

COMPLICATED GRIEF IN OLDER ADULTS:  
A RANDOMIZED CONTROLLED TRIAL OF  
COMPLICATED GRIEF GROUP THERAPY

by

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## ABSTRACT

This randomized controlled trial evaluated the efficacy of complicated grief group therapy (CGGT) in the treatment of older adults meeting clinical criteria for complicated grief, as compared to a sample of older adults receiving modified grief support group-treatment as usual (TAU). The CGGT intervention was an adaptation of complicated grief therapy administered as group therapy. A total of 39 participants were randomly assigned to conditions. Twenty-six participants completed the 16 week intervention; CGGT n = 12, TAU n = 14. Primary outcome measures included the Prolonged Grief Disorder Scale (PG-13), the Brief Grief Questionnaire (BGQ), and the Clinical Global Impressions Scale (CGI). Participants who received CGGT demonstrated higher treatment response than participants receiving TAU. While participants in both groups showed improvement in measures of complicated grief, participants in the CGGT group realized significantly greater improvement. More importantly, when complicated grief was measured on PG-13, nearly half of CGGT participants realized clinically significant improvement. On the BGQ, all 12 of the CGGT completers had scores upon follow-up that, had they scored at that level at pretest, would have disqualified them for study enrollment. This high level of clinical significance suggests that those in the CGGT group were effectively treated for complicated grief. This study offers evidence that CGGT holds promise for treatment of complicated grief in older adults and merits further inquiry in other populations.

In memory of those remembered and held dear in the hearts of study participants.

“Do not be daunted by the enormity of the world's grief.  
Do justly, now. Love mercy, now. Walk humbly, now.  
You are not obligated to complete the work,  
but neither are you free to abandon it.”  
Talmud (attributed)

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## CHAPTER 1

### INTRODUCTION

Complicated grief (CG) is a distressing psychological condition with negative health and life quality consequences. Among older adults, complicated grief is under diagnosed, minimized as a factor affecting mental health and function, and undertreated. While the bereavement experience of older adults has been associated with less mourning (Parkes, 2007), secondary consequences such as social isolation may lead to grief of longer duration and poorer health and mental health outcomes than observed in younger persons.

Complicated grief disorder is a state of chronic mourning (Zhang, El-Jawahri, & Prigerson, 2006). The hallmark symptom of the disorder is persistent yearning for the deceased (Prigerson et al., 1996; Prigerson et al., 1999). Prigerson and colleagues have characterized this as “a psychological protest against the reality of loss and a general reluctance to make the adaptations to life in the absence of the loved one” (Prigerson, Vanderwerker & Maciejewski, 2008 p. 170). Persons experiencing complicated grief frequently present with recurrent intrusive thoughts of the person who died, preoccupation with sorrow including ruminative thoughts, excessive bitterness, alienation from previous social relationships, difficulty accepting the death, and perceived

purposelessness of life. This symptom disturbance contributes to profound social, occupational and functional disturbance.

### Prevalence of Complicated Grief

In the community population, an estimated 10-20% of grieving persons meet criteria for complicated grief (Middleton, Burnett, Raphael, & Martinek, 1996; Simon et al., 2007). Among persons receiving outpatient psychiatric care, estimates of complicated grief have ranged from 20% (Zisook, 1985), to over 50 % of this population; with 31% having moderate CG, and 29% having severe CG (Piper, Ogrodniczuk, Azim, & Weideman, 2001). Older adults grieving the death of a child or spouse have been found to have higher prevalence of CG (Gurland, Sadavoy, Lazarus, Jarvik, & Grossberg, 1996; Kinoshita, Sorocco, Gallagher-Thompson, Maddux, & Winstead, 2008; Ott, Lueger, Kelber, & Prigerson, 2007).

### Consequences of Unaddressed Complicated Grief

The chronicity of complicated grief and its enduring distress have been associated with increased risk of cardiac disease, hypertension and cancer (Latham & Prigerson, 2004; Mitchell, Kim, Prigerson, & Mortimer, 2005; Prigerson et al., 1997; Prigerson et al., 1996). Depression, anxiety and suicidality are common co-morbidities (Latham & Prigerson, 2004; Mitchell, Kim, Prigerson & Mortimer, 2005). Impaired social relationships, higher rates of hospitalization, and poorer quality of life are reported among persons with complicated grief (Boelen & van den Bout, 2005; Ott, Lueger, Kelber, & Prigerson, 2007; Silverman et al., 2000).

### Problem Statement

Older adults are at high risk for complicated grief and few studies have addressed complicated grief in this population. Few interventions have been designed and evaluated to address this debilitating condition in persons already underserved in society.

### Purpose of the Study

The current research seeks to compare the efficacy of complicated grief treatment (CGT; Shear, Frank, Houck, & Reynolds, 2005) administered as group therapy with standard group therapy (usual care) in older adults presenting with complicated grief. Group psychotherapy can provide emotional support in the face of loss, bring grieving persons together in a comfortable setting to reduce isolation, foster relationships and create common bonds, provide a forum for sharing experiences, listening and learning, and the development of effective coping skills, and provide opportunity for suffering persons to not only gain support, but also provide help and support to others (Hughes, 1995). The adaptation of CGT to a group therapy model may provide benefits to older adults experiencing complicated grief.

### Organization of the Dissertation

This dissertation has six chapters. The first chapter is an overview of complicated grief and its presentation in older adults. Chapter 1 also describes the statement of the problem under study and purpose of this research. Chapter 2 reviews the theoretical literature on normal grief and key theories that contribute to the contemporary understanding of complicated grief. In this chapter, discussion of current discourse

concerning the inclusion of complicated grief as a distinct disorder in the *Diagnostic and Statistical Manual of Mental Disorders-V*, presently under review, is included. Chapter 2 also describes the value of group psychotherapy as a treatment modality with application to this disorder and to the population of older adults. Chapter 3 consists of a systematic review of existing studies on treatment interventions for complicated grief in older adults. Chapter 4 describes the manualization of Complicated Grief Therapy for group psychotherapy, details the procedure for recruiting and training treatment therapists, evaluation personnel, technical staff and treatment fidelity evaluators. The methods of the research study, including design, sampling, research setting, instrumentation, procedure and statistical analysis is also presented in Chapter 4. Chapter 5 includes results and findings of the research. In Chapter 6, a summary and discussion of study findings, including limitations of the research and implications for further study is presented.

This study has promise for contributing to our understanding of a serious health and mental health concern in an underserved and potentially vulnerable population. The rigor of the study enhances the evidence base for social work interventions with grieving older adults and positively impacts social work advocacy, best clinical practices and policy development in mental health and health care.

## CHAPTER 2

### LITERATURE REVIEW

Death is the most natural and inevitable of human events, yet few are prepared for the loss of a close friend or family member. Grief is understood to be a normal reaction to loss, and an essential part of dealing with loss, especially loss through death. When one considers grief, it is important to recognize that grief is universal – virtually every person will experience it at some time -- and also unique – virtually every person experiences grief in their own way. Grief as a normative process includes psychological, social and somatic reactions to the perception of loss, and is experienced variably over time. The term mourning describes both the individual and collective reaction to loss and refers to traditions, religious and cultural responses, and resultant interpersonal experiences. The term bereavement describes the state of having suffered a loss (Rando, 1984).

#### Theoretical Frameworks of Bereavement

Historical and current conceptualizations of bereavement fall into nine major models (Kissane, 2005). Efforts to scientifically study grief date to Freud's theories of the developing child's relationship with mother and Darwin's observations of weeping



monkeys. Psychodynamic theory, initiated in the work of Freud (1912) and developed by Klein (1940), describes the impact of early relationships on the formation and loss of subsequent relationships. The work of Darwin (1872) informs the ethological theories of grief and emphasizes the role of physiological phenomenon. Attachment theory focuses on the relationship bond affected by loss and is represented in the work of Bowlby (1969, 1973, 1977, 1980), Ainsworth (1978), and Parkes (1975). The interpersonal theories describe the nature of the deceased's relationship to the bereaved and are found in the work of Shapiro (2001) and Horowitz (1989). Psychosocial assumptive theories focus on the world-view of the bereaved, and are the basis of the early work of Parkes (1975). The role and meaning of cultural influences in grief encompasses the sociological models of bereavement developed by Klass (1996) and Rosenblatt (2001). The impact of family supports on grief outcome is found in the family systems theories of Walsh and McGoldrick (1991) and Kissane (1996). Cognitive stress-coping theories have been advanced by Stroebe and Schut (1999) and Kavanagh (1990), and view grief as a function of learned patterns of coping. An emphasis on the traumatic aspects of loss and grief form the basis of traumatic grief models espoused by Prigerson and Jacobs (2001). These theories have received variable levels of testing and analysis. Many represent broader psychosocial views applied to the experience of grief. Some are endorsed with little evidence and reside in clinical practice as anecdotal truths.

Of the theories described above, attachment theory and the cognitive-behavioral dual-process theory specifically address problematic grief; that grief which falls outside the parameters of the normal bereavement experience. The contribution of these two theories with respect to complicated grief is further informed by a stage-process view of

grief. In addition, the work of Doka (1985a, 1989, 2008) conceptualizing disenfranchised grief has implications for the impact of loss in persons presenting with complicated grief. A summary and synthesis of these theoretical orientations follows.

### Attachment Theory

The application of relational attachment to bereavement is derived from the theoretical work of Bowlby (1969, 1973, 1980) and Ainsworth (Ainsworth, Blehar, Waters & Wall, 1978) concerning normal maternal child attachment and the impact of maternal loss on adult psychopathology. In their study of human relationships, attachment theorists have identified four major patterns of attachment; secure, avoidant/dismissive, anxious/ambivalent and disorganized/disoriented. These attachment patterns are presumed to characterize the nature of the grief reaction that will occur with the loss of an attachment figure. There has been considerable exploration of this phenomenon with a variety of relationships types, with the degree of the attachment, and with regard to the griever's emotional appraisals of the deceased.

With respect to complicated grief, attachment theorists postulate that secure individuals will express but not become overwhelmed by the painful emotions associated with grieving. Individuals who are avoidant/dismissive suppress attachment-related emotions during the relationship, a pattern that persists in bereavement as prolonged absence of conscious grieving. Individuals who present with anxious/ambivalent attachment patterns are preoccupied with the relationship, overly dependent, highly expressive of emotion, but unable to constructively address attachment-related feelings upon the loss of the relationship. Those with a disorganized/disoriented attachment have

been traumatized in relationships, resulting in a compromised ability to express and resolve attachment-related losses. Research has identified childhood neglect and abuse (Silverman, Johnson, & Prigerson, 2001) and early childhood separation anxiety (Vanderwerker, Jacobs, Parkes & Prigerson, 2006) as risk factors for complicated grief among older bereaved adults. In summary, attachment theory suggests that persons with insecure early life attachments, particularly those with anxious/ambivalent attachment patterns and those with disorganized/disoriented attachment patterns, are at risk for complicated grief upon the death of significant persons in adulthood. The contribution of attachment disorders to the risk of complicated grief among older adults warrants examination.

#### Dual Process Theory: A Cognitive-Behavioral Model

Stroebe and Schut (1999, 2007) developed the dual process model of bereavement in response to the untested acceptance of a “grief work” explanation of bereavement consistently presented in the literature, and derived from psychodynamic and attachment theories. In the view of grief work, the bereaved must confront the loss and come to terms with loss to avoid negative consequences, inferring that the griever must bring the loss into awareness as much as possible and that suppression of thoughts related to the death is pathological.

Strobe and Schut identify several inadequacies in this conceptualization of grief work as the dominant explanation for the process of grieving. First, there is a lack of specification in defining the stressor of bereavement; besides the loss of the person, they note, there are lost roles, lost functions, and other secondary losses unaccounted for in

this explanation. Secondly, the grief work model does not describe the process of grieving or its context; specifically for the authors, it does not address the dynamics of confrontation-avoidance, nor does it account for the social and interpersonal setting of grief. Third, the outcome variables of the grief work model presuppose a medical model of grief, presuming that grief is pathological and that successful grieving achieves a “cure.” The other possible outcomes of grief: positive growth, and finding meaning in the “durable narrative” (described by other authors as “continuing bonds”) of the relationship, are not adequately explained in the grief work model.

In Stroebe and Schut’s view, a theory of grief must account for the stressors associated with bereavement and the cognitive strategies involved in coping. They postulate that it is the relationship between the stressors and the cognitive coping mechanisms that explain grief. They describe adjustment as composed of three elements, loss-orientation, restoration-orientation and oscillation between the two. Loss-orientation encompasses thoughts about the death and both pleasant and unpleasant feelings, and is consistent with the description of grief postulated in the grief work theory.

The second element, restoration-orientation, describes what needs to be dealt with; loneliness, for example, and how it is dealt with, and not with the result of this process. When a close relationship ends in death, not only is there grief for the deceased person, but also necessary adjustments to the substantial changes that are secondary consequences of loss. Restoration-orientation, then, is not an outcome variable, but a description of the tasks of adjusting to life without the deceased; the skills and functions the loss necessitates, as well as the accompanying emotions such as relief, pride, loneliness and fear. This element is congruent with cognitive stress theories.

The central component of dual process theory is oscillation, which accounts for the dynamic nature of the grieving process. Oscillation is a cognitive and emotional alternation between loss- and restoration-orientation coping. In these oscillations, the bereaved confronts the loss, alternating with periods of avoiding thoughts of the loss. This time of avoidance is viewed as an effective short-term strategy described as “time-off.” During these intervals, the bereaved may focus on the future, learning new tasks, creating new roles, while avoiding thoughts of loss and sorrow. Stroebe and Schut contrast this aspect of avoidance with denial in a pathological sense, recognizing that the effort to transition to a restoration focus is significant, but not as psychologically demanding as long-term repression of reality.

In describing this as the normative process of adaptive grieving, dual process theory has implications for the understanding of complicated grief. Stroebe and Schut contend that complicated bereavement is best explained as “an absence of the type of confrontation-avoidance processing (oscillation) that is associated with adjustment” (p.217). Examples include resisting loss-orientation, found in persons who are unwilling to confront the reality of death and carrying on with life as though the death had not occurred; or, resisting restoration-orientation, found in persons who resist accommodation to the practical life changes death brings.

The dual process theory of Stroebe and Schut has been tested qualitatively and quantitatively by many researchers in the intervening decade. In their more current model, the processes of loss-orientation and restoration-orientation have been expanded to include alternation between the positive and negative aspects of construction and reconstruction (an example would be fluctuating between positive reappraisal of the

deceased and negative event interpretation). This more current model represents a greater appreciation of the complexity and individuality of grief and suggests “oscillation within oscillation.”

The relationship between contemporary attachment theory and dual-process theory suggests that persons who have avoidant/dismissive attachments may have a fixed loss-orientation and never fully experience the death or the thoughts and emotions of grief. Persons with anxious/ambivalent attachments may grieve with great emotional intensity, but without the ability to do either the grief work of loss-orientation or the tasks of restoration orientation. Those individuals with disorganized/disoriented attachment may be unable to reconcile the loss of the original or subsequent attachment figure to addressing the reality of the loss or to the tasks of restoration. The complementary elements of attachment and dual-process theories that account for a poor grief experience suggest that persons with insecure attachment histories are less able to navigate the process of grief and are more predisposed to complicated grief.

### Stage Theories of Grief

Implicit in several of the grief theories described above is an assumption that grief proceeds in stages. The idea that grief follows a progressive temporal course is pervasively held in both popular culture and in the clinical professions. Attachment theories of Bowlby (1969, 1980) and of Parkes (1972, 1983) proposed four discrete stages in grief adjustment; shock, yearning, disorganization/despair, and reorganization. Though developed to address the person’s gradual awareness of impending death, Kubler-Ross’ (1969) stages of dying; denial, dissociation, isolation, anger, bargaining,

depression and acceptance, have been widely applied to the grief experience of bereaved persons. Bonanno, Wortman, Lehman, and associates (2002) identified five different grief trajectories. Jacobs (1993) viewed normal grief as a progressive transition through numbness-disbelief, separation distress, depression-mourning, and recovery. Some researchers and clinicians have discounted stage theory as too linear or too inflexible. Work by Wortman and Silver (1989) has cast doubt on the inevitability of depression as a stage of normal grief.

### Current Research on Grief Stages

Recent research by Maciejewski, Zhang, Block, and Prigerson (2007) systematically investigated stage theory, and sheds light on the differences between normal and complicated grief. This research project assessed community participants without psychiatric diagnoses in the longitudinal Yale Bereavement cohort study. The authors combined the benchmark stages of various theories, disbelief, yearning, anger, depression and acceptance into a model for analysis. Study findings lent partial support to stage theory. The researchers found that disbelief was not the initial, dominant grief indicator. Acceptance was the broadly endorsed indicator across the 24-month time interval. Yearning was the dominant negative grief indicator post loss. Tracking these responses, Maciejewski, and colleagues rescaled the responses, taking into account the rise, fall, and timing of psychological change, and recalibrated their hypothesized model to the patterns of respondents. In the derived model, disbelief decreased from an initial high at 1 month postloss, yearning peaked at 4 months postloss, anger peaked at 5 months post loss, and depression peaked at 6 months postloss. Acceptance gradually and steadily

increased through the 24-month study. These findings suggest that grief does proceed in a nonlinear series of stages, with each stage peaking and diminishing as successive stages present. In that these indicator-stages crested within 6 months following the death, the findings support a view that high levels of grief indicators after 6 months merits clinical consideration of complicated bereavement.

### Social Supports and Disenfranchised Grief

It has been established that lack of social support is a risk factor in grief outcome (Sanders, 1993; Stroebe & Stroebe, 1987). As it relates to attachment theory, the presence of supportive relationships would be predicted to be insufficient compensation for the loss of a primary attachment figure and the resultant emotional loneliness would not be ameliorated by the mere presence of others (Bowlby, 1971; Bowlby, 1979; Shaver & Tancredy, 2007). Stroebe and Schut (2007) observed that emotional loneliness, the grieving person's longing for the deceased, can only be resolved "by the integration of another emotional attachment or the reintegration (after separation) of the one who is lost. However, social support should reduce social loneliness that results from the absence of an engaging social network" (p. 362).

Recent work by Wilsey and Shear (2007) has explored the nature and meaning of social supports among persons with complicated grief and has demonstrated that the presence of supportive others was not sufficient to address profound grief. Further, the presence of helpful people did not offset the impact of those perceived to be unhelpful or insensitive to the grieving person's loss. While the supportive presence of others may help persons proceeding through a normal grief process, Wilsey and Shear found only



limited positive impact of social supports on the grief experience of those with complicated grief.

While not a grief theory, Doka's (1985a, 1989, 2008) examination of disenfranchised grief, the unsupported bereavement experience in persons whose loss may be outside social and cultural norms, also bears on complicated grief. Doka defines disenfranchised grief as "grief that results when a person experiences a significant loss and the resultant grief is not openly acknowledged, socially validated or publically mourned" (2008, p. 224). The griever has no social permission to grieve, nor subsequent entitlement to social support or benefit. Doka studied this phenomenon in bereaved homosexual partners, in ex-spouses, and in survivors of suicide or homicide. The experience of disenfranchised grief has applications across many interpersonal relationships and may be relevant to older adults whose social relationships may be compromised or lacking.

