


## Original Investigation

# Treatment of Complicated Grief in Elderly Persons

## A Randomized Clinical Trial

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**IMPORTANCE** Complicated grief (CG) is a debilitating condition, most prevalent in elderly persons. However, to our knowledge, no full-scale randomized clinical trial has studied CG in this population.

**OBJECTIVE** To determine whether complicated grief treatment (CGT) produces greater improvement in CG and depressive symptoms than grief-focused interpersonal psychotherapy (IPT).

**DESIGN, SETTING, AND PARTICIPANTS** Randomized clinical trial enrolling 151 individuals 50 years or older (mean [SD] age, 66.1 [8.9] years) scoring at least 30 on the Inventory of Complicated Grief (ICG). Participants were recruited from the New York metropolitan area from August 20, 2008, through January 7, 2013, and randomized to receive CGT or IPT. The main outcome was assessed at 20 weeks after baseline, with interim measures collected at 8, 12, and 16 weeks after baseline.

**INTERVENTIONS** Sixteen sessions of CGT (n = 74) or IPT (n = 77) delivered approximately weekly.

**MAIN OUTCOMES AND MEASURES** Rate of treatment response, defined as a rating from an independent evaluator of much or very much improved on the Improvement subscale of the Clinical Global Impression Scale.

**RESULTS** Both treatments produced improvement in CG symptoms. Response rate for CGT (52 individuals [70.5%]) was more than twice that for IPT (24 [32.0%]) (relative risk, 2.20 [95% CI, 1.51-3.22];  $P < .001$ ), with the number needed to treat at 2.56. Secondary analyses of CG severity and CG symptom and impairment questionnaire measures confirmed that CGT conferred a significantly greater change in illness severity (22 individuals [35.2%] in the CGT group vs 41 [64.1%] in the IPT group were still at least moderately ill [ $P = .001$ ]), rate of CG symptom reduction (1.05 ICG points per week for CGT vs 0.75 points per week for IPT [ $t_{633} = 3.85$ ;  $P < .001$ ]), and the rate of improvement in CG impairment (0.63 work and Social Adjustment Scale points per week with CGT and 0.39 points per week with IPT [ $t_{503} = 2.87$ ;  $P = .004$ ]). Results were not moderated by participant age.

**CONCLUSIONS AND RELEVANCE** Complicated grief treatment produced clinically and statistically significantly greater response rates for CG symptoms than a proven efficacious treatment for depression (IPT). Results strongly support the need for physicians and other health care providers to distinguish CG from depression. Given the growing elderly population, the high prevalence of bereavement in aging individuals, and the marked physical and psychological impact of CG, clinicians need to know how to treat CG in older adults.

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Among the 40 million Americans older than 65 years, 40% of women and 13% of men are widowed.<sup>1</sup> Bereavement rates for other close relationships are also high.<sup>2,3</sup> About 9% of bereaved older women experience complicated grief (CG),<sup>4</sup> a serious mental health problem<sup>5,6</sup> associated with negative health outcomes, functional impairment, and increased suicidality.<sup>7-9</sup> Typical symptoms include prolonged acute grief with intense yearning, longing, and sorrow; frequent thoughts and memories of the deceased; and difficulty comprehending the painful reality and imagining a future with purpose and meaning, with complicating maladaptive approach and avoidance behaviors, dysfunctional thoughts, and disruptive dysregulated emotions. The *DSM-5* includes provisional criteria for CG as “persistent complex bereavement disorder” in section 3 among conditions in need of further study.<sup>10</sup> A diagnosis of prolonged grief disorder is currently proposed for inclusion in the *International Classification of Diseases, 11th Revision*.<sup>11</sup> Until criteria are finalized, individuals with CG can be identified reliably using the Inventory of Complicated Grief (ICG), a 19-item self-report questionnaire.<sup>12</sup> Simon<sup>13</sup> provides an illustrative case example.

