the correlations were no longer significant when examined by treatment group. On the ICG, the result was the reverse; the alliance-outcome correlation was insignificant for the whole sample, but significant for the CGT group alone. See Table 1 for a summary of correlations by treatment group.

Table 1. Simple Correlations Between Alliance and Outcomes by Treatment Group

<table>
<thead>
<tr>
<th>Alliance (WAI)</th>
<th>CGI</th>
<th>ICG</th>
<th>WSAS</th>
<th>CGI</th>
<th>ICG</th>
<th>WSAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGT</td>
<td>.26</td>
<td>.34*</td>
<td>.31</td>
<td>.11</td>
<td>-.11</td>
<td>.04</td>
</tr>
<tr>
<td>IPT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. p* <= .05, p** <= .01, p*** <= .001

(Path C)

The regression equations, controlling for earlier change in outcome (weeks 1 to 3) on the ICG and WSAS revealed no statistically significant relationship between alliance and subsequent change in outcome on any of the measures (CGI: OR = 1.04, SE = .03, p = .14; ICG: B = .13, SE
There was, however, a statistically significant interaction between alliance and treatment group on outcome (ICG: B = .57, p=.03). The interaction indicated that there was a significant positive relationship between alliance and outcome within the CGT arm, but a null relationship between alliance and outcome in the IPT arm, see Figure 3. A summary of regression results by treatment group is in Table 2.

Table 2. Regression Results: Association Between Alliance and Outcomes by Treatment Group

<table>
<thead>
<tr>
<th></th>
<th>CGT</th>
<th>IPT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CGI</td>
<td>ICG</td>
</tr>
<tr>
<td>Alliance (WAI)</td>
<td>OR (SE)n 35</td>
<td>B (SE)n .46 (.22) 35*</td>
</tr>
<tr>
<td></td>
<td>CGI</td>
<td>ICG</td>
</tr>
<tr>
<td></td>
<td>OR (SE)n 34</td>
<td>B (SE)n -.10 (.14) 34</td>
</tr>
</tbody>
</table>

Note. p* <= .05, p** <= .01, p*** <= .001

A Controlling for treatment group and prior symptom change

*b Non-standardized units

Figure 3. Relationship Between Alliance and Change in Grief by Treatment Group

Alliance Mediating Outcomes

According to both the Baron and Kenny and MacArthur approaches, there must be a statistically significant relationship between treatment group and mediator for mediation to be established (Path B). This was true for alliance measured at week 4. Although alliance did not show a significant main effect association with outcome, a significant interaction between
treatment group and alliance on outcome (ICG) indicated a significant Path C for the CGT group, fulfilling the MacArthur criteria for mediation. The indirect effect of treatment on ICG through alliance for CGT = 5.02 * .46 = 2.3 ICG points and for IPT 5.02 * -0.10 = -0.5 ICG points. Previously Shear et al. (2005) found the total effect of CGT vs. IPT on ICG to be 8.3 ICG points, therefore 28% (calculated as 2.3/8.3 = .28) of this effect can be explained by the indirect effect through alliance gained within the CGT group.

**Discussion**

This study examined the role of therapeutic alliance in explaining the differential efficacy of 16 sessions of CGT compared to IPT in relieving symptoms of CG. Early alliance did not predict subsequent change in CG symptoms in the sample as a whole when controlling for early symptom change; however it did predict change in ICG in the CGT group and accounted for roughly one-third of the difference in outcome on the ICG between the two treatments.

The significant correlation between alliance and outcome of .24 on the CGI and WSAS is consistent with prior research, but slightly lower than the most recent meta-analysis, showing an aggregate correlation of .275 (Horvath et al., 2011). When controlling for early symptom change and treatment group using logistic and multiple regression however, the overall associations between alliance and outcome became statistically insignificant. These results should caution us to think more critically about the simple correlations reported in the alliance literature.