#### Synthesis of Theoretical Conceptualizations of Complicated Grief

Each of the theories presented makes a partial contribution to the understanding of complicated grief. Attachment theories postulate that the nature and quality of childhood attachments predict the individual's ability to experience the death of the original or subsequent attachment figures with healthy resolution. Dual process theory conceptualizes the mechanism of normal grief, illuminating the potential areas of difficulty if normative oscillation between loss-orientation and restoration-orientation does not occur. The intersection of these two theories suggests that poor attachments are a risk for inadequate oscillations between loss-orientation and restoration-orientation

tasks achievement necessary for healthy grief resolution. The recent work in stage theory adds a time parameter to the grief process, indicating that persons who are unable to initiate grief (avoidant/dismissive) or have little resolution of grief symptoms at 6 months post loss (anxious/ambivalent and disorganized/disoriented) are likely to present a clinical picture of complicated grief.

The additional risk factors of disenfranchised grief and the real or perceived inadequate social supports frequently found in some older adults suggest that persons with these concerns are likely candidates for complicated grief.

#### Complicated Grief as a Distinct Psychiatric Condition

From the earliest conceptualizations of grief in psychodynamic theories, efforts to demarcate the line between normal and non-normal grief have been controversial. While both researchers and clinicians have generally agreed that there are real distinctions, it is only recently that actual delimiters have been studied. Historically, grief that could not be resolved was variously referred to as pathological, atypical, abnormal, traumatic, unresolved, dysfunctional, complicated, disenfranchised, or maladaptive grief. Most of the recent literature and most psychometric instruments presently use the term “complicated grief.” Recent work, described below, has advocated changing terminology to “prolonged grief disorder,” but consensus on new diagnostic nomenclature has not yet been reached.

As it has received more attention, many researchers and clinicians have advocated for recognition of complicated grief as a distinct psychiatric disorder (Boelen & van den Bout, 2008; Boelen, van den Bout, & de Keijser, 2003; Dillen, Fontaine, & Verhofstadt-

Denève, 2008; Lichtenthal, Cruess, & Prigerson, 2004; Prigerson, Vanderwerker, & Maciejewski, 2008; Shear et al. 2011; Simon et al., 2001; Zhang, El-Jawahri, & Prigerson, 2006; Zisook, et al., 2010; Zisook, Shear, & Kendler, 2007), and have requested inclusion of the diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> Edition* (DSM-V), and the *International Statistical Classification of Diseases and Related Health Problems, 11<sup>th</sup> Edition* (ICD-11), both under development. Complicated grief is not presently included in the ICD-10 and is considered an adjustment disorder in the DSM-IV. Careful study (Prigerson et al., 2009; Zhang et al., 2006) has established that while CG may have features in common with other psychiatric disorders such as Major Depressive Disorder (MDD) and Post-traumatic Stress Disorder (PTSD), and may be co-morbid with these conditions, it has unique features that distinguish it from these disorders. Moreover, with the exception of early childhood abuse, risk factors associated with CG have not been predictive of MDD or PTSD. Finally, accepted therapeutic treatments, including antidepressant medications and psychotherapies for MDD and PTSD have not been found to be clinically efficacious for CG (Prigerson et al., 2009).

Using longitudinal data from the Yale Bereavement Study, a consensus panel of bereavement experts (Prigerson et al., 2009; Zhang et al., 2006) recommended the following criteria for complicated grief, renamed Prolonged Grief Disorder, for inclusion in the DSM-V:

A diagnosis of Prolonged Grief Disorder requires that the bereaved person must have persistent and disruptive yearning, pining, and longing for the deceased. Diagnostic criteria specify that an additional four of the following eight symptoms be experienced at least several times a day and/or to a severely distressing and disruptive degree: trouble accepting the death; inability to trust others since the death; excessive bitterness related to the death; feeling uneasy about moving on;

detachment from formerly close others; feeling life is meaningless without the deceased; feeling that the future holds no prospect for fulfillment without the deceased; feeling agitated since the death. The symptomatic distress has to endure for at least 6 months and must be associated with significant impairment in social, occupational, or other important domain of functioning. (p. 1192)

Further study by Simon and colleagues (2011), using item response analyses and factor analysis of 782 bereaved individuals, identified symptom clusters of complicated grief. These six symptom clusters include yearning and preoccupation with the deceased, anger and bitterness, shock and disbelief, estrangement from others, hallucinations of the deceased, and behavior changes—either avoidance or proximity seeking.

While the merits of the proposed diagnostic criteria are under review, concerns raised by other scientists and clinicians warrant attention. The affirmation of a psychiatric diagnosis to a normal human condition elicits questions about stigmatization of grieving persons, the ongoing relationship between the griever and the deceased, and possible disregard for the continuum of the grief experience (Rubin, Malkinson, & Witztum, 2008).

These considerations with respect to diagnostic clarity and inclusion in the DSM-V and ICD-11, while worthy, do not diminish the evidence that complicated grief is not fully responsive to current treatments for depression, anxiety, posttraumatic stress disorder, or other psychiatric conditions. As this applies to the older adult, a multifactorial picture emerges to account for the high risk of and higher prevalence of CG in this population. The social, physical, and emotional consequences of unaddressed CG are debilitating, and treatments for CG merit development and evaluation.

Research on bereavement interventions has been hampered by many factors, including lack of a theoretical basis for treatment, considerable variations in length of

time before treatment onset, widely disparate study populations, methodological shortcomings of the research, and undetected moderator variables that result in high variation of outcome and only modest treatment effect. The interventions reported in the literature are often poorly described and have insufficient treatment intensity, limiting both application and replication. Few replication studies are conducted or reported in the bereavement literature. The impact of history, maturation and statistical regression in both research design and treatment is infrequently accounted for. Much of the clinical work in the care of persons at risk for or experiencing complicated grief continues to be done without an evidence base. The mental health professions and the clients served would benefit from careful evaluation of interventions used in the care of grieving older adults with persistent mental illness.

#### Background on Complicated Grief Therapy (CGT)

One promising treatment for complicated grief, developed by Shear and colleagues (Shear, Frank, Houck, & Reynolds, 2005), is reported in a recently published randomized, controlled trial. Complicated Grief Therapy (CGT) is a manualized treatment protocol applied in individual psychotherapy, involving phases of psychoeducation, application of dual-process (loss and restoration) approaches, focused attention on trauma-like symptoms, and planning for the future. The Shear study compared CGT with interpersonal psychotherapy among outpatient psychiatric clinic patients found to meet criteria for complicated grief. Findings suggested that both treatments significantly reduced symptoms of complicated grief, but the response rate was greater and the time to response was shorter for those receiving CGT.

Rationale for Adapting CGT to Group Therapy Format  
(Complicated Grief Group Therapy, CGGT)

Group work is known to provide advantages in psychosocial care including the provision of social support and cost-effectiveness, but few RCT studies have evaluated group therapy interventions for complicated grief. Yalom and Leszcz (2005) have described the following therapeutic advantages of group work that distinguishes it from other treatment modalities: Group therapy instills hope, acknowledges universality to the psychological experience, imparts information, generates altruism, permits corrective recapitulation of (the) family group, provides opportunity for socialization, fosters appropriate imitative behavior, promotes interpersonal learning, creates group cohesiveness, provides safe catharsis, and attends to existential factors in the human experience. With respect to the unique needs of grieving persons, group therapy can provide emotional support in the face of loss, bring grieving persons together in a comfortable setting to reduce isolation, foster relationships and create common bonds. Groups also provide a forum for sharing experiences, listening and learning, the development of effective coping skills, and provide opportunity for suffering persons to not only gain support, but also provide help and support to others.

Yalom and Leszcz (2005) suggest that attention to the following concerns are essential when adapting traditional group work models to specialized clinical groups: careful assessment of clinical situation- *Determine the “immutable” goals*; clear formulation of goals- *Develop goals that are appropriate within existing clinical restraints*; and modification of traditional technique for the clinical needs of the population- *Retain the basic principles and therapeutic factors of group therapy, but*

*alter the techniques to achieve specific goals.* In adapting group methodology, they note that the “therapist must adapt to the clinical situation and the dynamics of the special clinical population” (p. 488).

In the case of groups serving clients with a history of “trauma,” Yalom and Leszcz emphasize the importance of establishing safety, trust and security, being with others having similar “trauma,” providing psycho-education to reduce isolation, and having specific interventions for “trauma.”

As a final caveat, Yalom and Leszcz disabuse the application of group therapy for only cost-reduction or time-saving purposes. In addressing this area of contention, the authors criticize “therapists (for) using groups to increase the efficiency of delivering (therapy) to individual clients—not to tap the unique benefits of the group arena”...but comment favorably on “a second generation, more sophisticated (therapy) group application, in which the essential elements of group life are being acknowledged and productively utilized by... group therapists” (p. 513).

## CHAPTER 3

### A SYSTEMATIC REVIEW OF INTERVENTIONS TO TREAT COMPLICATED GRIEF IN OLDER ADULTS

Using the recently published *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) guidelines (Moher et al., 2009), a systematic review (SR) was conducted to locate studies which evaluate clinical interventions targeting complicated grief in older adults. The PRISMA guidelines define a systematic review as “a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies included in the review” (Moher et al., 2009, p. 3).

#### Introduction

There have been few published systematic reviews or meta-analyses of grief interventions. Allumbaugh and Hoyt (1999) conducted a meta-analysis that included 35 studies encompassing a wide variety of interventions and populations. Malkinson (2001) evaluated outcome studies of cognitive-behavioral therapies addressing grief, linking outcomes to theoretical adherence. Forte and colleagues (2004) conducted a systematic review of bereavement interventions that included pharmacotherapies, individual



therapies, support groups, counseling and systems-oriented interventions in diverse populations, concluding that given a "paucity of reports of controlled clinical trials, no rigorous evidence-based recommendation regarding the treatment of bereavement is currently possible except for the pharmacologic treatment of depression" (p. 1). Pistrang, Barker, and Humphreys, (2008) reviewed effectiveness studies of a variety of mutual help groups for mental health problems, four of which addressed bereavement in adults. To date, no systematic review of psychotherapeutic interventions for older adults with complicated grief has been conducted. The studies evaluated in these four SRs have been included in this review.

The scope of this systematic review included psychotherapeutic interventions for older adults meeting criteria for complicated grief. Inclusion criteria for this search were limited to experimental or quasi-experimental studies evaluating clinical outcomes. Exclusion criteria were studies involving children or adolescents as participants, studies describing normal grief (if not contrasted to complicated grief) or describing interventions to assist with normal bereavement, studies concerning complicated grief which addressed theoretical models, etiology, incidence/prevalence, diagnostic parameters, or clinical correlates (risks/protectors) of complicated grief, prevention interventions for complicated grief, and non-English studies without available translation.

### Search Strategy

Given the many current and historical terms that refer to complicated grief, an expansive terminology was used in searching databases, journal articles and the grey literature. Figure 1 illustrates the search process.

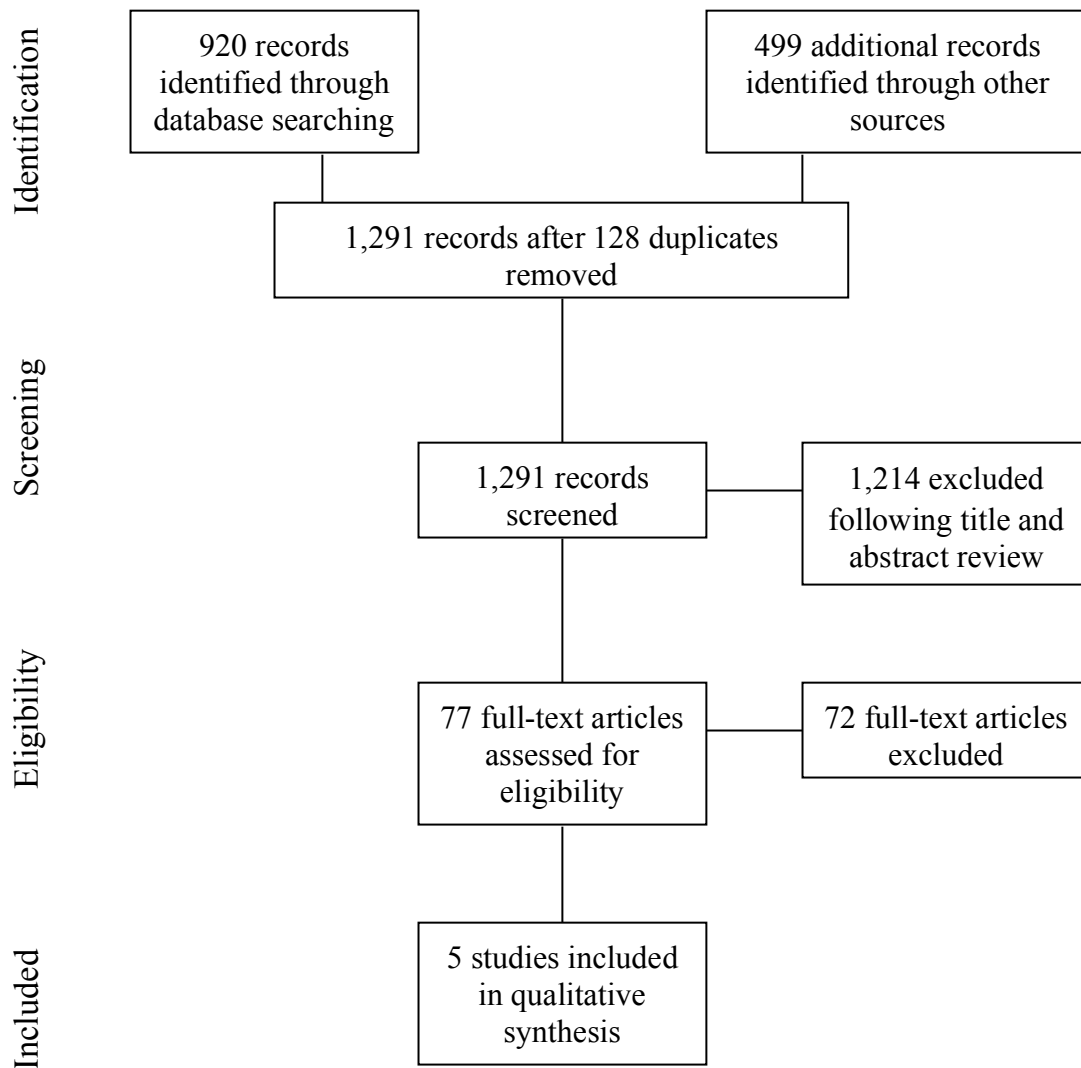


Figure 1. Systematic review of complicated grief interventions in older adults

The following databases were searched:

Academic Universe, Academic Search Premier, Ageline, CINAHL, CogNet, DynaMed ERIC, Family & Society Studies Worldwide, Google Scholar, Health Services & Sciences Research Resources (HSRR), Health Source: Consumer, Health Source: Nursing and Academic Edition, Medline (Cambridge, EBSCO, NLM, Plus), Ovid, PAIS International, Population Index, ProQuest Digital Dissertations, PsycARTICLES-Psychology & Behavioral Science Collections, PsycINFO, PubMed, Social Sciences Citation Index, Social Service Abstracts, Social Work Abstracts, Sociological Abstracts, Trip database, Scopus, Biomed Central, Cochrane Central Register of Trials, Science Citations index, Current Controlled Trials, National Research Register, and Web of Knowledge. Articles from 1985 on were included in the search strategy.

To locate all articles concerning complicated grief, these databases were searched with the following search string: complicated grie\* OR complicated mourn\* OR complicated bereave\* OR unresolved grie\* OR unresolved mourn\* OR unresolved bereave\* OR patholog\* grie\* OR patholog\* mourn\* OR patholog\* bereave\* OR traumatic grie\* OR traumatic mourn\* OR traumatic bereave\* OR prolong\* grie\* OR prolong\* mourn\* OR prolong\* bereave\* OR conflicted grie\* OR conflicted mourn\* OR conflicted bereave\* OR death reaction OR death impact OR death outcome OR unresolved loss OR traumatic loss OR disenfranchised grie\* OR disenfranchised mourn\* OR disenfranchised bereave\* OR dysfunctional grie\* OR dysfunctional mourn\* OR dysfunctional bereave\* OR maladaptive grie\* OR maladaptive mourn\* OR maladaptive bereave\* AND ( counsel\* OR self-help OR psychother\* OR group counsel\* OR group interv\* OR self-help group OR group treat\* OR group\* counsel\* OR support group\* OR

self-help group\* OR group psychotherap\* OR psychotherapy group\* OR psychiatr\* OR psychoeduc\* OR treat\* OR intervention) AND aging OR geriat\* OR older adult\* OR elder\* OR senior cit\* OR adult\* NOT ( Alzheimer\* OR demen\* ) NOT hospital NOT ( drug\* OR medic\* ) NOT ( substance OR abuse ) NOT sex off\* NOT ( child\* OR teen\* OR adol\* ) This search yielded 920 references, and titles were reviewed for inclusion.

The following key journals from 1985 on were individually searched using the complicated grief terms: *Aging and Mental Health, American Journal of Geriatric Psychiatry, Clinical Gerontologist, Consulting Psychology Journal: Practice and Research, Counseling and Clinical Psychology, Counseling and Human Development, Death Studies, Evidence Based Mental Health, Gerontologist, International Journal of Geriatric Psychiatry, The Journals Of Gerontology, Journal of Hospice and Palliative Care, Journal of Mental Health, Journal of Mental Health Counseling, Journal of Palliative Medicine, Journal of Social Work Practice, Omega: The Journal of Death and Dying, Palliative and Supportive Care, Reviews in Clinical Gerontology Social Work, Social Work in Groups, Social Work in Health Care*. In these searches 158 articles were located of which 35 were unique from the previous searches.

The grey literature was searched to locate clinical trials and unpublished findings. To be most inclusive, the search was conducted using the terms “grief,” “loss,” and “bereavement.” This search included the following sites: National Cancer Institute-Clinical Trials (<http://www.cancernet.gov/clinicaltrials/ctrp/page3>), World Health Organization Clinical Trials (<http://www.who.int/ictrp/en>), National Institutes of Health-RePORT Expenditures and Results (<http://projectreporter.nih.gov/reporter.cfm>), International Registry of Clinical Trials (<http://www.controlled-trials.com/>),

OPENSIGLE (<http://opensigle.inist.fr/>), ProQUEST Digital Dissertations (<http://proquest.umi.com.tproxy01.lib.utah.edu/>), PAIS (<http://www.csa.com/factsheets/pais-set-c.php>), the Cochrane Database of Systematic Reviews and the Cochrane Trials Register (<http://www.cochrane.org/>), and the Campbell Collaboration (<http://www.campbellcollaboration.org/library.php>). This search revealed 336 citations, of which 5 were clinical trials. Of these, three were closed trials and did not meet inclusion criteria, one was a preventative CG intervention for families of dying patients, and one was a phase 2 trial of a published article (Shear, Frank, Houck, & Reynolds, 2005) that met inclusion criteria.