Interpersonal psychotherapy (IPT)<sup>14,15</sup> is a well-known evidence-based treatment for depression. Observations that CG symptoms did not respond to IPT<sup>16</sup> led us to develop a targeted CG treatment (CGT) based on an attachment theory model<sup>17-19</sup> using techniques derived from prolonged exposure,<sup>20</sup> IPT,<sup>21</sup> and motivational interviewing.<sup>22</sup> A previous randomized clinical trial<sup>23</sup> showed better response to CGT than IPT among middle-aged adults. Confirmation of this result in older adults is needed, especially because clinicians are sometimes reluctant to use exposure-based treatment in geriatric populations<sup>24-26</sup> and because CG can be confused with depression. We now report results of a study comparing 16 sessions of CGT or IPT in older adults examining CG symptoms and impairment, depressive symptoms, treatment expectations and tolerability, and 6-month relapse rates among treatment responders.

## Methods

The study was approved by the institutional review boards of the New York State Psychiatric Institute and Columbia University. Written informed consent was obtained from all participants before the baseline assessment.

### Design

Study participants underwent telephone screening and in-person assessment and were randomized 1:1 using computer-generated blinded simple randomization to receive 16 sessions of CGT or IPT. Independent evaluators (including A.G.) blinded to treatment assignment conducted assessments at baseline; at 8, 16, and 20 weeks after the first treatment visit; and monthly during a naturalistic follow-up period. Participants completed self-report questionnaires at the same points and at week 12. Treatment response was determined at week 20 as a score of 1 or 2 on the Improvement subscale of the Clinical Global Impression Scale (CGI-I).<sup>27,28</sup>

### Recruitment

Bereaved individuals 60 years or older were recruited from August 20, 2008, through January 7, 2013, to a university-based clinic using community outreach, including advertising. The minimum age was decreased to 50 years during the final 8 months of recruitment.

### Inclusion and Exclusion Criteria

Participants scored at least 30 on the ICG and were confirmed by one of us (M.K.S. or N.S.) to have CG in the clinical interview establishing prolonged acute grief symptoms accompanied by complicating dysfunctional thoughts, feelings, or behaviors.<sup>29</sup> Those participants with current substance use disorder (in the past 6 months), a lifetime history of psychotic disorder, current bipolar I disorder, active suicidality requiring hospitalization, a Mini-Mental State Examination score<sup>30</sup> below 24, or a pending lawsuit or disability claim related to the death or who were undergoing concurrent psychotherapy were excluded. Antidepressant use (33 participants [21.9%]) or anxiolytic use (24 [15.9%]) was permitted if it was continuous for at least 3 months and if the dosage was unchanged for at least 6 weeks.

### Assessment Measures

Independent evaluators completed the Structured Clinical Interview for *DSM-IV* Axis I Disorders<sup>31</sup> with a supplemental module for CG, the Columbia Suicide Severity Rating Scale,<sup>32</sup> and the CG-focused CGI-I,<sup>27,28</sup> a 1-item rating of CG improvement, ranged from 1 (very much improved) to 7 (very much worse). Interrater reliability of the CGI-I was determined using a randomly selected sample of these ratings (27 ratings [17.9%]). The  $\kappa$  coefficient was 0.68. Self-report questionnaires include the ICG; the Work and Social Adjustment Scale,<sup>33,34</sup> which rated grief interference with functioning in work, home management, private leisure, social leisure, and family relationships; the Grief-Related Avoidance Questionnaire,<sup>18</sup> which rated avoidance of loss-related situations; and the Beck Depression Inventory.<sup>35</sup>

### Assessment Procedures

The independent evaluators were 3 mental health professionals blinded to treatment assignment and trained to achieve acceptable reliability on rating instruments. Nine instances of unblinding were reported in weekly meetings of the independent evaluators; 7 occurred during the follow-up period after the assessment at week 20. Assessments were audiotaped and a randomly selected sample was corated. Questions about ratings were discussed in weekly meetings, and the independent evaluators' instruction manual was updated accordingly. Week 20 ratings were reviewed with an experienced clinical researcher not connected with the study. The telephone assessments began at week 8. The CGI-I rating was based on a brief open-ended discussion with the participant and administration of CG symptom and impairment measures.