It is only through mediation analysis, however, that we know whether alliance accounts for the difference in treatment effects. The results presented here show that early alliance is related to treatment group, that it is associated with subsequent outcome in CGT and that it accounts for 28% of the treatment effect of CGT over IPT. In the context of other mediators
found to be operating in CGT (identified by this author in paper #2, i.e. avoidance, depression or guilt) alliance accounts for a modest but statistically significant portion of the treatment effect.

The idea that the alliance-outcome relationship varies by treatment type, was also supported in a study that found that alliance predicted improvements in depression in cognitive-behavioral therapy (CBT) but not in emotion-focused therapy (EFT) (Beckner et al., 2007). The authors of this study were surprised that alliance was more strongly related to outcome in CBT than EFT and speculated that it may have been the transparent process, structure, clear goals and expectations of CBT, which accounted for this difference.

Structure and transparency may also partly explain the differential impact of alliance on outcome in CGT vs. IPT. Patients feel themselves to be collaborators when the therapist lays out the theoretical model of the treatment, the goals and the activities, all the while asking for input and feedback. Each session follows a format that is explicitly shared with the patient at the beginning of the hour and repeated each week. This process builds trust, reduces anxiety and gives the patient a feeling of mutual responsibility for the treatment.

Also important is the therapeutic stance. CGT emphasizes a “companionship alliance” from the very first session (Shear, 2013). This entails a very supportive and active therapeutic role, a statement by the therapist early in the treatment about being the patient’s companion during the treatment process, some disclosure of personal information by the therapist, and conveyance of a strong belief in the treatment and in the patient’s capacity to overcome the obstacles that are interfering with the normal grieving process. In IPT, these attitudes may be communicated but in a less explicit way.

The third factor, which may explain the findings in this study, is the psycho-educational component. This helps patients to understand the difference between normal grief and
complicated grief and how CGT works to clear out the obstacles that have kept them from moving on. Patients feel enormous relief and hope for change when they understand what they have been going through, that they are not alone in this process and that there is a treatment specifically designed to help them. In IPT, complicated grief symptoms are explained in the context of depression rather than as a separate syndrome requiring a unique treatment approach. This may not elicit the same level of hope and/or motivation in the patient as in CGT.

Results from this analysis showed that the interaction between early alliance and treatment group accounted for some of the treatment effect difference but not all of it. This supports the view that alliance is a necessary component of the treatment but not the only important ingredient. In a prior study carried out by this author, it was shown that 5 other variables mediated outcome in CGT, including the reduction in guilt/self-blame related to the deceased or the death, negative thoughts about the future, cognitive anxiety symptoms, depression and avoidance (see paper 2). These variables are closely related to targets within the treatment, supporting the view that specific techniques matter a great deal. Taken as a whole, these findings suggest that a good working alliance, *in conjunction with specific techniques* make CGT successful in the treatment of CG.

This study has several limitations. Most notably, there was no baseline measure of alliance. Since alliance develops over time and cannot be measured before the treatment starts, getting a baseline measure is not possible. Therefore an assumption was made that alliance was the same in both treatment groups at baseline and “changed” or developed by week 4. This assumption was based on randomization and the fact that participants did not differ on any of the baseline characteristics or clinical symptoms measured in this study. Additionally, symptom
change (ICG and WSAS) did not differ between groups during weeks 1 through 3, making it unlikely that alliance at week 4 was affected by differences in early symptom change.

Generalizability of the findings may be compromised by the use of completers rather than the intent-to-treat group, leaving open the possibility that those who dropped out of treatment were different from those who stayed in. An analysis of the variables at baseline, however, showed no difference between completers and drop-outs.

Another limitation is that alliance was measured by only one instrument and by only one rater. Although prior research has shown that self-reported alliance is most predictive of outcome, it would also be useful to examine whether therapist-reported alliance or a different measurement tool would produce different results. Another limitation is that this study did not control for any patient factors that may have affected the alliance. Variables such as attachment style or comorbid personality disorder should be explored in subsequent studies of alliance in CGT.
References