Conference proceedings from the past 4 years (2005-2010) were searched from the following organizations: American Academy of Hospice and Palliative Medicine, American Geriatrics Society, Association for Death Education and Counseling, Gerontological Society of America, Hospice and Palliative Care Nurses Association, International Geriatrics and Gerontology Association, and International Association for Hospice and Palliative Care. This review did not reveal additional studies of interventions for complicated grief. All searches were initially performed August 16, 2009, and were rerun on June 20, 2010.

Of the initial 1,419 articles, dissertations and trials located, 128 were duplicates and 951 were not relevant upon screening of titles. Of the 340 potentially relevant articles, 263 were found to be not relevant upon review of abstracts.

A full reading of 77 full papers and prospective trials was conducted. Among articles reviewed were the four review articles. The interventions cited in these papers were located and fully reviewed. Reference sections of full papers were scanned for

additional relevant studies, but no additional studies that met inclusion criteria were noted. After excluding studies that were descriptive reports, single case studies, prevention studies and reports of the care of normal grief, five studies remained which met inclusion criteria.

### Synthesis of the Evidence

The five studies included represent both individual and group therapies. Given the heterogeneity of studies in terms of measurement criteria, treatment settings, and outcomes, both narrative and tabular synthesis is included. The outcomes of interest for this synthesis include normal grief, complicated grief (variously measured as complicated grief, maladaptive grief, unresolved grief, and intrusive and avoidant thoughts of grief) and psychological co-morbidities.

Table 1 summarizes the participants, methods, interventions, follow-up and results of each of the five studies. Table 2 presents outcome measures, scales used, statistics, allocation assignments, and effect size.

### Treatment of Complicated Grief: A Comparison Between Cognitive-Behavioral Therapy and Supportive Counseling

In a study that compared the effectiveness of two different models of individual cognitive behavioral therapy with supportive counseling, Boelen, de Keijser, van den Hout, and van den Bout (2007) found greater improvement in complicated grief symptoms for those participants receiving exposure therapy followed by cognitive

restructuring than for participants receiving cognitive restructuring followed by exposure therapy, and each of these conditions produced better outcomes than for participants in the supportive counseling condition. This finding was consistent for both completers and intention-to-treat groups. In comparing the two cognitive behavioral approaches, exposure therapy was found to have a greater contribution to the overall effect than cognitive restructuring.

Table 1

*Grief Intervention Study Characteristics*

Study	Participants	Intervention	Follow-up	Results
Boelen, de Keijser, van de Hout & van den Bout (2007)	Adults/all loss types $n = 54/39$ completers CR + ET = 23 ET + CT = 20 Supportive (usual care) = 11.	<b>Individual therapy:</b> 6 sessions cognitive restructuring + 6 sessions exposure therapy, vs. 6 sessions ET + 6 sessions CR, vs. 12 sessions supportive counseling	Post-treatment & 6 months	CT + ET & ET + CT conditions showed greater improvement than SC. ET showed greatest contribution to effect; ET + CT & was more efficacious than CT + ET.
Marmar, Horowitz, Weiss, Wilner & Kaltreider (1988)	Adult female widows $n = 61/55$ completers. Brief dynamic therapy $n = 31$ , Mutual support group $n = 30$ .	12 session <b>individual</b> brief therapy vs. 12 session mutual support <b>group</b>	Post-treatment, 4 months & 1 year	Among completers, Both group improved on intrusion, avoidance anxiety and depression. Treatments equally effective.

Table 1 (continued)

Study	Participants	Intervention	Follow-up	Results
Piper, McCallum, Joyce, Rosie & Ogrodniczuk (2001)	Adults/all loss types <i>n</i> = 139/107 completers Interpretative group <i>n</i> = 53 Supportive group <i>n</i> = 54	<b>Group therapy:</b> 12 sessions of interpretive therapy vs. supportive therapy	Post-treatment	Participants in both therapy groups improved. High QOR participants improved more in interpretive therapy, low QOR participants improved more in supportive therapy.
Shear, Frank, Houck & Reynolds (2005)	Adults/all loss types <i>n</i> = 95/69 completers. Interpersonal therapy <i>n</i> = 46, Complicated grief therapy <i>n</i> = 49.	<b>Individual therapy:</b> 16+ sessions of IPT vs. CGT.	Post-treatment; 16-24 weeks from initiation.	CGT showed higher and faster treatment response than IPT.
Wagner, Knavevelsrud & Maercker, 2006.	Adults/all loss types <i>n</i> = 55/51 completers. Internet therapy <i>n</i> = 26, Wait list control group <i>n</i> = 29	<b>Individual therapy:</b> 2 sessions of internet therapeutic writing per week for 5 weeks	Post-treatment & 3 month	Intervention group showed improved scores on intrusion, avoidance, maladaptive behavior & general psychopathology.



Table 2

*Grief Intervention Study Outcome Measures*

Study	Outcome Measures	Scales	Statistic	Allocation assignment	Effect Size
Boelen, de Keijser, van de Hout & van den Bout (2007)	Complicated grief	ICG; traumatic grief evaluation	ICG for ET + CT $F(2, 34) = 25.03, p < .001$	Very good Allocation by minimization to balance for violent/non-violent death & type of loss	Completers ET + CT $d = 1.80$
	Normal grief	TRIG	For CG-group difference-completers $\chi^2(2, N=39) = 5.53, p = .063.$		Intent-to-treat ET + CT $d = 1.29$
	Psychiatric symptoms	SCL-90	intention-to-treat $\chi^2(2, N=54) = 7.85, p = .02$		
Marmar, Horowitz, Weiss, Wilner & Kaltreider (1988)	Stress	IES SRRS	For psychiatric symptoms-group difference-completers $t = 2.03, p < .05$	Very good Random assignment	Brief therapy $d = 1.1-1.3$
	Psychiatric symptoms	SCL-90 BDS BPRS			Mutual support group $d = 0.47-0.67$
	Social functioning	SAS GAS			

Table 2 (continued)

Study	Outcome Measures	Scales	Statistic	Allocation assignment	Effect Size
Piper, McCallum, Joyce, Rosie & Ogrodniczuk (2001)	15 measures		Mean diff	Excellent Matched pairs by QOR & PM scores, then random assignment to treatment	Average ES across 15 variables, $d = .75$
	Depression	BDI	I = 8.6 S = 5.6		
	Intrusion	IES-intrusion	I = 8.9 S = 7.4		
	Pathol. grief	PGI	I = 3.8 S = 7.4		
	Grief	TRIG	I = 7.3 S = 5.1		
	Avoidance	IES-avoidance	I = 9.4 S = 8.7		
Shear, Frank, Houck & Reynolds, 2005.	Global functioning	CGI	$X^2 = 7.56, p .006$ (95% CI, 1.16-3.49)	Excellent, no significant stratum effect for site or type of death, data aggregated across strata.	Completers ES = 1.64 Intention-to-treat ES = 1.35
	Complicated grief	ICG	$F(2, 66) = 5.18$ $p = .03$		
	Social adjustment	WASA	$F(2, 66) = 4.47$ $p = .04$		
	Depression	BDI	$F(2, 66) = 5.92$ $p = .02$		
	Anxiety	BAI	$F(2, 66) = 1.94$ $p = .17$		

Table 2 (continued)

Study	Outcome Measures	Scales	Statistic	Allocation assignment	Effect Size <i>d</i>	
Wagner, Knavevelsrud & Maercker, 2006.	Intrusion	IES-intrusion	F (1, 48) = 11.16, $p < .002$	Very good Random allocation.	Combined intrusion, avoidance and failure to adapt ES = 1.25-1.52	
	Avoidance	IES-avoidance	F (1, 48) = 17.21, $p < .0001$			
	Failure to adapt	Failure to adapt scale	F (1, 48) = 9.79, $p < .01$			
	Depression		F (1, 48) = 9.35, $p < .01$			ES = 1.74
	Anxiety	BSI-depression	F (1, 48) = 6.73, $p < .01$			ES = .96
		BSI-anxiety				

Using allocation to balance groups for violent/non-violent death and type of loss, a total of 54 participants were assigned to the three conditions and received 12 treatment sessions. Inclusion criteria were clearly established. Participants were assessed for complicated grief, normal grief and psychological comorbidities using appropriate, well-validated measures and were reassessed following treatment and at 6 months. Treatment protocols, therapist training and treatment fidelity were carefully monitored. There was a 27% drop out rate, and noncompleters were also assessed upon 6-month follow up. Effect size obtained was  $d = 1.80$  for completers and  $d = 1.29$  for intent-to-treat. Findings were evaluated for clinical as well as statistical significance. The standard for clinical improvement was set as two standard deviations from the pretreatment mean, and was near significant for completers and significant for the intent-to-treat group in both CBT conditions.

Boelen and colleagues report encouraging findings in the contribution of exposure therapy and the value of targeting avoidant thinking in successfully treating complicated grief. The authors note the limitations of the study design, including relatively small Ns and the resultant need to allocate participants through minimization.

A Controlled Trial of Brief Psychotherapy  
and Mutual-Help Group Treatment of  
Conjugal Bereavement

In a study conducted in 1988 by Marmar, Horowitz, Weiss, Wilner and Kaltreider, 61 adult widows who sought treatment for unresolved grief reactions were

randomly assigned to either individual brief dynamic psychotherapy or to mutual help support groups facilitated by widowed nonclinician volunteers. Given the year this study was conducted, unresolved grief and psychological co-morbidities were determined according to criteria in the DSM-III. Two primary symptoms in current diagnostic criteria for complicated grief, intrusive thoughts and avoidant behavior were included in the DSM-III criteria for unresolved grief, but yearning, now increasingly accepted as an essential component of complicated grief, was not.

Participants were evaluated with the most reliable and valid instruments in use at the time of the study, and were randomly assigned to treatment conditions. The brief dynamic treatment modality was referenced, but no description of therapist training or treatment fidelity was provided. Though overall attrition was low, nearly all attrition was realized in the support group condition, and Ns for both conditions were low.

Participants in both conditions were found to have reduction in stress levels and improved social and work functioning. Participants receiving individual brief dynamic therapy were found to have greater, but not significantly better, improvement in psychological symptoms than support group participants. Among completers, the Marmar study found treatments to be equally effective between conditions. Effect sizes were reported as  $d = 1.1-1.3$  for brief therapy,  $d = 0.47-0.67$  for mutual support group. Marmar and colleagues reported a longer than anticipated time course in symptom reduction than noted in previous studies, and recommended lengthening the treatment interval.

In addition to differential attrition from one treatment condition, an important limitation of this study was the comparison of two highly variable interventions, clinician

facilitated individual therapy and nonclinician support group counseling. Had differences between conditions been found, it would be difficult to determine if the effect was attributable to the therapy, to the use of clinician/non-clinician counselor, or to the group/individual treatment modality.

### Patient Personality and Time-Limited Group

#### Psychotherapy for Complicated Grief

This study by Piper, McCallum, Joyce, Rosie and Ogrodniczuk (2001) reports a randomized clinical trial that investigated the interaction of two theoretically relevant personality characteristics - quality of object relations (QOR) and psychological mindedness (PM) – with two forms of grief treatment, interpretive group therapy and supportive group therapy for patients who met criteria for complicated grief. Study findings suggest that high-QOR patients improved more in interpretive therapy and low-QOR patients improved more in supportive therapy. A main effect was found for PM. High-PM patients improved more in both therapies with respect to grief symptoms. For general symptoms, interpretive therapy was found to be more successful than supportive therapy for all participants.

The Piper study had a strong design. The sample consisted of 139 psychiatric outpatients diagnosed with complicated grief, and assessed as clinically appropriate for group work. Inclusion criteria using standardized instrumentation were carefully established. The determination of personality characteristics was conducted by a blinded assessor in separate interviews. Participants were matched in pairs by personality, gender, medication use and age. When 10 pairs were obtained, one participant from each pair

was randomly assigned to one of the two group conditions. There was a 23% dropout rate. Of the 107 completers, 53 were in the interpretive condition, 54 in the supportive condition. Sample demographics were detailed; therapist training, therapy content and process, and treatment integrity were defined in the article. The details of personality assessment, both with respect to theory and instrumentation, were well articulated. All outcomes used established scales with defined reliability and validity scores. The researchers calculated residual scores (pre and posttreatment), corrected for pretest score influence, and used orthogonal rotation reduced the variables to three groups. This accounted for most of the variance, grouped as general symptoms, grief symptoms, and target objective severity. The criterion of statistical significance was used for the completers and on the intent-to-treat sample. The criterion of clinical significance and reliable change was used with completers. Statistical methodology was clearly explained and rationale provided. Potential confounding variables (therapist, medication use, and group) were identified, discussed and determined to have negligible influence on outcomes. Tables were clear, and an averaged effect size of  $d = .75$  was reported across 15 variables. The authors also took care to explain the parameters of statistical significance, clinical significance and reliable change. One limitation was that post-test measures were only obtained at group termination with no longer-term follow up.

The Piper study has promise for targeted interventions for higher risk individuals and groups. These authors note the economic as well as therapeutic value of group work, and the potential to assign clients to the most appropriate care on an evidence-based protocol is encouraging.

### Treatment of Complicated Grief: A Randomized Controlled Trial

This study by Shear, Frank, Houck and Reynolds (2005) represents the first randomized controlled trial to compare the efficacy of an intervention specifically designed to treat complicated grief with standard psychotherapy. Shear and colleagues reported change in grief measures between bereaved adults receiving two different forms of treatment; interpersonal therapy (IPT) and complicated grief treatment (CGT), administered as individual counseling. IPT, an established efficacious treatment in grief with depressive features, was considered standard treatment and served as the control condition. Participants were adults meeting diagnostic criteria for complicated bereavement recruited by professional and self-referral. Treatment response was measured by self-reported Inventory of Complicated Grief score, work adjustment scale, Beck Depression Inventory, Beck Anxiety Inventory scales and Clinical Global Impression Score. Each instrument has well-established validity and reliability and is a widely used indicator of complicated bereavement or psychological symptomology.

The study included a total of 95 participants randomly assigned to groups in a design further stratified by treatment site and type of loss (violent vs. nonviolent death). Each group received 16 treatment sessions from therapists specifically trained in each modality following standardized treatment protocols with established reliability.

The methodology in this study established equivalent distributions of scores across study groups for both demographic and clinical variables. Findings indicated significant improvement in both treatment conditions, but a much greater improvement in the CGT group. The effect was still greater among those who had lost a family member to violent death in CGT group. Effect size for change in complicated grief was reported



as  $d = 1.64$  for completers and  $d = 1.35$  for intent-to-treat group. Effect of attrition was accounted for with follow up contact and estimated improvement on continuous measures; attrition rates were the same for each group. This study's findings lend support to the use of the symptomatically targeted format of CGT as more effective in the treatment of complicated bereavement than standard care. Additional studies are underway by Shear's group to further study this intervention in older conjugally bereaved adults with psychiatric co-morbidities using individual CGT.

### Internet-Based Cognitive-Behavioral Therapy for Complicated Grief: A Randomized Controlled Trial

This study by Wagner, Knaevelsrud and Maercker (2006) investigated the effect of an internet-based cognitive behavioral therapy program on grief symptoms in adults meeting diagnostic criteria for complicated grief, but not necessarily having other psychological co-morbidities. All loss types were included, but the majority of participants were grieving the death of a child. Fifty-five screened participants were randomly assigned to treatment or waitlist conditions. Treatment included five weeks of twice weekly 45-minute therapeutic writing assignments with the participant receiving email feedback from therapists within one working day. Therapists were psychologists trained in cognitive behavioral therapy and therapeutic writing for treatment of PTSD. Therapist feedback was based on CBT protocol and included modules in exposure to bereavement cues, cognitive reappraisal, and integration and restoration. There was no attrition of treatment participants at end of treatment, but one participant was lost to 3-month follow-up.

Participants receiving treatment improved significantly in symptoms of intrusion, avoidance, maladaptive behavior, and general psychopathology relative to waitlist control participants. Effect sizes were reported as  $d = 1.25-1.52$  for the combined intrusion, avoidance and failure to adapt measures, and treatment effect was sustained at follow-up.

The authors attributed the efficacy of the treatment to the targeted focus on trauma symptoms such as avoidance using imaginal exposure and attention to restoration of personal goals. They also postulated that the anonymity of the Internet facilitates disclosure of feelings of pain and shame, but for this reason advised care in screening clients.

One limitation of the study is the very high proportion of participants who had lost a child. The inherent trauma of loss of a child may suggest that those participants are more responsive to treatment that addresses trauma-like symptoms such as avoidance of painful thoughts and feelings, and this effect may not be generalizable across other loss types.

The results of these five studies suggest that interventions specifically designed to address the unique clinical presentation of complicated grief have merit. While affirming the value of supportive traditional psychotherapy, the four most recent studies (Boelen et al., 2007; Piper et al., 2001; Shear et al., 2005; Wagner, Knaevelsrud, & Maercker, 2006) represent adaptations of cognitive behavioral therapy that target symptoms of persistent disruptive yearning for the deceased, trouble accepting the death, inability to trust others since the death, unease at moving on, detachment from formerly close others, and feeling that life has no meaning without the deceased; those symptoms which are included in the emerging diagnostic consensus for complicated grief. Further efforts to develop

intervention programs and research protocols for the treatment of complicated grief should meet the standards of rigorous evaluation, have demonstrated effectiveness and be suitable for implementation in community and clinical settings.

## CHAPTER 4

### METHODS

This research investigated the efficacy of treating complicated grief using two different groups of older adults. One group received the adapted CGT treatment; the other received standard grief support group care (treatment as usual, TAU). In this chapter, I introduce the research question and associated hypotheses. I then detail the three phases of this project: (a) the adaptation of the Complicated Grief Therapy Manual for individual therapy for complicated grief group therapy (CGGT), (b) recruiting and training research evaluation personnel and group facilitators for both conditions, and (c) the research design and methods for the study.

#### Research Question

Is complicated grief group therapy (CGGT) more efficacious than usual group care (treatment as usual, TAU) in treating complicated grief in older adults meeting diagnostic criteria for complicated grief?

H<sub>0</sub>: There is no difference in treatment response between participants receiving CGGT and participants receiving TAU.

H<sub>a</sub>: There will be a significantly different treatment response between participants receiving CGGT and participants receiving TAU.

I attempted to design, implement and evaluate this randomized-controlled trial according to guidelines suggested by the Consolidated Standards of Reporting Trials (CONSORT, 2010). I summarize CONSORT criteria adherence of this study in the discussion section.

### Study Phase I: Manualization of CGT for Group Psychotherapy

In the first phase of my dissertation research, I modified the CGT treatment manual (Shear, 2003; Liberty Version) for use in a group psychotherapy format. According to Carroll and Rounsaville (2008), treatment manuals have become essential components in randomized clinical trials of psychosocial intervention research for establishing clinical efficacy. The value of well-crafted treatment manuals includes: specification of the independent (treatment) variable in clinical trials; provision of clear definitions of standards and criteria for evaluating adherence and competence in delivering treatment; facilitating training of therapists and reducing variability in the delivery of treatment; provision of quality assurance standards; facilitating replication of studies; and fostering dissemination and transfer of effective therapies to clinical practice.