### Therapists

Different therapists administered CGT and IPT, including 5 licensed clinical social workers (3 for CGT and 2 for IPT),

2 doctoral-level social workers (1 for CGT and 1 for IPT), 2 psychology doctoral students (1 for CGT and 1 for IPT), and 5 doctoral-level psychologists (2 for CGT [including N.S.] and 3 for IPT). None had prior experience working with grief. No CGT therapists had prior experience with CGT. Two of the 7 IPT therapists were experienced in providing IPT.

### Interventions

Complicated grief treatment was delivered as in a prior study<sup>23</sup> using an unpublished manual of protocol supervised by the principal investigator (M.K.S.). The aims of CGT included resolving grief complications and facilitating natural mourning. Informed by the dual-process model,<sup>36</sup> each session contained both loss-focused and restoration-focused components. In phase 1, therapists reviewed the patient's history and bereavement experience, introduced a grief-monitoring diary, explained CG and CGT, began work on aspirational goals, and held a conjoint session with a significant other. Phase 2 included exposure-based procedures termed *imaginal* and *situational revisiting*, work with memories and pictures, and a continued focus on personal goals. Phase 3 was a midcourse review, and phase 4 included an imaginal conversation with the deceased, completion and consolidation of treatment aims, and attention to treatment termination. Additional information can be obtained from the Center for Complicated Grief (<http://www.complicatedgrief.org>).

Interpersonal psychotherapy was delivered according to a published manual<sup>37</sup> and supervised by one of the manual's authors. During the introductory phase, mood symptoms were reviewed and identified, an interpersonal inventory was obtained, and the interpersonal model was explained. Therapists used a grief focus, accompanied by a secondary focus on role transition or interpersonal disputes if indicated. Therapists helped patients to see how bereavement and other interpersonal events can affect emotions and mood. They discussed the patient's relationship with the deceased, encouraged a realistic assessment of the positive and negative aspects of this relationship, reviewed the circumstances of the death, and worked to help the patient develop or enhance satisfying relationships and activities in the present. In the termination phase, gains were reviewed, future plans were made, and feelings about ending treatment were discussed.

Treatment fidelity assessment showed good discrimination between treatments and a strong association between CGT procedures and response to treatment (M.K.S., Y.W., N.S., N.D., C.M., and A.G., unpublished data, April 2014).

### Statistical Analysis

The study was designed to examine the difference in the rate of response to CGT compared with IPT among all randomized patients ( $n = 151$ ). Statistical significance was defined as  $P < .05$  with a 2-tailed test. Data were analyzed using commercially available software (SAS, version 9.3).<sup>38</sup> We first used descriptive analyses to check the range and distribution of all variables at baseline. We further checked to ensure equivalent distribution of prognostic factors across study arms at baseline, including all key demographic and clinical variables. We used

$\chi^2$  tests to compare group differences at baseline for categorical outcomes. Two-sample  $t$  tests were used for normally distributed continuous outcomes; otherwise, Wilcoxon rank sum tests were used.