Carroll and Rounsaville describe three stages in the development of treatment manuals: Stage I, where the critical role of the manual is to define the treatment conceptually for preliminary evaluation of feasibility and efficacy; Stage II, where the manual is used for therapist training, dismantling treatment effects, and connecting process to outcome; and Stage III, where the manual is used to evaluate various

clinicians, settings, populations, or staging replications. Shear's (2003) manual, *Complicated Grief: A GuideBook for Therapists*, as provided to me, is a Stage II manual, and the completed Stage III version is presently in press. For the purpose of adaptation of the CGT manual for group therapy, I consider my modifications to be a Stage I translation, which includes:

Purpose: A preliminary evaluation of feasibility and efficacy.

Focus: Pilot/feasibility trials.

Role of manual: Initial specification of treatment techniques, goals and format, and, initial specification of theoretical "active ingredients" (after Carroll & Rounsaville, 2008, p. 226).

Carroll and Rounsaville (2008) outline the contents of a Stage I manual as follows:

1. Overview, description and rationale,
2. Conception of the disorder or problem,
3. Treatment goals,
4. Contrast to other approaches,
5. Specifications of defining interventions,
6. Session content, and,
7. General Format.

Items 1-3 have been systematically addressed in the CGT manual for individual therapy. This present manual content is concise and well-written and no modifications of this text are necessary for the purposes of this study. There is the additional value in keeping as much of the present manual intact as possible to maximize the comparison of the actual treatment modalities (individual vs. group), rather than introduce variations in text or

style between the manuals.

### Quality of Group Interventions

MacGowan (2008) has established standards for evaluating the quality of group interventions and these standards are also relevant for group intervention design. To develop and establish an efficacious group intervention, MacGowan specifies that

the treatment has a sound theoretical basis, ...the treatment has a manual that specifies the components of the intervention and how to administer it with attention to group work principles and ...at least two good between-group design experiments have found the intervention technique to be superior (statistically significantly so) to a psychotherapy placebo or to another intervention/technique and/or equivalent to an already established intervention/technique in studies with adequate statistical power (p 53).

These standards were followed in the adaptation of CGT to the group therapy intervention for complicated grief and in the design of the CGGT manual developed in this study.

### Description of the Two Conditions:

#### Complicated Grief Group Therapy and Treatment as Usual

Treatment differentiation is an important element of treatment integrity, necessitating that “treatment manuals are distinct enough that little overlap among various treatments exists” (Nezu & Nezu, 2008, p. 271). In writing the manuals, I attempted to distinguish the elements of each intervention, while being true to the CGT manual (Shear et al., 2003; Liberty Version) and the historic application of the TAU manual. The two interventions also reflect the contrast between support groups and

therapy groups. Support groups help participants cope during a difficult life transition and include the following characteristics; facilitator leadership, focus on the shared concerns, experiences and goals of members, operate with relative informality, have highly interactive communication with high self-disclosure, and yield productive social contacts and the opportunity for participants to be useful (Toseland, 1990). Therapy groups are more structured and more intensive than support groups. They are designed to decrease self-defeating behaviors while increasing productive behaviors and attitudes thorough the application of techniques targeting the goals negotiated between the group facilitator and participants (Johnson & Johnson, 2012).

#### Grief Support Groups-Treatment as Usual Condition

This grief support group intervention is a 16-week adaptation of a grief support group model I developed in 2007 for groups conducted at Caring Connections: A Hope and Comfort in Grief Program located at the University of Utah College of Nursing. Support groups in the established program are of 8-week duration and are facilitated by licensed clinicians, including social workers, psychologists, counselors, psychiatric nurse practitioners and professional chaplains. Groups are organized by type of loss, and serve those grieving the death of a child, a parent, a spouse, and those who have lost a close other to suicide or homicide. As of spring 2012, 1,200 persons have participated in these grief support groups. The groups reflect the content provided in similar grief support groups conducted across the United States, including the normal grief process, managing relationships with others, managing emotions and thoughts, stress, coping skills, and plans for a new life (Hughes, 1995). While the groups conducted at Caring Connections



are similar in content and scope to groups conducted in other settings, the use of clinician facilitators (vs. peer-facilitated or self-help models of care) has enabled the program to serve participants with more distressing complicated grief.

The adapted manual for the TAU grief support groups includes the following content areas; “the normal grief experience,” “one’s personal experience of grief,” “how grief affects thoughts and feelings,” “coping skills,” “relationships,” “stress and relaxation,” “communication skills,” and “understanding and accepting the new life.” The manual includes session guidelines and goals for the facilitator, and homework for participants in each session. The manual was adapted for the research study by expanding each of the eight content areas from one to two weeks, and extending session duration from 90 to 120 minutes, with no further modification of content or group process.

### Complicated Grief Group Therapy

This intervention is an adaptation of Shear’s *Complicated Grief Guidebook* (Shear et al., 2003; Liberty Version) for individual grief therapy. I designed the intervention to be 16 weeks in length, the median duration of treatment determined as effective in the RCT (Shear et al., 2005). As in the TAU condition, sessions are 120 minutes in length. The intervention includes psychoeducation about normal and complicated grief, guided discussion, and five structured activities—“revisiting the story of the death,” “identifying and working on personal goals,” “inviting a significant other to attend a session,” “having an imaginal conversation with the deceased,” and “bringing in pictures and memorabilia.” Homework is assigned in each session and is closely related to

intervention activities. In the first session, participants are taught to assess their grief experience, monitor emotions and plan daily activities using structured assessment sheets completed on a daily basis, and brought to subsequent sessions for review with facilitators and other group members. Participant grief status is self-assessed using “subjective units of distress” (SUDS), a self-derived metric benchmarked to each participant’s own baseline grief experience. Participants are instructed in the SUDS scale by facilitators in the initial session.

In Shear’s model, the activities comprise the core of the intervention. Many of the activities are implemented in more than one session. Revisiting the story of the death occurs five times in the course of the group. Working on personal goals is implemented in eleven sessions. Bringing in photographs and personal items for discussion is scheduled in two sessions, and recollection of the deceased using structured memory questionnaires occurs in five sessions. The activity in which participants invite a supportive other to attend the group occurs in session 6 and 7, with half of participants bringing a guest in session 6, and the other half bringing a guest in session 7. The imaginal conversations with the deceased take place in sessions 12 and 13. In this activity, each participant has a three-part conversation with the deceased—first, sharing thoughts and feelings with the deceased as portrayed by an empty chair; then, responding in the role of the deceased to the self as represented by an empty chair; and finally, again in the role of the self speaking to the deceased, as portrayed by the empty chair, concluding the conversation with personal observations and comments. Each conversation is facilitated by one of the group facilitators. Two sessions are dedicated to this activity, as each three-part conversation takes approximately 25 minutes.

A summary of the treatment course for TAU and CGGT conditions is presented in Appendix A.

Study Phase II: Recruiting and Training Evaluation Personnel  
and Group Facilitators for Both Conditions

Treatment clinicians utilized as group facilitators in this study were recruited from two sources. Some were recruited from the roster of group facilitators serving Caring Connections: A Hope and Comfort in Grief Program. Others were recruited from the clinical psychotherapist staff in the Master's Program at Valley Mental Health (Salt Lake County, Utah). Group facilitators participating in the study were masters-level credentialed licensed mental health providers, authorized to participate in research by the Collaborative IRB Training Initiative (CITI). Each facilitator had at least 2 years of psychotherapy experience in group work. Of the four facilitators, two were licensed professional counselors and two were licensed clinical social workers. Two facilitators were males and two females. Recruited facilitators were randomly assigned to either the control or the experimental group condition, using numbers drawn from a random number table, and assigned by blinded study personnel. Facilitators were blinded to condition throughout the study. Two clinicians were assigned to each condition, serving as co-facilitators. Each facilitator consistently facilitated either the control or experimental grief groups over the course of the two 16-week groups.

Therapist competence is an essential component of treatment integrity and requires both therapist adherence to protocol and quality of implementation (Nezu & Nezu, 2008). To maximize assurance of therapist competence, I provided training,

ongoing supervision and continuous monitoring of facilitator activity. Prior to leading groups, I trained facilitator pairs in either CGGT or TAU, presenting treatment-specific content on theory, relationship-building behaviors, protocol implementation behaviors, protocol-specific behaviors, and treatment-specific behaviors (after Nezu & Nezu, 2008 p. 274). To promote treatment protocol adherence, I conducted ongoing group skills supervision for facilitators following each group session immediately after the facilitators had assessed participants, separately for usual care and CGGT, throughout the study period.

Participants were evaluated during the study by independent evaluators. Evaluators were second year master's social work students I trained in administration of the six study assessment instruments to assure accuracy and reliability. Evaluators were blinded to treatment assignment.

All sessions were video recorded by simulation technology specialists (STMs) of the University of Utah College of Nursing Simulation Center. STMs were CITI authorized to participate in human research. As the STMs are nonclinicians, there was a modest risk of vicarious traumatization with exposure to grieving participants. I trained the STMs in normal and complicated grief, group processes and participant safety measures, and debriefed them during and after sessions to assure their well-being as non-clinician staff (Scheese & Supiano, *manuscript in review*).

Two practicing psychotherapists highly experienced in treatment of persons with complicated grief and otherwise not affiliated with the study evaluated treatment fidelity. The purpose of this evaluation was to determine if the interventions under study were implemented in a competent manner consistent with the theoretical and procedural

standards of the manuals. One treatment evaluator was a licensed clinical social worker, the other a PhD psychiatric nurse practitioner. The procedures used in the treatment fidelity evaluation are detailed later in this chapter.

### Study Phase III: Research Design and Methods for the Study

#### Population Under Study

The population studied was older adults who experienced the death of a close family member or friend at least 6 months prior to recruitment. Only those who met clinical criteria for complicated grief were asked to participate.

#### Participants

A potential participant pool of 55 persons was involved in this study.

#### Sample Size

Power analysis (Faul, Erdfelder, Lang, & Buchner, 2007) conducted prior to study indicated a sample size of 26 was required to perform primary analyses of treatment effect (two way repeated-measures ANOVA), with a priori effect size = .25, power .90. Attrition is frequently a concern for statistical analyses in clinical intervention studies, frequently exceeding 30% of the sample (White et al., 2010) and may result from participant nonadherence, additional death occurring during study, voluntary withdrawal, scheduling problems, or other factors. To achieve a sufficient pool of participants completing the groups, 55 persons were recruited for inclusion.

### Implementation Study Cohort

Fifty-five prospective older adult participants, age 60 or greater, were recruited to participate in the research study in accord with the advertising and recruitment guidelines specified by the University of Utah Institutional Review Board. Individuals responding to advertising were screened for clinical presentation of complicated grief. The following factors would have excluded interested individuals from participating: Refusal to participate following screening, active suicidality (likely hospitalization), active substance abuse, positive dementia screen, or pending lawsuit related to the death. Those meeting screening criteria on the Brief Grief Questionnaire (BGQ, Shear & Essock, 2002) were offered an opportunity to participate. Interested individuals were mailed two copies of the approved Informed Consent document. Potential participants who returned the completed consent document were randomly assigned to either the control group or experimental group. Randomization was accomplished using a random number table, with assignments made by blinded study personnel. Participation was voluntary.

Participants were community residing older adults, age 60 years or greater, with reported death of significant family member/friend more than 6 months prior to recruitment who met diagnostic criteria (minimum score of 5) for complicated grief as measured on the Brief Grief Questionnaire (BGQ, Shear & Essock, 2002).

Participant recruitment for cohort 1 began in January 2011 and screening, enrolling and pre-assessment was conducted until the study began in March 2011. The first cohort concluded with 6 week follow up assessment in June 2011. Recruitment for cohort 2 began in June 2011, with two prospective participants requesting enrollment in May 2011. Those two prospective participants were screened in May; one did not pursue

the study, due to work conflict; the second was enrolled in cohort 2, pretested in May and reassessed with cohort 2. Cohort 2 was screened, enrolled and preassessed in July and August 2011, and the groups began in August 2011. The second cohort concluded with 6 week follow up in January 2012.

### Human Subjects Considerations

Treatment clinicians participating in this study as group facilitators were credentialed licensed mental health providers and CITI authorized. The University of Utah Institutional Review Board approved the research protocol, including consent documents, recruitment procedures and treatment implementation for this study. Additional informed consent documents were developed and approved by the Institutional Review Board for family and friends of persons in the experimental condition who participated as supportive others in the study.

Because persons with severe levels of grief may represent an inherently vulnerable population, care was taken to assure independent evaluation of participant well-being. The group facilitators and I were aware of pretreatment physical and emotional conditions of participants, by participant report and with permitted contact with care providers, as needed. I directly monitored group process and treatment progress of each participant. Had there been a mental health emergency, I would have accessed psychiatric or medical emergency care through the University of Utah Hospital Emergency Department, as per the existing safety protocol in the Caring Connections Grief Support Program.

## Study Design

The design of the study (Figure 2) was a two-by-four, prospective, randomized controlled clinical trial (RCT). The independent variable in this study was group type, with one group receiving experimental methods based on the work of Shear et al. (2005), CGGT vs. TAU. The dependent variable was treatment response, measured as change in scores on Prolonged Grief Disorder Scale and Brief Grief Questionnaire. Participants were also evaluated for depression using the Beck Depression Inventory (Beck, Brown,

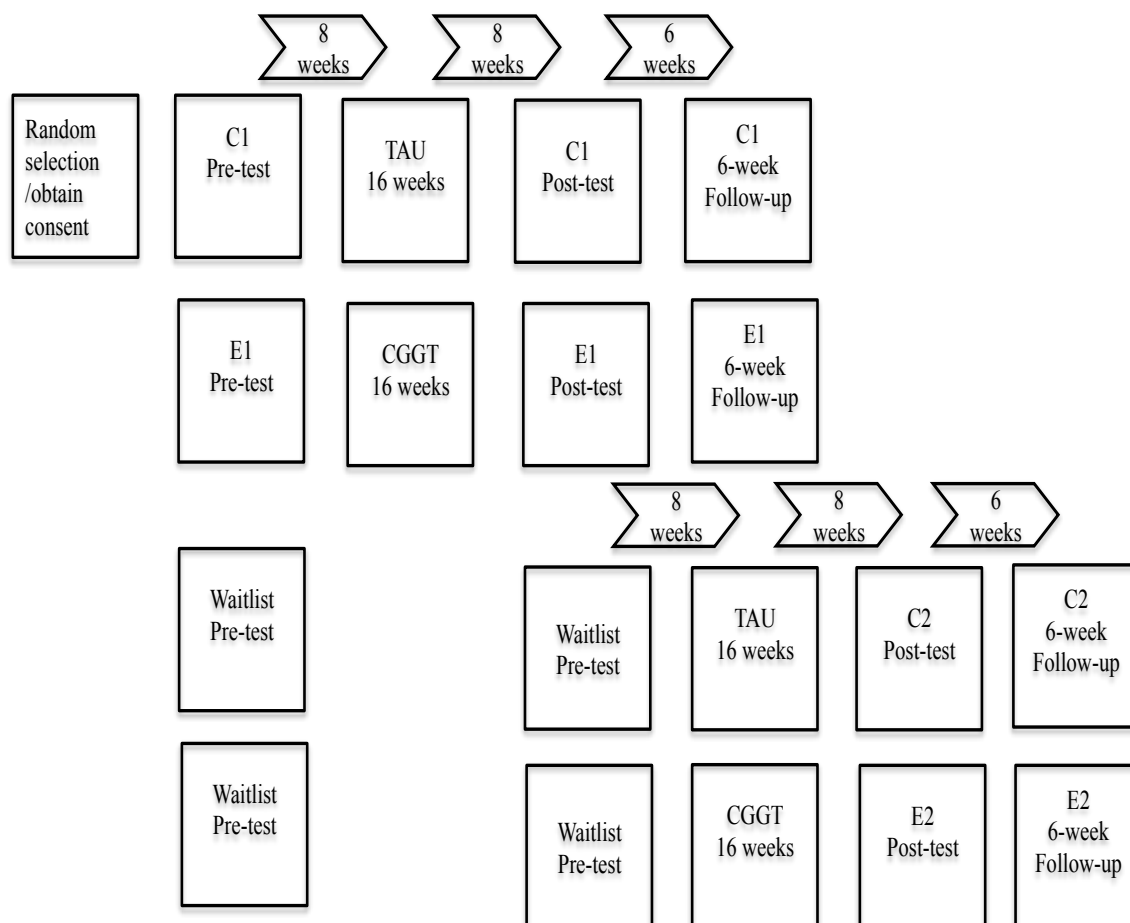


Figure 2. Study Design



Steer, Eidelson, & Riskind, 1987) and for anxiety, using the Beck Anxiety Inventory (Beck, Epstein, Brown, & Steer, 1988). Demographic variables assessed included age, race, and gender. Additional information obtained from participants included medication use, mental health diagnos(es), type of death (violent/nonviolent, sudden/anticipated), type of relationship, time since death, and involvement in other mental health treatment. These were determined to assure similarity between groups, and assessed as potential moderating variables.

## Study Measures

### Grief Questionnaire

The Brief Grief Questionnaire (BGQ, Shear & Essock, 2002) is a 5-item Likert scale self-report of the presence of grief symptoms reported as “not at all” to “a lot.” Possible scores range from 0-10; a total score of 5 or more is positive for complicated grief. The BGQ has a high reported reliability (Cronbach’s alpha .75) and high discriminant validity (average extracted variance .39) (Ito et al., 2012).

This instrument was used for the initial screening of participants upon intake, and repeated at 6-week follow-up for completers, or upon termination for noncompleters.

### Complicated Grief

The Prolonged Grief Disorder Scale (PG-13) is the current version of the Inventory of Complicated Grief Scale (ICG-R, Prigerson & Maciejewski, 2009, Prigerson et al., 2001), a 13-item assessment of the nine identified symptoms indicative of

Prolonged Grief Disorder or complicated grief. Items describe an emotional, cognitive, or behavioral state associated with complicated grief. The diagnosis of complicated grief requires two “separation distress” symptoms (either yearning, intrusive thoughts of the deceased or pangs of separation distress), and five of the following nine symptoms experienced at least once per day; feeling emotionally numb, feeling shocked, feeling that life is meaningless, role confusion, mistrust of others, difficulty accepting the loss, avoidance of the reality of the loss, bitterness, and difficulty moving on with life. Identified symptoms must be associated with functional and social impairment, and must have been present for at least 6 months. Respondents rate the frequency with which they experience each item on a 5-point Likert scale, ranging from “not at all” to “several times/day”, or, “not at all” to “overwhelmingly.” The total score is a sum of scores ranging from 11 to 55. The PG-13 has a demonstrated association with severity of depressive symptoms and a general measure of grief suggesting a valid, yet distinct, assessment of emotional distress (Prigerson & Maciejewski, 2009, Prigerson, Vanderwerker & Maciejewski, 2008). The PG-13 has high internal consistency (Cronbach’s alpha .94) and test-retest reliabilities (.80), and demonstrated internal consistency and convergent and criterion validity. For this study, inclusion score = positive response to item 1 or 2, positive response to items 3 and 13, and a score of 20 or greater on items 4-12. Psychometric evaluation of the PG-13 continues in Prigerson’s research team, and the validity and reliability indicators to date meet or exceed the ICG-R performance levels (personal communications, Holly G. Prigerson, July 13, 2010; May 7, 2012).

## Depression

The Beck Depression Inventory-second edition (BDI-II, Beck and Steer, 1987) is a self-administered tool for screening and assessing the severity of depression. Twenty-one items assess the intensity of depression in diagnosed patients as well as detect possible depression in normal population. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. Most items on the BDI-II are rated on a 4-point scale ranging from 0 to 3. The BDI-II is scored by adding the ratings for the 21 items, with a maximum total score is 63. The BDI-II has demonstrated reliability, with internal consistency (Cronbach's alpha) of .92 for clinical patients and .93 for nonclinical individuals and test-retest reliability of .93. The determination of concurrent validity, two comparisons between BDI-II and its previous version resulted in correlations of .93 and .84.

## Anxiety

The Beck Anxiety Inventory (BAI, Beck et al., 1988) is a 21-item scale that measures the severity of self-reported anxiety in adults and adolescents. It consists of descriptive statements of anxiety symptoms which are rated on a 4-point scale with the following correspondence: "Not at all" (0 points); "Mildly; it did not bother me much" (1); "Moderately; it was very unpleasant, but I could stand it" (2); and "Severely; I could barely stand it" (3). The BAI total score is the sum of the ratings for the 21 symptoms. Each symptom is rated on a 4-point scale ranging from 0 to 3. The maximum score is 63 points. The BAI has reported reliability for internal consistency, Cronbach's alpha, ranged from .92 to .94 for adults. The alphas for the Diagnostic and Statistical Manual of

Mental Disorders, Third Edition—Revised (DSM-III-R) anxiety disorder groups ranged from .85 to .93. Test-retest reliability (1-week interval) was reported at .75. Concurrent validity was reported as the correlation with the Hamilton Anxiety Rating Scale-Revised at .51.

### Cognitive Impairment

Mini-Cog<sup>TM</sup>-screen (Borson, Scanlan, Brush, Vitaliano, & Dokmak, 2000) combines an uncued three item recall test with a mid-assessment recall distractor. Score of 0-2 indicates a positive screen for cognitive impairment and would rule out participant from study inclusion. The Mini-Cog has sensitivity ranging from 76-99%, and specificity ranging from 89-93% with 95% confidence interval. A chi square test reported 234.4 for Alzheimer's dementia and 118.3 for other dementias ( $p < 0.001$ ). This tool has strong predictive value in multiple clinical settings (Borson et al., 2000; Borson et al., 2003).

### Suicide Risk

The Columbia Suicide Severity Rating Scale (C-SSRS)-Screening version. (Posner, Brent, Lucas, Gould, Stanley, Brown, Fisher, Zelazny, Burkner, Oquendo, & Mann, 2009) is a five item branching questionnaire that assesses suicidal ideation and behavior. This instrument is now the standard NIMH screen for all clinical trials. The C-SSRS has demonstrated sensitivity, very high predictive, discriminant and convergent validity, and interrater reliability. Positive identification of suicide risk (active ideation) will rule out participant from study inclusion.

### Age

Century age scored by year of birth and month of birth was used as the measure of age.

### Race

The standard *Centers for Medicare and Medicaid Services* (CMS) demographic was used to describe racial status.

### Gender

The standard CMS demographic for gender was used.

### Primary and Secondary Diagnosis

The primary and secondary DSM-IVR diagnosed condition were used, as diagnosed by primary clinician if in treatment.

### Medication Use

The *Centers for Medicare and Medicaid Services* (CMS) computerized medication classification algorithm was used to document medication use.

### Nature of Loss

Short answer responses to questions regarding type of death (violent/non-violent, sudden/anticipated), type of relationship, and time since death were used to record the nature of the loss.

### Involvement in Other Mental Health Care

Participant involvement in mental health care was documented as type of, frequency and focus of other mental health care.

### Permission to Contact Health Care and Mental Health Care Clinicians

Contact information and permission to contact providers will be obtained prior to participation to acquire additional clarification of psychological status and to assure participant safety.

### Clinical Global Impression (CGI) Scales

The Clinical Global Impressions Scales (Guy, 1976) were used to determine individual participant baseline status and weekly change. These scales have been used for the past 30 years in virtually all FDA-regulated and most clinical trials of psychosocial interventions. The CGI scales have demonstrated high levels of validity, .86 to standard measures; and are strongly associated with both self-report (Cronbach's alpha .62) and clinician administered measures (Cronbach's alpha .72) of specific symptomatology and impairment across multiple conditions (Busner & Targum, 2007, Zaider et al., 2003). The Clinical Global Impressions-Severity Scale (CGI-S) was used to establish the baseline performance of participants and was rated by facilitators rating on the following 7 point scale: 1=normal, not at all ill; 2=borderline mentally ill; 3=mildly ill; 4=moderately ill; 5=markedly ill. The Clinical Global Impressions-Improvement Scale (CGI-I) was used by facilitators to assess weekly change, and 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 7 indicate minimally, much,

and very much worse, respectively. The CGI-I was also used with noncompleters who had participated in at least one treatment session.

## Study Protocol

### Personnel

Katherine Supiano, LCSW, PhD candidate, served as Principal Investigator (PI) on this study, under the supervision of Dr. Marilyn Luptak. All study personnel were CITI authorized.

Independent evaluators conducted telephone assessments prior to the first group session, and at 6 weeks following the group.

Group facilitators participating in the study were master's-level clinicians having at least 2 years of group psychotherapy experience and who received extensive training in CGGT, or TAU.

Session video recording was conducted by staff simulation technology specialists employed by the University of Utah College of Nursing.

Two practicing psychotherapists highly experienced in treatment of persons with complicated grief and otherwise not affiliated with the study served as treatment fidelity evaluators.

### Assessment Procedures

After written informed consent forms were received from participants and random assignment to conditions had occurred, evaluators conducted telephone assessment using the PG-13 (Prigerson & Maciejewski, 2009), and the Beck Inventories for depression

(Beck & Steer, 1987) and anxiety (Beck et al., 1988). Use of the BGQ in addition to the PG-13 was intended to provide triangulation of measures. Evaluators also administered the The Mini-Cog<sup>TM</sup>–screen-telephone version (Borson, Scanlan, Brush, Vitaliano, & Dokmak, 2000), and Columbia-Suicide Severity Rating Scale (C-SSRS, Posner et al., 2009) to rule out potential participants having dementia or active suicidality. Participants also answered questions regarding the type of relationship to the decedent, type of death, time since death, use of medications and involvement in other mental health care. All participants were pretested within four weeks of group initiation.

Each group condition included sixteen 120-minute treatment sessions. Participants were re-evaluated using the PG-13, and the anxiety and depression self-report inventories at mid-point in the group (8 weeks), and immediately following the group (16 weeks). Evaluators conducted telephone interviews with participants at 6 weeks following conclusion of group, and reassessed participants using the BGQ, the PG-13, and the depression and anxiety inventories. The group facilitators and I monitored medication status and participant well-being continuously throughout the study. Participants were evaluated on a weekly basis by group facilitators immediately following each session. Group facilitators used the Clinical Global Impressions (CGI) score to indicate change in grief status.

For participants who dropped out after their second treatment session, group facilitators provided a CGI score and a brief narrative justifying their rating. Non-completers also answered the BGQ at termination. If noncompleters failed to inform study staff of intent to withdraw from the study at a group session, evaluators contacted them by telephone to assess their reasons for withdrawal, and completed the BGQ.



### Group Process Procedures

Of the initial 27 potential participants recruited for the study and screened for eligibility, 22 were eligible for inclusion. These 22 potential participants were randomly assigned to either the control group 1 (TAU) condition,  $N = 11$ , or to the experimental group 1 (CCGT) condition,  $N = 11$ . These two groups were run concurrently on different weeknights to avoid cross-contamination of conditions and to mitigate history and maturation effects as threats to internal validity. After the first two groups were completed, the second series of groups were initiated, consisting of the second 17 eligible participants randomly assigned to the control group 2 (TAU) condition  $N = 8$ , or to the experimental group 2 (CCGT) condition,  $N = 9$ .

### Treatment Procedures

I reviewed the established treatment protocols for CGT as delineated in the Shear Manual, modified the protocol for group psychotherapy, and manualized it for this group therapy intervention. I adapted the manual for group therapy-TAU for a 16-week format, with no modification of content.

All research activity was conducted in the Simulation Learning Center (SLC) of the University of Utah College of Nursing. Study groups were conducted in a debriefing conference room, a comfortable and attractive room designed and equipped similarly to conference rooms that serve as the real life setting for Caring Connections grief support group sessions within the College of Nursing building. The study protocol incorporated mid-tech, high fidelity simulation: mid-tech because of the use of the information technology (IT) equipment and software used to capture the data, and high fidelity due to

the high degree of realism. As a research setting, the debrief conference room of the SLC optimized the balance between experimental control and ecological validity, replicating the “real-world” of a therapy group environment within the laboratory setting. One Pan-Tilt-Zoom camera and two microphones are discreetly mounted in the ceiling and unobtrusive. The room comfortably seats 8-10 participants and includes natural lighting, an electronic white board, and adequate room for placement of easels/flip charts for facilitating group therapy. The room and camera placement allow study participants to habituate to the camera, creating an ideal atmosphere for observation.

The control room provided a remote location where group interaction could be observed and recorded without interruption or interference with the group. The control room contains multiple stations from which to observe and record simulation scenarios throughout the center. One station was designated for observing and recording the grief group interactions, while other stations were often in use simultaneously recording student immersion simulations. The Simulation Technology Specialist (STS) and I sat side by side in the SLC control room, adjacent to, and out of view of the debrief room. I observed the group sessions to monitor participant safety, treatment fidelity and quality assurance. While observing, I coded treatment elements and made extensive memo observations. The STS managed the recording equipment, set up and positioned the camera, monitored audio-visual quality and provided oversight for hardware and software ensuring smooth functioning of all technologies associated with the session.

Digitally recorded content of group sessions was “stream-captured” and recorded in its entirety into Studiocode<sup>®</sup> software. Studiocode<sup>®</sup> is a video recording performance tagging software which permits preliminary coding of identified events in “real-time” for

later robust analysis. I “live coded” events throughout each session and tagged the events for later analysis. I took extensive field notes for later examination. Simultaneous gathering of qualitative and quantitative data further integrated data for analysis.

As per privacy protocol of the SLC, video content was not retained in the center beyond 72 hours. Following each group session, video recording content was immediately downloaded into Studiocode<sup>®</sup> software and held in secure backup. To assure the confidentiality and privacy of participants, only those SLC staff who worked with this study were allowed access to participant information. All data and video recording content, including transcripts, were secured in a locked cabinet within my locked office. To maintain participant privacy, no public use of the video recording content was permitted. Participants were informed of the confidentiality guidelines of group participation. Because this was a group process, participants were advised of the possibility of a breach of confidentiality by other study participants.

### Statistical Methods

There were two groups in each of the two conditions: Control group-TAU 1 (C<sub>1</sub>) and 2 (C<sub>2</sub>), and Experimental group-CGGT 1 (E<sub>1</sub>) and 2 (E<sub>2</sub>). Upon completion of data collection, data were entered into SPSS-19. Data from all assessments was prescreened for missing cases and outliers. There were no missing cases and 1 missing case score. I obtained descriptive statistics including the variable means, standard deviations, range of scores, and skewness and kurtosis of distributions, to assure that there were no violations of the assumptions required of selected statistics. Preanalysis of the data included running  $\chi^2$  and independent t-tests to compare the groups on demographic and clinical

variables:  $X^2$  for race, gender, type of relationship, cause of death, type of death, primary and secondary diagnoses, prior losses, current life stressors, medication use, self-report of health and other mental health care. Independent t-tests were run on BGQ, PG-13, anxiety, depression scores, and time since death and age. This comparison of groups  $C_1$  and  $E_1$  allowed me to compare conditions to assure similar groups at pretest. Group similarity was statistically sufficient, allowing me to collapse  $C_1$  and  $C_2$ , and collapse  $E_1$  and  $E_2$  to create  $C_{tot}$  ( $N = 18$ ) and  $E_{tot}$  ( $N = 16$ ) respectively.

I conducted Repeated Measures (RM ANOVA) between  $C_{tot}$  and  $E_{tot}$  at Time 1 (pretest), Time 2 (8 week midpoint), Time 3 (posttest) and Time 4 (6 week follow-up). This was done with a factorial RM ANOVA to build in the treatment effect. The advantage of a repeated measures design was that variability in the data is reduced, thus increasing the power to detect effects. This approach might have created a violation in the assumption of independence of test scores, a resulting concern about sphericity (homogeneity of covariance), and an increased risk of a Type I error. Violating sphericity suggested that the  $F$  statistic could not be compared to the normal tables of  $F$ . To address this, I used the Mauchly's test in SPSS, to determine if the assumption of sphericity has been violated. Because the Mauchly's test statistic was significant and the condition of sphericity was not met, I applied the Greenhouse-Geisser correction (Greenhouse & Geisser, 1959). The RM ANOVA  $F$  for each outcome measure was evaluated for significance at  $p < .05$ . Achieving that level of significance allowed me to conclude that there was a significant difference between the four times, but not which times differed from each other. Because there are no associated post hoc tests for repeated measures variables in SPSS, I used the paired t-test procedure to compare all

pairs of levels of the independent variable, and then applied a Bonferroni correction to the determined probability for accepting this test. The resulting probability value was used as the criterion for statistical significance. I conducted Bonferroni corrections by dividing the probability value (0.05) by the number of tests conducted, in this case four, comparing all levels of the independent variable. I made four comparisons and the appropriate significance level is  $0.05/4 = 0.0125$ . Therefore, I accepted the t-tests as significant only if they had a value of  $p < 0.0125$ . It is also important that the time interval for follow-up is clinically appropriate, and in this study, a 6-week follow-up was sufficient to assess sustained improvement.

Assumptions of the RM ANOVA statistic are: sufficient N, normal distribution of dependent variable, variances of the dependent variable are the same for each group, and independence of scores on test variables.

#### Participant Attrition: Follow Up to Compare Completers and Non-completers

Experimental mortality is a potential problem in intervention research, and there are many reasons for participant noncompletion. In the Shear et al. (2005) study, dropout rates were 27% in CGT group and 26% for IPT (equivalent of TAU) group, with 10% of participants refusing to participate in some elements of treatment. It is important to note that attrition is a fundamental issue in mental health treatment as it is in intervention research, and while this negatively impacts statistical analysis, it does reflect the reality of the issue under study. I anticipated that participants would withdraw for both situational and personal reasons, individually or upon recommendation of the treatment team. I have addressed attrition by documenting reasons for termination and by obtaining

termination CGI and BGQ ratings from facilitators and evaluators in the intention-to-treat subset in both conditions.

### Weekly Clinical Progress Scores

Following each session, the group co-facilitators met privately to evaluate the progress of each participant using the CGI scale, rating observed change from 1 to 7 where 1 through 3 indicate very much, much, and minimally improved, respectively; 4 indicates no change; and 5 through 7 indicate minimally, much, and very much worse, respectively. I used these ratings to determine individual differences in treatment response. Individual difference analysis is a method used in health-related quality-of-life (HRQOL) studies to describe how individual participants respond to the same treatment, that is, differences that qualify the generality of the overall treatment effect (Donaldson & Monipour, 2002). I utilized all 16 evaluation points for each individual within each condition to identify and illustrate nuanced change within individuals that is not captured by relying on group means alone. To do this, I converted weekly scores to individual cases and graphed them to illustrate change.

### Group Observation

For this study, I actively observed group process and quantified my observations for two purposes. First, I wanted to capture an initial count and the proportion of the types of interactions between facilitators and participants and between participants to assess group process and compare the two groups. Second, I wanted the actual count of the actions of facilitators to assess treatment adherence.

I created a code book to quantify observation of facilitator actions and participant actions. Participant actions of interest to me included “responds positively to content,” “responds negatively to content,” “responds positively to facilitator,” “responds negatively to facilitator,” “responds positively to another participant,” and “responds negatively to another participant.” Facilitator actions of interest included, “applies appropriate content,” “reinforces participants” and “reinforces group process.” For the CGGT groups, I also coded the facilitator actions of “applies appropriate technique” for the specialized actions in the imaginal conversation activity and for the supportive other activities. I also coded participant actions of “responds positively/negatively to imaginal conversation” and “responds positively/negatively to supportive other.” The coding templates are included in Appendix B. These counts are merely a numeric representation of interactions, and do not reflect the duration of any one interaction. The live coding was accomplished using Studicode<sup>©</sup> software, and was supplemented with extensive concurrent memo-writing for later in-depth content analysis.

To generate summary counts of participant and facilitator actions, I first removed four sessions from each of the CGGT group totals; sessions 6 and 7 (the visits of the supportive others) and sessions 12 and 13 (the imaginal conversation activity) as the group dialogue for those sessions is markedly dissimilar to the other 12 CGGT sessions and does not provide a meaningful comparison to the TAU sessions. I calculated means of each action, and the percentage of each action for sessions in each group.

### Treatment Fidelity

I have described my efforts to assure treatment fidelity through careful manualization of the two treatment conditions, and in detailed training and monitoring of facilitators. In addition to these measures, I assessed facilitator protocol adherence using real time coding of facilitator actions and group member interactions. I personally observed and coded these actions and interactions.

To obtain unbiased assessments of therapist adherence, I utilized two highly experienced clinicians as independent treatment fidelity evaluators. I trained treatment evaluators in the essential elements of study interventions and oriented them to the treatment fidelity assessment tool, a modified version of the CGT-OA Adherence Rating Scale (Shear, 2010). Treatment fidelity evaluation took place in four phases. I first divided the 64 sessions into 20-minute segments. I removed the first 10 minutes and the last 10 minutes of each session from the selection pool, as that time included introduction and closure comments in both conditions. I separated the 20-minute segments into control group 1 and 2, and experimental group 1 and 2, and six segments were drawn from the pool by blinded study personnel, three from the CGGT groups and three from the TAU group. These were evaluated in the order drawn (C<sub>2</sub>, E<sub>2</sub>, C<sub>1</sub>, E<sub>1</sub>, E<sub>2</sub>, C<sub>1</sub>) by both evaluators. The fidelity evaluators independently scored the first two segments in the same order using the adherence tool. After the first two ratings, I calculated kappa coefficient, a derivation of intergroup correlation coefficient that adjusts percentage of agreement to account for the probability of agreement by chance. As per protocol, I held subsequent discussion with fidelity evaluators to improve scoring reliability. The fidelity evaluators rated the next four segments in the same order. When an acceptable kappa



coefficient was obtained between the two raters, I scored facilitator adherence to treatment. These evaluators then rated selected segments of the experimental condition video to assist in dismantling treatment effects for later analysis, and to obtain further suggestions for future protocol improvement. A summary of the treatment fidelity plan for the study is presented in Table 3.

Table 3

*Treatment Fidelity Plan*

Quality Focus Area	Information Used to Evaluate Fidelity
Design	Separation of groups No treatment contamination
Facilitator Training	Training manuals Direct observation
Delivery	Direct observation-coding and memo-writing of facilitator behavior
Receipt	Direct observation-coding and memo-writing of participant behavior Homework adherence
Enactment	Direct observation-coding and memo-writing of participant behavior

## CHAPTER 5

### RESULTS

In this chapter, I describe the participant samples and review issues of participant well-being, attendance and attrition. I compare the control (TAU) and experimental (CGGT) groups across measures at pretest. I summarize the comparison of the two groups on outcome measures for complicated grief, depression and anxiety, and detail weekly change in participants in each condition. I summarize the group process observations, comparing the two groups on participant actions and facilitator actions. The chapter concludes with an analysis of treatment integrity in the study.