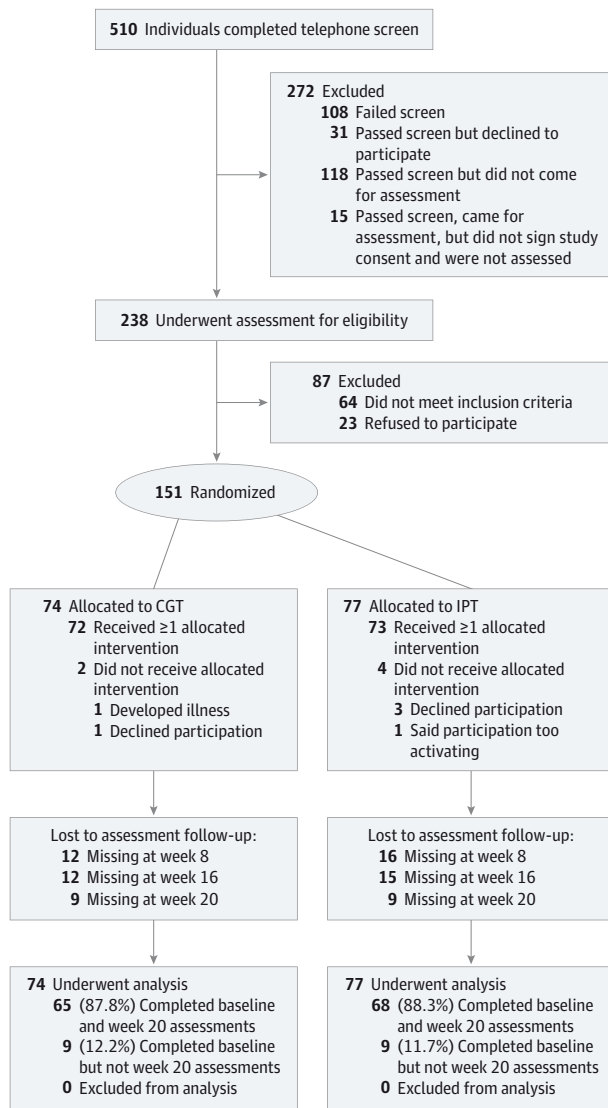
The difference in response rates for IPT and CGT at week 20 was analyzed based on the intention-to-treat principle, including all randomized participants. We used a weighted  $\chi^2$  test, with inverse probability weighting, a widely used statistical technique, to adjust for missing an assessment at week 20.<sup>39-41</sup> This 2-stage procedure first determines predictors of assessment completion. We used a logistic regression model that included a range of predictor variables (treatment assignment, sex, age, race, marital status, educational level, employment level, relationship to the deceased, time since the loss, violent death status, baseline ICG score, lifetime major depression, lifetime posttraumatic stress disorder [PTSD] status, and current antidepressant and anxiolytic use) to compute the probability of completing a follow-up assessment at week 20. A weight variable (denoted as  $w_i$ ) based on the inverse of this probability was created. Each completed week 20 assessment was multiplied by  $w_i$  so that greater weight was assigned to results from participants more similar to those who were less likely to complete the assessment (ie, more likely to be missing). Robust variance estimators were computed to account for the uncertainties due to estimating those weights. As a sensitivity analysis, unweighted analyses were performed for treatment completers only and for the intention-to-treat sample with an assessment at week 20. We further calculated the number needed to treat as  $1/(\text{proportion responding to CGT} - \text{proportion responding to IPT})$  as an estimate of the number of patients who would need to be treated with CGT instead of IPT to get 1 additional response.

We conducted several secondary analyses. The Severity subscale of the CGI was analyzed using a weighted  $\chi^2$  test, with inverse probability weighting to account for missing data. Longitudinal analyses were performed using mixed-effects linear models with random intercepts and random slopes to compare the rate of change in CG and depressive symptom scores between the CGT and IPT groups. Measures of CG symptoms included the ICG, Work and Social Adjustment Scale, and Grief-Related Avoidance Questionnaire. Depressive symptoms were assessed using the Beck Depression Inventory. Last, exploratory analyses tested for moderator effects on the primary outcome by examining the interaction of treatment by moderator in an inverse probability weighting-based logistic regression model.

### Power Analysis

Power analysis for the primary outcome variable, CGI-I score of at least 2, was computed based on the  $\chi^2$  test using commercially available software (PASS, version 12.0).<sup>42</sup> With the proposed sample of 160, assuming a 15% unavailability for and loss to follow-up and a 2-sided significance level of .05, we had sufficient power of greater than 80% to detect a 25% to 30% difference in the proportion responding. For example, with a 25% response in the IPT arm, we had 91% power to detect a 52% response in the CGT arm (ie, a difference of 27%).

Figure 1. Study Flowchart



CGT indicates complicated grief treatment; IPT, interpersonal psychotherapy.