#### Participants

Twenty-six participants completed the groups, 12 in the CGGT condition and 14 in the TAU condition. The one participant waitlisted was randomized into second phase of the study following retesting. One participant died between the conclusion of the group and the 6-week follow-up. The posttest Brief Grief Questionnaire (BGQ) score for that participant is a missing value; the Prolonged Grief Disorder Scale (PG-13), Beck anxiety Inventory (BAI), and Beck Depression Inventory-II (BDI-II) scores were valued according to intention-to-treat principle, using last reported score carried forward to

impute missing data from those outcome measures. Over the course of the study, three participants were hospitalized, two for elective surgery and one for suicidal ideation; all three of these participants remained in the study. Two participants had grandchildren born during the study and both endorsed this as a positive life event. There were occasional absences due to vacations, family events, or illness of a family member. For anticipated absences, participants attended the group by conference call, including one participant who had a 2-week rehabilitation in skilled nursing facility. One participant moved out of state at midgroup, but attended by conference call for 2 weeks during her move, then relocated back to the home of a local family member to complete the group. Figure 3 summarizes the flow of participants in the study and details participant attrition. Participant attrition was 25% for CGGT and 26% for TAU, consistent with expectations for psychotherapy intervention research, and was accounted for in termination scores on BGQ and facilitator termination CGI scores.

### Baseline Measures

I compared the two group cohorts to assure that the two CGGT groups and the two TAU groups were similar at preintervention assessment, using  $X^2$  across categorical measures and independent t-tests across continuous measures. Group  $E_1$  had a poorer self-report of health than  $E_2$ ,  $t(14) = 2.47$ ,  $p = .03$ , but the groups were otherwise sufficiently similar to allow me to collapse  $C_1$  and  $C_2$ , and collapse  $E_1$  and  $E_2$  to create TAU  $C_{tot}$  ( $N = 18$ ) and CGGT  $E_{tot}$  ( $N = 16$ ), respectively. I examined the distributions of all variables and they met requirements for normality.

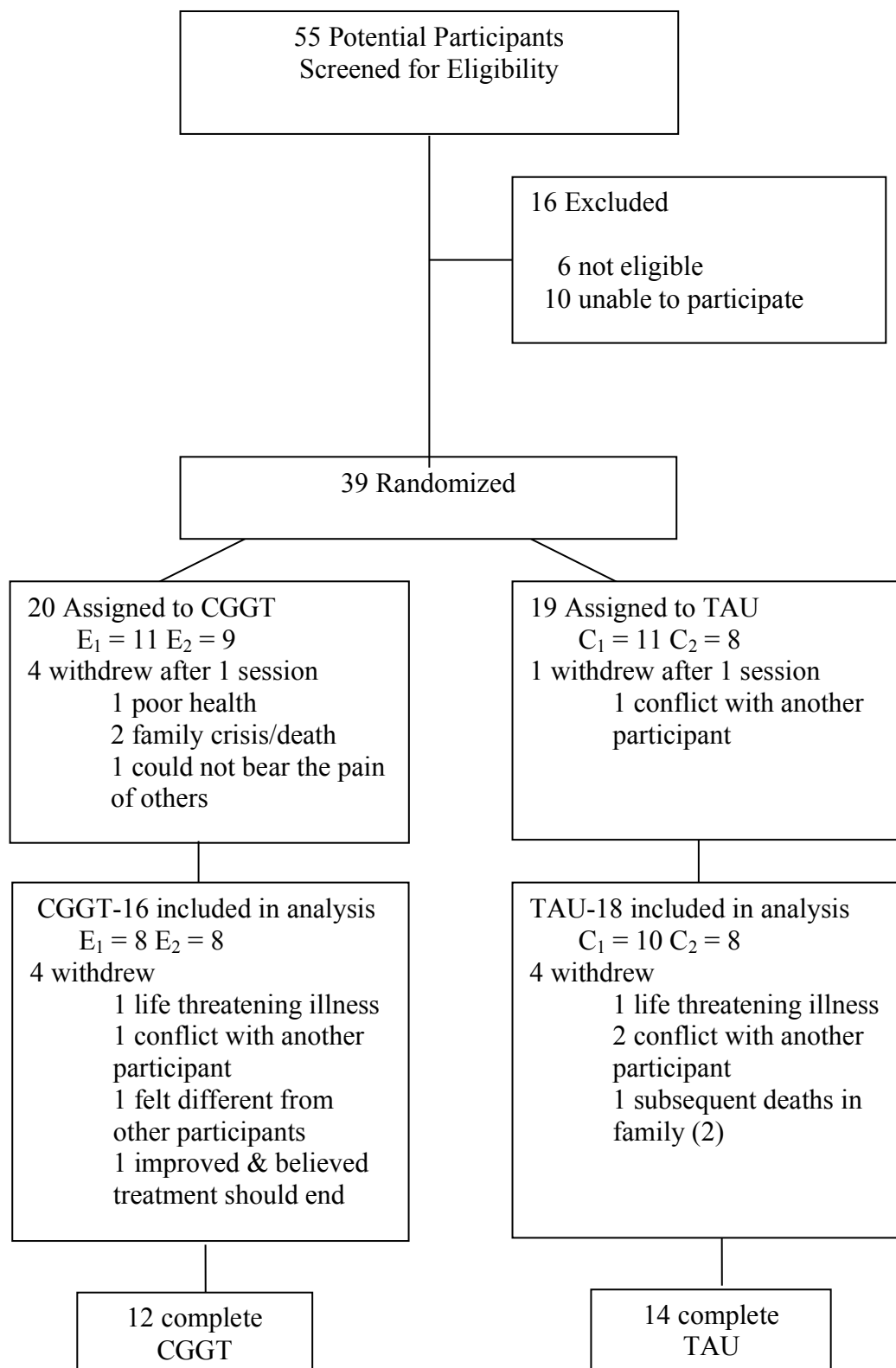


Figure 3. Participant flow in the study.

To determine if the CGGT group and the TAU group were similar prior to the start of the intervention, I compared the groups across all demographic variables, screening BGQ and preintervention PG-13, BAI and BDI-II using independent t-tests on continuous variables, and  $X^2$  statistics on categorical measures. Table 4 shows the pretreatment comparison of the CGGT and TAU groups. The two groups were similar in age, gender, relationship to deceased and time since death. There is some variation in the groups by cause of death, with the CGGT group having six suicide deaths and the TAU group having the only homicide death. When deaths are attributed to sudden vs. expected death, however, no significant difference is found between the two groups. No significant differences were observed in prior losses that affect grief, self-report of health, use of psychotherapy, use of medications, or substance abuse history. The TAU group endorsed a higher level of life stressors. No significant differences between the groups were found in current depression or depression within the past five years.

The CGGT and TAU groups were similar across outcome measures at pretest, as presented in Table 5. On screening BGQ, the CGGT group score was 7.06 and the TAU group score was 7.33. The BGQ group scores were nonsignificantly different,  $t(32) = -.591, p = .559$ . On PG-13, the CGGT group score was 37.17 and the TAU group score was 37.72, also a nonsignificant difference,  $t(32) = -.207, p = .559$ . Pretest scores on BAI and BDI-II also revealed no significant differences between CGGT and TAU groups at pretest; on BAI the CGGT group score was 14.69 and the TAU group was 16.38,  $t(32) = -.466, p = .644$ ; and for BDI-II, CGGT the score was 23.94 and for TAU 22.11,  $t(32) = .493, p = .625$ . It is noteworthy that the mean anxiety scores on the BAI

Table 4

*Pretreatment Comparison of Groups on Demographic Variables*

	CGGT (n = 16)	TAU (n = 18)	$\chi^2$ or t value	df	P value
Age-mean(SD),	67.9 (7.87)	67.4 (5.98)	.181	32	.858
Male	4	2	1.12	1	.289
White	16	18	Ns		
Relationship to deceased					
Spouse/partner	9	12			
Adult child	1	1			
Sibling	0	1			
Parent	3	4			
Grandchild	2	0			
Other	1	0			
			4.47	5	.484
Time since death					
6-9 months	4	5			
9-12 months	3	1			
12-18 months	4	6			
18-24 months	1	1			
24-36 months	1	2			
>36 months	3	3			
Mean time since death			1.73	32	.885
Cause of death					
Chronic illness	6	5			
Acute illness	4	10			
Accident	0	2			
Suicide	6	0			
Homicide	0	1			
			11.59	4	.021

Table 4 (continued)

	CGGT (n = 16)	TAU (n = 18)	$X^2$ or t value	df	P value
Death expected (yes)	10	8	1.108	1	.292
Prior losses that affect grief (yes)	10	15	1.89	1	.169
Stressors that affect grief (yes)	11	17	3.85	1	.050?
Self report of health (good)	3.06	3.00	.147	32	.884
Receiving therapy (yes)	10	8	1.11	1	.292
Currently on medication (yes)	8	13	3.04	3	.385
Endorses depression	10	14	.952	1	.329
Endorses depression within past 5 years	9	11	.083	1	.774
Substance abuse history (yes)	0	1	.916	1	.339

Table 5

*Pretreatment Comparison of Groups on Outcome Measures*

Outcome measure	CGGT (n = 16) <i>M (SD)</i>	TAU (n = 18) <i>M (SD)</i>	$X^2$ or t value	df	p value
BGQ	7.06 (1.29)	7.33 (1.19)	-.591	32	.559
PG-13	37.13 (6.71)	37.72 (9.64)	-.207	32	.837
BAI	14.69 (10.88)	16.38 (10.3)	-.466	32	.644
BDI	23.94 (10.31)	22.11 (11.3)	.493	32	.625

for both groups are clinically interpreted as “very low anxiety,” and the mean depression scores on the BDI-II for both groups are clinically interpreted as “moderate depression.”

### Comparison of CGGT and TAU on Outcome Measures

Repeated-measures analysis of variance (RM ANOVA) was conducted to evaluate the effect of the interventions CGGT and TAU on the dependent variables complicated grief (BGQ) at pretest and follow-up, and complicated grief (PG-13), anxiety (BAI) and depression (BDI-II) at four intervals; pretest, 8 week midpoint, 16 week posttest and follow-up 6 weeks after posttest (Table 6).

#### Change in Complicated Grief

For complicated grief as measured by PG-13, a RM ANOVA was conducted to evaluate the effect of group assignment on PG-13 at four test intervals. The Time effect and Group x Time interaction effect were tested using the multivariate criterion of Wilks’s lambda ( $\Lambda$ ). The Time main effect was significant,  $\Lambda = .15$   $F = 40.89$  (3, 22),  $p < .001$ . The interaction effect Group x Time was also significant,  $\Lambda = .39$   $F = 11.52$  (3, 22),  $p < .001$ . A very large effect size of  $\eta^2 = .61$ , Cohen’s  $d = 1.34$  [95% CI = .483, 2.187] was found. Four pairwise t-tests were conducted to follow up on the significant interaction between groups for each time period. I controlled for familywise error rate across these tests using the Bonferroni correction,  $\alpha = .05/4 = .0125$ . For the TAU condition, only the Time 1 (pretest) to Time 4 (6 week follow-up) was significant,  $t(15) = 4.93$ ,  $p < .0125$ . For the CGGT condition, three time intervals were significant; Time 1 (pretest) to Time 2 (midpoint),  $t(11) = 4.02$ ,  $p < .002$ , Time 3 (posttest) to Time 4 (follow



Table 6

*Posttreatment Comparison of Groups on Outcome Measures*

Outcome Measure	Time 1	Time 2	Time 3	Time 4	RM ANOVA		
	Pretest M (sd)	Midpoint M (sd)	Posttest M (sd)	followup M (sd)	F (df)	P	d[CI]
<u>BGQ</u>							
CGGT	7.06 (1.29)			3.31 (1.30)			
TAU	7.29 (1.40)			6.53 (1.37)			
					37.92 (1, 31)	.000	2.42 [1.41, 3.34]
<u>PG-13</u>							
CGGT	41.58 (5.42)	35.08 (6.43)	29.33 (10.99)	23.00 (9.02)			
TAU	38.79 (9.46)	35.38 (10.34)	30.14 (7.93)	30.29 (9.37)			
					11.52 (3, 22)	.000	1.34 [.483, 2.187]
<u>BAI</u>							
CGGT	16.33 (12.11)	15.25 (9.63)	13.75 (11.19)	8.33 (9.17)			
TAU	16.92 (9.73)	12.14 (8.87)	10.21 (9.77)	9.57 (7.80)			
					3.99 (3, 22)	.021	.786 [-.014, 1.59]
<u>BDI-II</u>							
CGGT	25.58 (11.38)	20.58 (9.07)	15.75 (8.97)	14.92 (10.66)			
TAU	22.86 (12.16)	19.21 (10.47)	12.29 (10.17)	15.64 (12.81)			
					.784	.516	

Note  $d$  = effect size, Cohen's  $d$ , CI = 95% confidence interval.

up),  $t(11) = 4.41, p < .001$ , and Time 1 (pretest) to Time 4 (follow up),  $t(11) = 9.08, p < .000$ .

The change in complicated grief as measured by the PG-13 is illustrated in Figure 4. The findings support the hypothesis that participants receiving CGGT demonstrated greater treatment response than participants receiving TAU. While both groups improved to the level of statistical significance, the CGGT group markedly improved. In addition to statistically significant improvement, 5 of 12 participants or 41% of the CGGT group achieved clinically significant improvement, defined as 50% reduction in PG-13 score (personal communication, Holly G. Prigerson, July 13, 2010). None of the 14 TAU participants achieved clinically significant change in complicated grief as measured by PG-13.

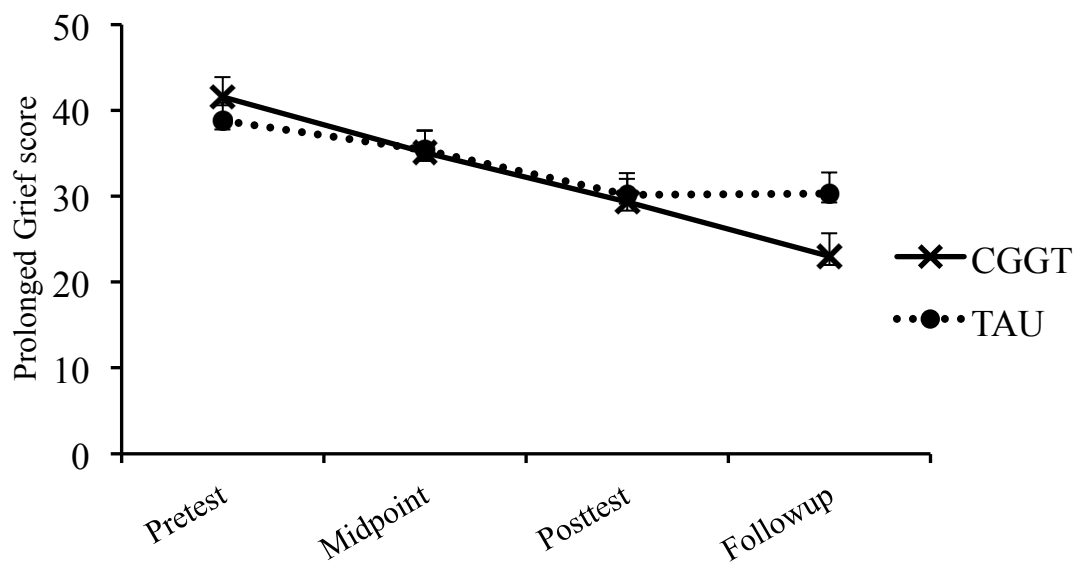


Figure 4. Change in complicated grief (PG-13).

To provide triangulation of measures for complicated grief, participants were given the screening BGQ again at 6-week follow-up. The Time main effect and Group x Time interaction effect were tested using the multivariate criterion of Wilks's lambda ( $\Lambda$ ). The Time main effect was significant,  $\Lambda = .263, F = 86.71 (1, 31), p < .001$ . The interaction effect Group x time was also significant,  $\Lambda = .45 F = 37.92 (1, 31), p < .001$ . A large effect size of  $\eta^2 = .55$ , Cohen's  $d = 2.42$  [95% CI = 1.41, 3.43] was found. Figure 5 displays the change in complicated grief as measured by BGQ. These findings lend additional support to the hypothesis that participants receiving CGGT demonstrated

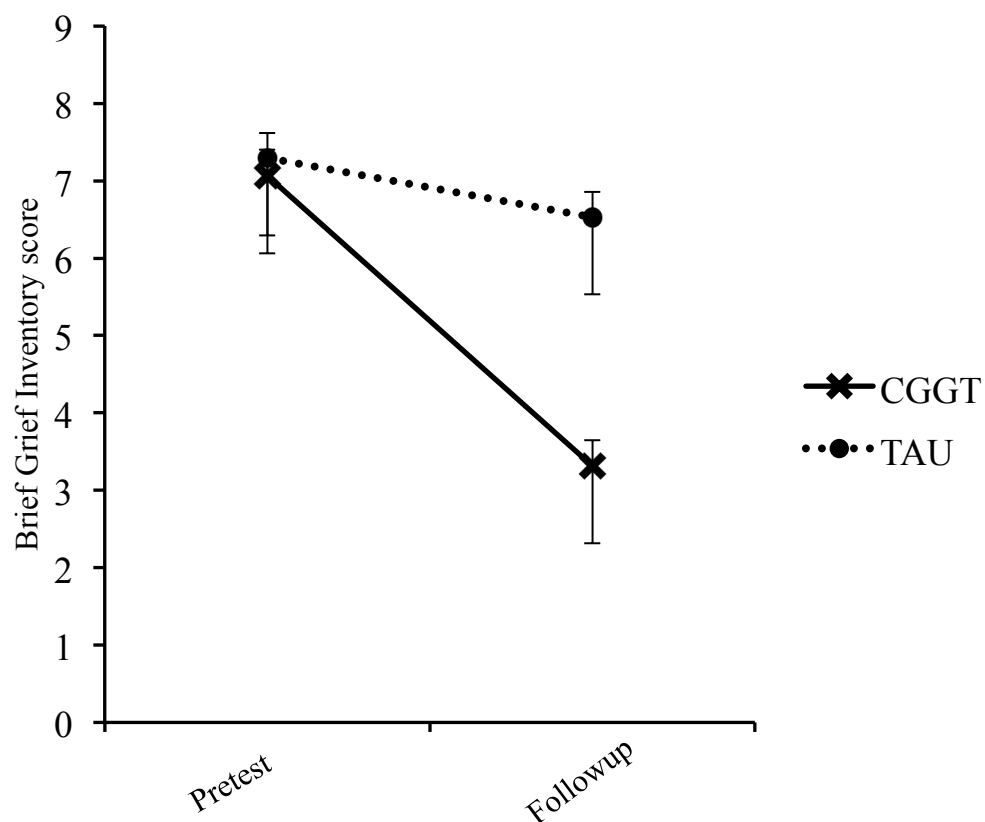


Figure 5. Change in complicated grief (BGQ).

greater treatment response than participants receiving TAU. Moreover, improvement in complicated grief among CGGT participants, as measured by the BGQ, also suggests clinical significance, in that 12 of the 12 CGGT completers (100%) scored 5 or lower on the BGQ at follow-up, in contrast to 1 of 4 (25%) of CGGT noncompleters, 3 of 14 (21%) TAU completers and 1 of 4 (25%) of TAU noncompleters. Table 7 displays the posttreatment comparison of treatment completers and the intent-to-treat group on BGQ.

### Change in Mood

To evaluate the effect of group assignment on anxiety as measured by the BAI, and on depression as measured by the BDI-II, the Time main effects and Group x Time interaction effects were tested using the multivariate criterion of Wilks's lambda ( $\Lambda$ ). For anxiety, the Time main effect was significant,  $\Lambda = .334$   $F = 14.62$  (3, 22),  $p < .001$ , and the interaction effect Group x Time was also significant,  $\Lambda = .648$   $F = 3.99$  (3, 22),  $p < .05$ . A medium effect size of  $\eta^2 = .352$ , Cohen's  $d = .786$  [95% CI = -.014, 1.59] was found. Four pairwise t-tests were conducted to follow up on the significant interaction between groups for each time period. I controlled for familywise error rate across these tests using the Bonferroni correction,  $\alpha = .05/4 = .0125$ . For the TAU condition, only the Time 1 (pretest) to Time 4 (6 week follow-up) interval was significant,  $t(11) = 3.42$ ,  $p < .006$ , and for the CGGT condition, only the Time 1 (pretest) to Time 4 (6 week follow up) interval was significant,  $t(13) = 5.65$ ,  $p < .000$ . Figure 6 illustrates change in anxiety. These findings suggest that, despite beginning the study with very low levels of anxiety,

Table 7

*Post-treatment Comparison of Treatment Completers and Intent-to-Treat Group (BGQ)*

	CGGT	TAU	<i>F</i>	df	<i>p</i> value	<i>D</i>	95% CI
<u>Intent to Treat</u>							
	n = 4	n = 4					
BGQ							
Pre-treatment	6.25	7.00					
Post-treatment	4.25	6.75					
Difference	2.00	0.25	1.96	1	.211	1.4	[-.787, 3.586]
<u>Treatment completers</u>							
	n = 12	n = 13 <sup>a</sup>			.		
Pre-treatment	7.33	7.39					
Post-treatment	3.17	6.46					
Difference	4.16	0.93	61.41	1	.000	3.137	[1.966, 4.308]

Note *d* = Effect size Cohen's *d*, CI = 95% confidence interval.

<sup>a</sup>1 TAU participant died between post-test and 6-week follow-up.

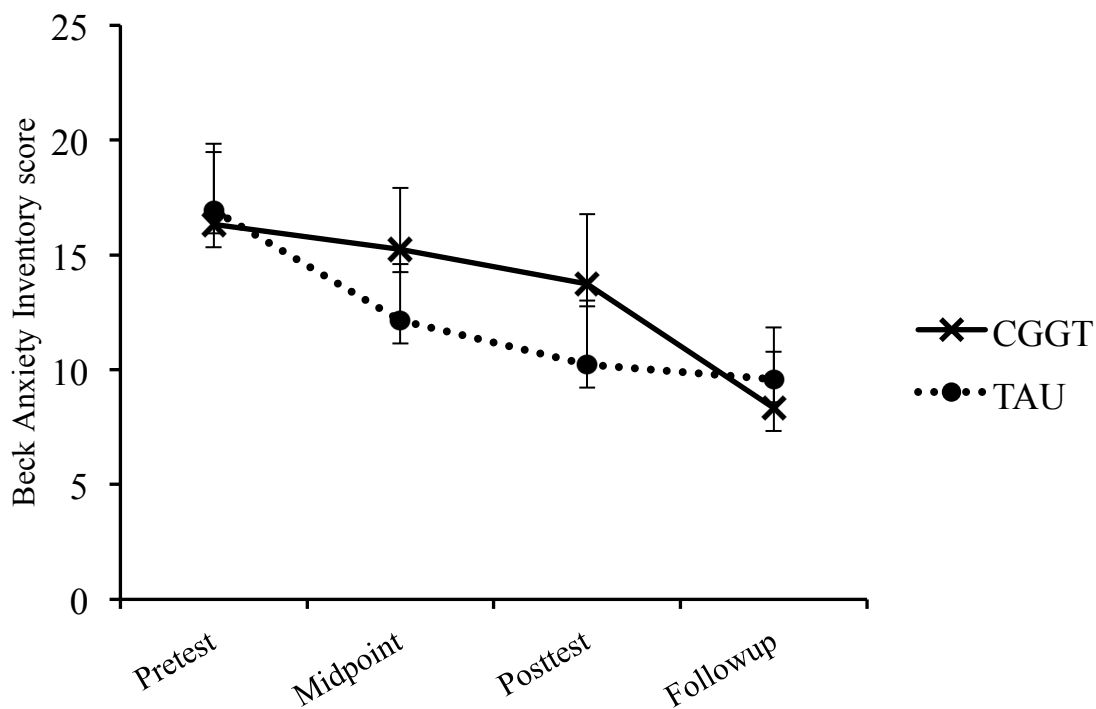


Figure 6. Change in Anxiety (BAI).

participants in both conditions realized improvement in anxiety, but that those in the CGGT condition realized significantly more improvement in anxiety.

For depression, the Time main effect was significant,  $\Lambda = .413$   $F = 10.41$  (3, 22),  $p < .001$ , but the interaction effect Group x Time was nonsignificant. Figure 7 displays the change in depression in both conditions.

#### Weekly Facilitator Evaluations of Participant Progress

Figure 8 is a display of the week-to-week change of each participant as assessed by facilitators using the CGI, with each line representing one participant (or an overlap of

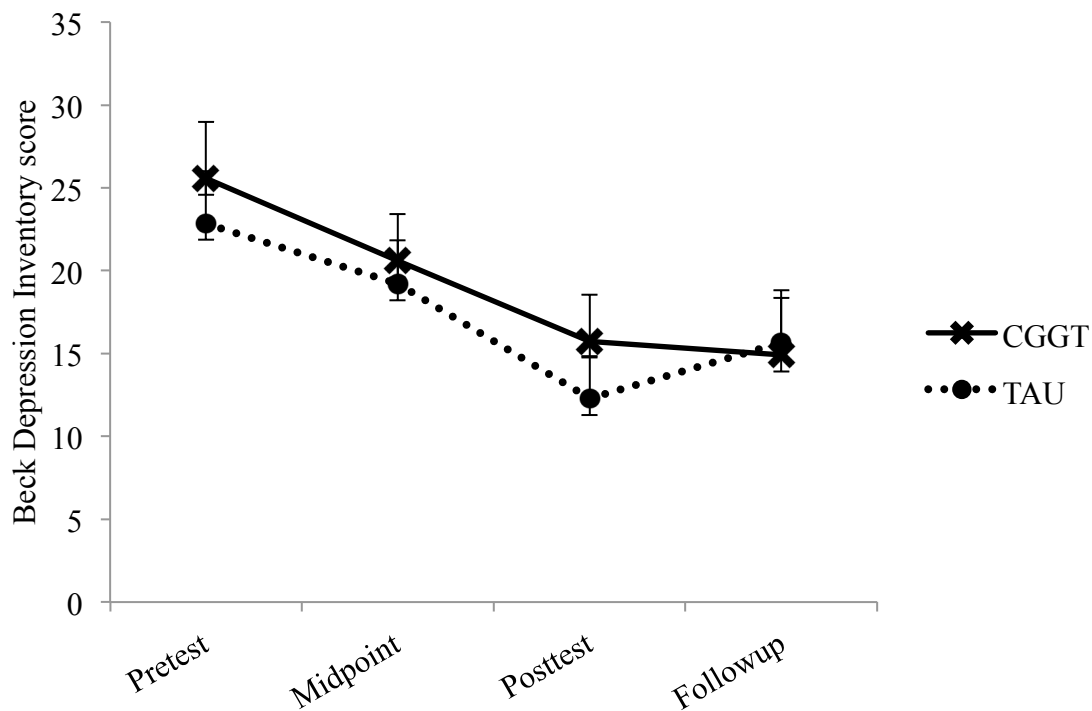


Figure 7. Change in Depression (BDI-II).

several participants). A visual review reveals a steady improvement in the CGGT group, and an erratic, though eventual improvement in the TAU group. When the individual assessments are aggregated (Figure 9), a clearer picture emerges of the weekly progress in each condition. The CGGT group shows a slow, steady improvement, while the TAU group appears to have a roller-coaster pattern of change with less overall improvement. The CGGT group achieved a final mean CGI score of 1, indicating “very much improved.” The TAU group finished with a final mean CGI score of 3, indicating “minimally improved.”

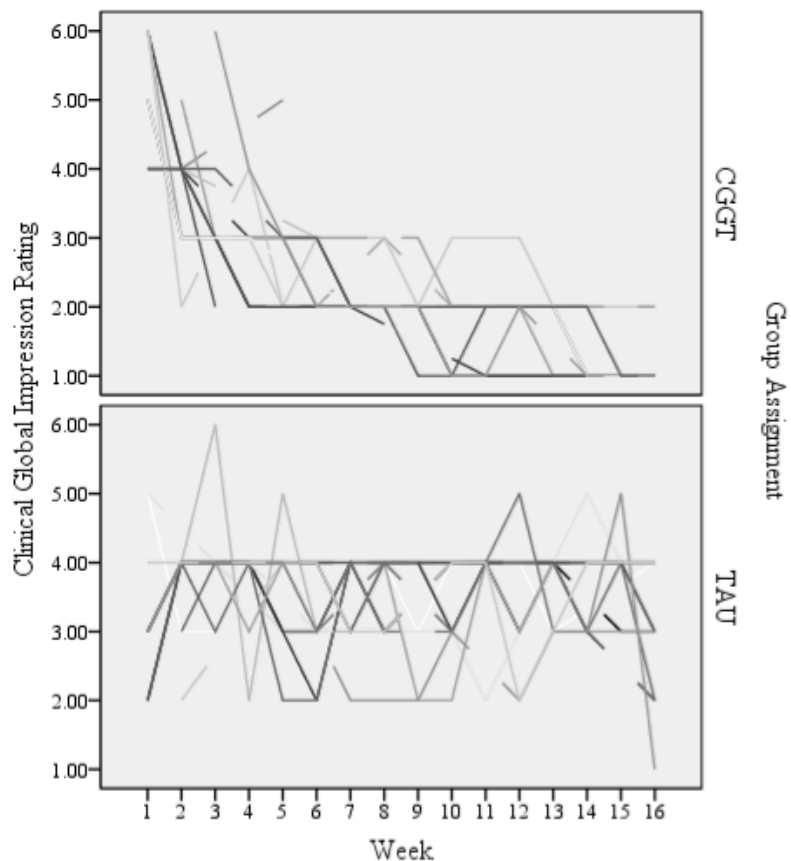


Figure 8. Weekly change in participants (CGI).

#### Group Process Observations

Table 8 compares group process observations of participants. TAU participants responded to each other 44% of the time, in contrast to 29% of the time in the CGGT group, while CGGT participants responded to the facilitator 47% of the time vs. 35% in the TAU groups. The CGGT participants responded to content a greater proportion of the time (23%) than did the TAU groups (17%). These findings are consistent with the difference between therapy groups and traditional support groups, in that there is more participant-participant interaction in support groups and less active direction by



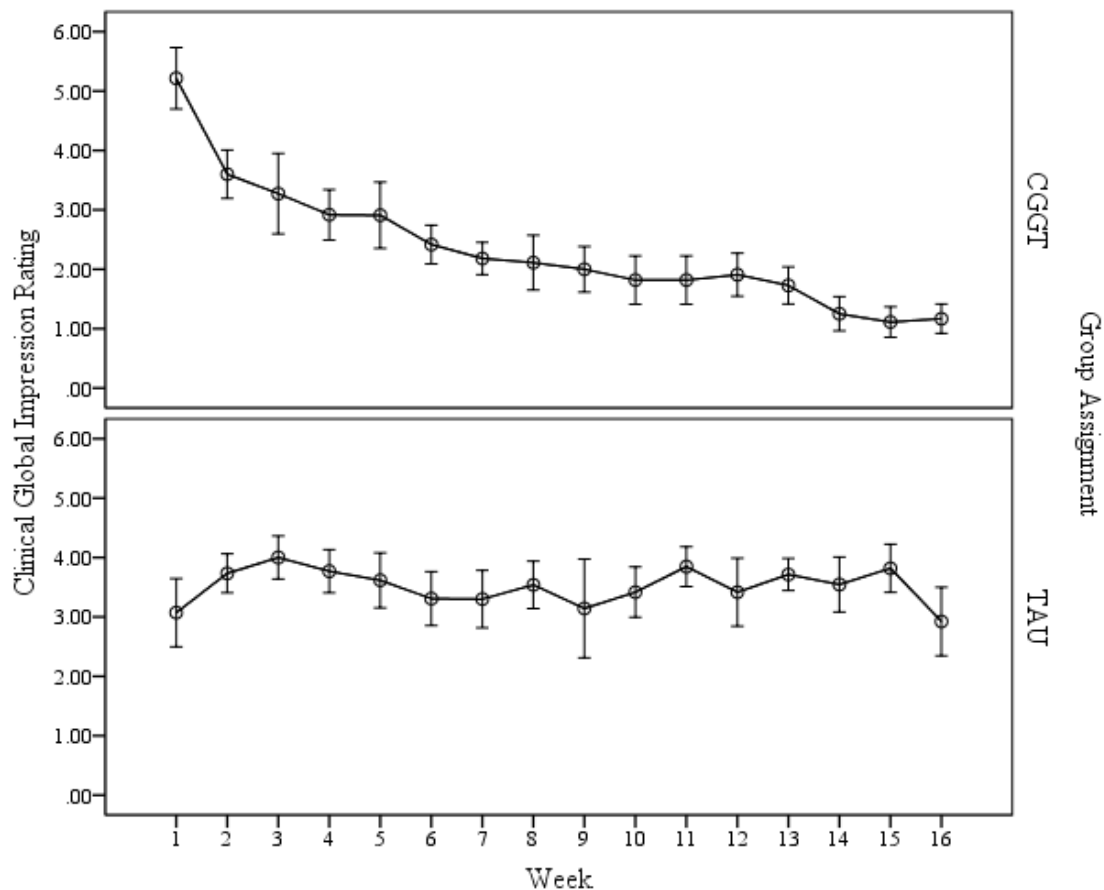


Figure 9. Weekly change in participants by group (CGI).

facilitators. The differences, while supporting the group process distinction between support group and therapy conditions, are modest however and determination of statistical significance is not possible from these data.

Facilitator actions are presented in Table 9. The application of specific technique counts were removed from overall CGGT facilitator action counts in the supportive other sessions (6 & 7) and the imaginal conversation sessions (12 & 13) and the resultant differences in group interactions between the two conditions yielded little difference between groups. The CGGT facilitators applied appropriated content 17% of the time vs.

Table 8

*Participant Interactions in Groups*

Participant actions	CGGT mean	CGGT % of actions	TAU mean	TAU % of actions
Responds (+) to content	20	23	15	17
Responds (+) to facilitator	40	47	31	35
Responds (+) to another participant	26	29	38	44

Table 9

*Facilitator Actions in Groups*

Facilitator action	CGGT mean	CGGT % of actions	TAU mean	TAU % of Actions
Applies appropriate content	13	17	14	22
Reinforces group process	10	16	13	20
Reinforce participants	40	67	39	58

22% of the time for TAU facilitators, reinforced group process 16% vs. 20% of the time, and reinforced participants 67% vs. 58% of the time.

### Treatment Fidelity

Fidelity evaluators assessed randomly selected 20-minute segments of sessions in both TAU groups and both CGGT groups. As per protocol, raters viewed two segments and then met with me to review ratings. After viewing and rating four additional segments, the ratings achieved a kappa coefficient value of .651, considered to be good agreement. The raters scored facilitators as correctly implementing the intervention as

manualized 87% of the time. Raters also subsequently rated 30 elements of the CCGT imaginal conversations with an interrater agreement kappa of .737, and scored facilitators as correctly implementing the intervention 93% of the time.

## CHAPTER 6

### DISCUSSION

In this randomized controlled trial, I compared complicated grief group therapy (CGGT) and treatment as usual (TAU) to determine if CGGT is more efficacious than TAU in treating complicated grief in older adults. The results of this study support the hypothesis that participants receiving CGGT demonstrate higher treatment response than participants receiving TAU. While participants in both groups showed improvement in measures of complicated grief, participants in the CGGT group realized significantly greater improvement. More importantly, when complicated grief was measured on PG-13, nearly half of CGGT participants realized clinically significant improvement. On the BGQ screening measure, all 12 of the CGGT completers had scores upon follow-up that, had they scored at that level at pretest, would have disqualified them for study enrollment. This high level of clinical significance suggests that those in the CGGT group were effectively treated for complicated grief.

In this chapter, I will summarize the findings of the study in the context of the experience of complicated grief. I will compare the results of my study to the Shear, et al. (2005) study of CGT, and weigh the advantages and disadvantages of group therapy for persons with CG. I will discuss the implications of this study with respect to the

necessity of specialized care for those experiencing CG and articulate those elements of CGGT that seemed most effective in the study sample. I will review the theoretical implications of these findings for our understanding of CG. I will discuss the strengths and limitations of the study as evaluated according to CONSORT criteria, and summarize the implications of this research for social work practice. I will conclude the chapter with suggestions for further research.

### Comparison CGT and CGGT

The Shear et al. (2005) study had similar findings to this research, in that the participants receiving specific CG therapy showed greater treatment response. Using the same criteria as the Shear study—treatment response defined either as independent evaluator-rated Clinical global Impressions Scale score of 1 or 2 or as time to a 20-point or better improvement in the self-reported Inventory of Complicated Grief (for this study, 50% score improvement on the newer PG-13 instrument)—this research also found a CGI or 1 or 2, significant improvement as measured by PG-13, with a clinically significant improvement in 41% of CGGT participants. The research design in this study approximates the Shear et al. (2005) study in length of intervention as well as use of measures and clinical indicators, allowing a meaningful comparison between individual and group treatment modalities and a broader application to older adults with complicated grief. The similar outcomes obtained in the studies suggest that for persons experiencing CG, specialized treatment is beneficial.

The process and activities of the CGGT intervention affirm the value of specialized care for those with CG, as the CGGT groups demonstrated a steady

progression toward improvement collectively and individually. The support group process as provided in the TAU groups may sufficiently address a normative grief process and may have additional benefit for some elements of CG for some persons, but the specific group interventions that target unique elements of CG appear more potent. Several activities address avoidance, for example. Revisiting the death story at five intervals with challenges and prompting from the facilitators and other participants, structured memory exercises, and the imaginal conversation encouraged participants to focus on difficult aspects of the death and of the relationship with the decedent. Goal setting and self-monitoring of emotions targeting the motivational symptoms of CG fostered self-awareness and skill-building. The incorporation of supportive others selected by participants into the treatment program challenges the real or perceived sense of social isolation. These elements represent focused interventions that uniquely distinguish CGGT from TAU.

If complicated grief is better addressed using specialized complicated grief therapy, what are the relative merits of group versus individual treatment? Both treatment modalities are successful as they directly address the troublesome features for complicated grief. Specifically, the nature of the attachment to the decedent, the patterns of avoidance, the thoughts and feelings of guilt and shame, and the social isolation of continuing in grief beyond a socially determined duration are addressed. The group treatment modality may offer some unique advantages unavailable in individual therapy. The therapy group is designed to generate a shared experience for grief that is unresolved and experienced as apart from the normal grief process. It reduces the isolation that is a consequence of avoidance behavior and potentially constricted social supports and it

provides an opportunity to give as well as receive support. This group intervention includes elements that Yalom and Leszcz (2005) identify as essential when conducting groups with those who have experienced trauma: immutable goals that are appropriate within the clinical realities of the condition; being with others who have had a similar trauma; safety and trust within the group; psycho-education specific to the condition; and specific trauma-focused interventions. In individual therapy, even the most experienced clinician could not bring all the varied personal losses represented in a group, and could not serve as peer to all group participants. Similarly, group participants give to and receive from each other; the facilitator is not positioned to “gain” from the experience of participants in the same way that other group members are. It is important to recognize that group participation is not for every person; some individuals are unable or unwilling to join with others, to share the distressing experiences of others or willing to self-disclose in a group setting. Another limitation of group work is the necessity of the group activities proceeding as scheduled, with a specified agenda and duration.

Individual therapy allows for more tailored treatment and an open-ended duration of care.

It is also essential to recognize and support those situations where persons may benefit from concurrent group and individual care. Many individuals in this study were engaged in individual therapy for depression concurrent with the TAU or CGGT interventions. While a potential study limitation, this occurrence was similarly distributed across TAU and CGGT conditions. Concurrent therapies need to be accounted for in examining research quality and that potential limitation will be addressed below. However, utilization of concurrent modalities does reflect appropriate mental health practice in the community.

### Theoretical Implications of the Study

I considered four theories as contributory to the design and implementation of this study; attachment theory, dual-process model (DPM), stage theory and the conceptual framework of disenfranchised grief. The findings of the study, including the successful impact of interventions that target the relationship between participants and decedents, suggest that persons with anxious/ambivalent attachments who are struggling to address feelings of attachment to the decedent and those with disorganized/disoriented attachments who perceive the death as a personally traumatic event, benefit from CGGT interventions as developed from attachment theory.

The CGGT interventions also specifically target the three elements of dual process theory, loss orientation, restoration orientation and the oscillation required for an effective grief process. The treatment elements of the imaginal conversation, structured memory activities and retelling of the death story address the loss orientation aspect of grief. Goal setting, self-care and inclusion of supportive other relationships target restoration orientation and the creation of the new life without the deceased. Self-assessment of grief, management of personal thoughts and feelings and the group experience itself facilitate oscillation. Moreover, these activities specifically target the absence of conflict-avoidance processing required for adjustment to the death by teaching valuable skills of effective grieving. These findings suggest that the DPM is suitable for examining the nature of complicated grief as well as normal grief.

The application of stage theory in this study is supported by study findings in two ways. First, the time frame of distressing symptoms persisting without change after 6 months postdeath offers a useful parameter of treatment initiation. Participants engaged



in the study endorsed an awareness of grief that had persisted without improvement. Second, the symptoms associated with grief; high levels of yearning, disbelief, anger, depression and very low levels of acceptance, and their lack of progression over time affirms the use of targeted interventions to address both these symptoms and the immobilization experienced by those with CG. Stage theory is intended to describe the normal process of grief. As a consequence, not all symptoms associated with CG are explained in the model; most particularly, the emotion of guilt and the behavior of avoidance are not accounted for in stage theory as most recently described by Maciejewski, Zhang, Block, and Prigerson (2007).

Finally, I considered Doka's (1985a, 1989, 2008) framework of disenfranchised grief to examine the experience of grievers whose grief is atypically distressed. It does appear that participants in both conditions endorsed an awareness of the non-normative nature of their grief and all understood they were in a research study to examine treatment for their complicated grief. Participants in both conditions appeared to form valuable relationships with group peers and with the facilitators, suggesting that a safe and respectful milieu was created that fostered acceptance of the complicated grief experience. The reality of "disenfranchisement" was specifically addressed in the CGGT group through the supportive other activities. The involvement of supportive others as invested and willing to help socially validated the CGGT participants and facilitated a quasi-public mourning event. The conceptual framework of disenfranchised grief appears relevant to complicated grief and interventions that mitigate the resultant social isolation are supported.

The clinical improvement in the CG scores of CGGT participants provides

additional affirmation of these theories with respect to both normal grief and complicated grief. Each theory is relevant to some aspects of the CG experience, and when blended into a larger framework, supports the conceptual foundation from which the interventions were developed.

### Strengths and Limitations of the Study

Overall, the challenge of producing a randomized control trial is justified by the potential of contributing more to our knowledge of complicated grief in older adults, as there is a dearth of high quality studies in this area. I designed the study with the goal of optimizing adherence to the CONSORT 2010 criteria for RCTs. In this dissertation, I have provided a structured summary of the scientific background, rationale for the study and hypotheses. I have described the trial design and sample size, participant eligibility, study location, interventions for each group, distinctions between interventions and how the interventions were administered, defined outcome measures and how they were assessed. I have described the method of randomization and procedures for concealment. I have detailed the statistical methods used to compare groups, and the flow of participants through the study, including attrition and reasons for losses. I have provided baseline information on participant demographics and clinical characteristics, and summarized outcome differences with effect sizes. I have carefully interpreted the results in light of potential benefits and harms to persons experiencing complicated grief. I have summarized limitations in the study and the scope of generalizability of findings. Finally, this study has been described to maximize value for meta-analysis.

Implementing this project as an RCT minimized threats to internal validity. In

this design, history, maturation, statistical regression and temporal causation are controlled for in the randomization process. Meticulous attention to randomization, blinding of participants, evaluators, facilitators and study personnel to condition reduced potential for selection bias, and minimized alternative explanations of effect.

The quality of the study was optimized by developing a Stage 1 CGGT treatment manual that was both faithful to evidence-based group therapy and consistent with the CGT treatment approach. Having high quality treatment manuals for both CGGT and TAU resulted in an unambiguous independent variable and interventions that are precise and replicable.

The study utilized reliable and valid measures of the dependent variable, complicated grief. I used a variety of grief measures; self-report measures (PG-13, BGQ, anxiety and depression scales), facilitator ratings, and videotape review to provide triangulation of data. While there is a slight potential for testing effect, none has been reported in use of the PG-13 (or its precursors, the ICG or ICG-R), and this risk was greatly offset by the value of knowing the pretreatment level of complicated grief in participants.

The primary limitation of the study is sample size, and this research is appropriately viewed as a pilot study of the CGGT intervention. The study also has threats to external validity, as it is uncertain how generalizable the findings from this study will be to general population of older adults with CG. It is possible that persons willing to participate in group therapy may already have lower levels of social isolation, more or better available social supports, or an ability to utilize the social support available in groups than nonparticipants. I am also unable to generalize these findings to

the larger, nonelderly population of persons with CG.

Participants who are on medication regimens to address complicated grief or other mental health concerns or who may have other ongoing mental health care were included. Despite the possible contamination of these supports in treatment effect, it is unethical to have participants forego ongoing care, or withdraw from any form of supportive relationship, thus exacerbating the life loss experience. An awareness of these supports allowed me to compare the two groups with respect to medication and psychotherapy use and confirm that the two groups were similar. It is important to note that participants in the Shear et al. (2005) study were also encouraged to maintain their medication regimen.

Compensatory therapist rivalry was a potential limitation in the study. To mitigate this possibility, I made a concerted effort to blind the facilitators. I carefully presented the project to facilitators as a study evaluating two different treatments, as opposed to comparing a “novel” versus placebo study. This was done to reduce the potential for therapist rivalry and enhance facilitator commitment to their respective conditions.

Finally, while I was able to address the treatment integrity issues of therapist competence and treatment adherence and quality with the use of independent treatment fidelity evaluators, a comprehensive treatment fidelity evaluation of all elements the interventions was beyond the scope of this study and will be a necessary component of developing a Stage II manual for the CGGT intervention.

### Implications for Social Work Practice and Policy

The rigor of this study contributes to the evidence on effective clinical care of older adults with complicated grief, a mental health concern likely to be prevalent in the practices of many gerontological clinical social workers. As research elicits a deeper understanding of the distinctions between normal grief and complicated grief, improved screening, diagnosis and treatment options are indicated for effective care of persons with CG. CGGT may be regarded as having potential as an emerging best practice intervention for the treatment of persons for whom current group treatment has been insufficient. Eventually, established parameters of care for persons with complicated grief should become the standard of care.

The experience of multiple and interacting losses is common among older adults. Complicated grief remains under recognized, under diagnosed and is currently treated with uncertain effectiveness in this population. It is congruent with principles of beneficence and justice in health care, as well as the social justice mission of the social work profession to advocate for appropriate care of persons with debilitating mental health conditions, particularly underserved persons. This research also provides evidence to support mental health policy positions regarding the inclusion of CG as a unique diagnosis in the DSM-V and the ICD-11, issues of relevance to social workers in practice, policy and research arenas.

### Recommendations for Further Research

I assert that efforts to develop and refine group interventions for persons with complicated grief merit further research inquiry. The logical next steps for this study are

to critically review the 128 hours of video, observing the relationship between intervention elements and outcomes in the context of the extensive memo-written notes and quantitative outcome measures. Integrating study observations with quantitative outcomes, particularly the individual differences data, will allow me to further define process-to-outcome effects of intervention elements. This integration would facilitate a careful dismantling of treatment effects and lead toward development of a stage II manual. Additional study groups would need to be conducted and evaluated to meet MacGowan's (2008) criteria for efficacious group intervention.

In a parallel study, I have conducted detailed individual interviews and focus groups with the supportive others who participated in the CGGT condition. Their comments, suggestions and insights will be incorporated into that aspect of CGGT.

With CGGT established as superior to TAU, I can redesign subsequent studies to a waitlist control group design, rather than the current experimental vs. control group design, and utilize available participants more efficiently. In a sufficiently powered study, I can apply CGGT to other populations of interest; particularly long-term bereaved spouse caregivers and suicide survivors.

### Conclusion

This RCT evaluated the efficacy of complicated grief group therapy (CGGT) in older adults meeting clinical criteria for complicated grief. Participants receiving CGGT demonstrated higher treatment response than participants receiving TAU. Many CGGT participants realized clinically significant improvement in CG, holding promise for a return to a normative grief process. The results of this study support prior research

recommending specialized treatment for persons with complicated grief. CGGT brings the additional advantages of group therapy, addressing the social isolation and disenfranchised status of those whose grief experience is profound. This study contributes to our understanding of the care of older adults with complicated grief, and CGGT merits further exploration and development in the treatment of CG in older adults and other populations.

## APPENDIX A

### COMPARISON OF CGGT AND TAU INTERVENTIONS

<u>Week</u>	<u>TAU</u>		<u>CGGT</u>	
	<u>Topic</u>	<u>Activities</u>	<u>Topic</u>	<u>Activities</u>
1	What is grief?	Discussion of losses, describe normal grief	The story of the death/symptoms of CG	Death retelling Grief monitoring skills
2	Common responses to loss/myths	Personal experiences in grief/sharing photos & mementoes	Grief-related emotions/setting personal goals	Guided discussion on emotion management and setting goals
3	Individual responses to grief	Sharing what works and doesn't work for participants/ introduce journaling	Grief-related emotions/setting personal goals	Guided discussion on emotion management and setting goals
4	Personal goals & expectations	Clarifying personal expectations with grief	Emotion management/activity planning	Cognitive restructuring; guided discussion on grief-related activities



Comparison of CGGT and TAU Interventions (continued)				
		<u>TAU</u>		<u>CGGT</u>
5	Thoughts & feelings	Discussion of common emotions and thoughts	Emotion management/activity planning/discuss supportive others	Cognitive restructuring; guided discussion on utilizing supportive others (SOs)
6	Managing distressing thoughts & feelings	Practice: ways to think, attribute, time and respond to feelings and thoughts	Supportive other visits-review of CG, participants self-views and goal setting	Review of CG/elicit perceptions and support of supportive others in attendance
7	Coping skills	Understanding healthy vs. unhealthy coping, skills inventory	Supportive other visits-review of CG, participants self-views and goal setting	Review of CG/elicit perceptions and support of supportive others
8	Healthy coping/physical skills	Discussion positive coping tools	Retelling of death story/guided discussion on goal setting	Guided discussion of SO visits/telling the death story/setting goals
9	Relationships: caring for yourself	Discussion of relationships/Self-care strategies	Emotion management/memories & pictures. Review self-care goals	Cognitive restructuring; guided discussion on emotions & memories
10	Relationships: caring for others	Discussion of relationship goals.	Memories/goal setting on future & self-care	Cognitive restructuring; guided discussion

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 Comparison of CGGT and TAU Interventions (continued)
 

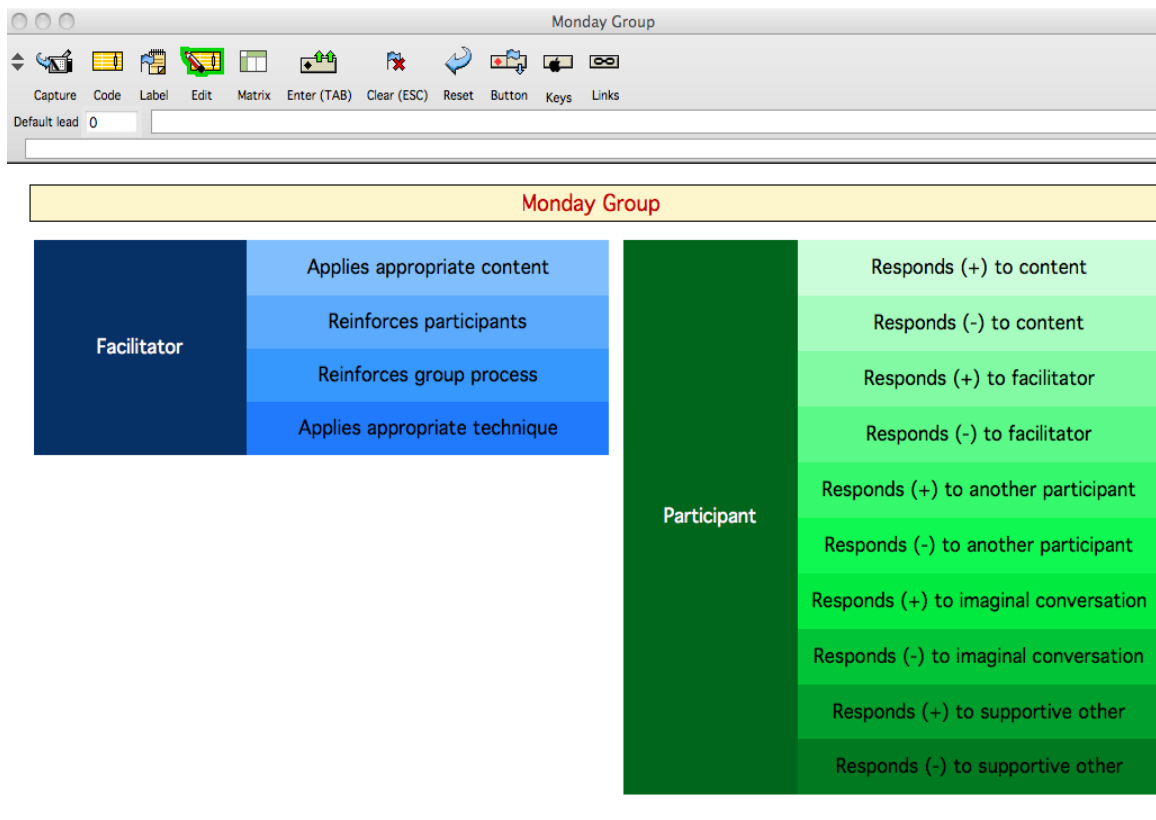
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		<u>TAU</u>		<u>CGGT</u>
11	Dealing with stress	Discussion of stressors/ healthy ways to deal with stress	Retelling of death story/emotion management/goal setting	Cognitive restructuring & guided discussion on the death story
12	Ways to relax	Practice: deep breathing, deep muscle relaxation, affirmations, meditation	Imaginal conversation with the deceased/goal-setting	Guided imaginal conversation with the deceased
14	Ways to remember the person who died	Discussion- personal ways to remember, shared ways to remember the person who died.	Memories & pictures/retelling of death story	Cognitive restructuring & guided discussion on the death story
15	Understanding and accepting your new life	Discussion- progress on the grief journey, discussion of life without the deceased. Goal setting	Memories & pictures/self-care and goals for future	Guided discussion to synthesize memories, emotions and death story
16	Signs of recovery-the new normal life.	Review goals for the new life, shared remembrance activity	Memories & pictures/self-care and goals for future	Guided discussion to synthesize memories, emotions and death story. Closure activity

## APPENDIX B

### GROUP PROCESS OBSERVATION CODES

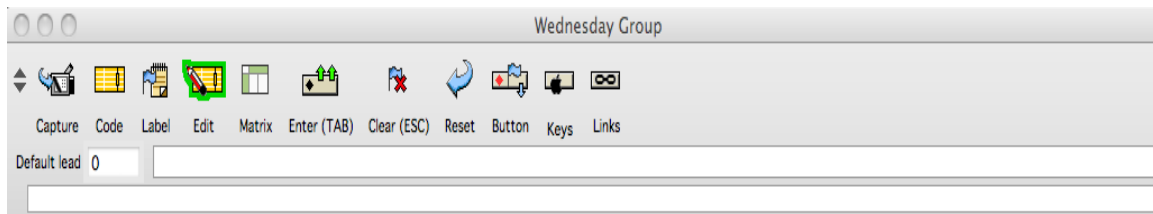
#### Experimental Condition CGGT



The image shows a software interface for 'Monday Group' with a toolbar containing icons for Capture, Code, Label, Edit, Matrix, Enter (TAB), Clear (ESC), Reset, Button, Keys, and Links. Below the toolbar is a 'Default lead' field with the value '0'. The main content area is titled 'Monday Group' and contains a list of observation codes organized into two columns: Facilitator and Participant.

Monday Group	
Facilitator	Applies appropriate content
	Reinforces participants
	Reinforces group process
	Applies appropriate technique
Participant	Responds (+) to content
	Responds (-) to content
	Responds (+) to facilitator
	Responds (-) to facilitator
	Responds (+) to another participant
	Responds (-) to another participant
	Responds (+) to imaginal conversation
	Responds (-) to imaginal conversation
	Responds (+) to supportive other
Responds (-) to supportive other	

## Control Condition TAU



### Wednesday Group

Facilitator	Applies appropriate content	Participant	Responds (+) to content
	Reinforces participants		Responds (-) to content
	Reinforces group process		Responds (+) to facilitator
	Responds (-) to facilitator		
	Responds (+) to another participant		
	Responds (-) to another participant		

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