## Results

### Sample Recruitment and Retention

The study flowchart is provided in **Figure 1**. Briefly, 510 individuals completed the telephone screen. Of these, 238 were deemed likely to have positive findings for CG, signed a written informed consent, and underwent assessment for eligibility in person. One hundred fifty-three participants (95.6% of the proposed sample) were randomized to CGT ( $n = 75$ ) or to IPT ( $n = 78$ ). Two randomized participants (1 in the CGT group and 1 in the IPT group) were subsequently determined to be ineligible before beginning treatment and were excluded from the study cohort. Six others (2 in CGT and 4 in IPT) never attended a treatment session. Among those who began treatment, completion rates were 59 individuals (82%) for CGT and

59 (81%) for IPT. Sixty-five CGT (87.8%) and 68 IPT (88.3%) participants completed the week 20 assessment.

### Baseline Sample Characteristics

Baseline sample characteristics are summarized in **Table 1**. All continuous variables were normally distributed, with the exception of time since the bereavement. The mean age of the participants was 66.1 (range, 50-91) years. The oldest elderly participants ( $\geq 75$  years) constituted 31 participants (20.5% of the sample). The sample was predominantly white (86.1%) and female (81.5%). Educational background was diverse, ranging from a high school degree or less (10.6%) to completion of postgraduate degrees; however, overall the sample was highly educated, with 52.3% having postgraduate degrees.

Median time since the loss was 3.2 (range, 0.5-45.3) years. For the total sample, 13.2% of the losses were violent; 46.4% lost a spouse or partner; 27.2% lost a parent; 18.5% lost a child; and 7.9% lost another relative or a friend. Mean (SD) baseline ICG score was 46.1 (9.4). Current mood and anxiety disorders were common: 45.7% met criteria for current major depression, 24.5% for generalized anxiety disorder, 15.2% for PTSD, and 11.9% for panic disorder. Incidence of current PTSD was higher in the CGT group (16 [21.6%] vs 7 [9.1%];  $P = .03$ ). More than half of the participants had experienced suicidal thinking since the loss of the loved one (44 [57.1%] in the IPT and 46 [62.2%] in the CGT group). We found no other significant differences between the 2 randomized groups (**Table 1**).

### Treatment Expectations and Exposure

We measured treatment expectations<sup>43</sup> during the first phase of treatment. Mean (SD) expectations for CGT and IPT were modestly positive and not different (6.6 [1.7] vs 6.2 [1.8], respectively;  $t_{115} = -1.18$ ;  $P = .24$ ). Most participants (81.9% in CGT and 80.8% in IPT) completed treatment. Among the treatment completers, the mean (SD) number of sessions before week 20 was 15.1 (1.3 [range, 11-16]) in the CGT group and 15.3 (1.0 [range, 11-16]) in the IPT group. Among those who started treatment, the mean (SD) number of sessions before dropout for the CGT group was 8.2 (4.3 [range, 1-15]); for the IPT group, 9.2 (4.5 [range, 1-14]).

### Primary Outcome Analyses

In an intention-to-treat analysis with inverse probability weighting, the rate of response was substantially and significantly greater for CGT than for IPT. Among those receiving CGT, 52 individuals (70.5%; 95% CI, 60.3%-82.6%) responded compared with 24 (32.0%; 95% CI, 22.7%-45.2%) among those receiving IPT (cohort relative risk, 2.20 [95% CI, 1.51-3.22];  $P < .001$ ; number needed to treat, 2.56) (**Figure 2**). When adjusted for current PTSD, the relative risk was 2.08 (95% CI, 1.42-3.07;  $P < .001$ ). The number needed to treat in the adjusted analysis was 2.60.

For sensitivity analyses, we conducted the intention-to-treat analysis using those participants who completed the assessment without weighting (65 participants in CGT and 68 participants in IPT) and found results almost identical to those in the primary analysis. Response rates were 69.2% for CGT and

Table 1. Baseline Comparison of Treatment Groups

Characteristic	Group <sup>a</sup>			Test Statistic <sup>b</sup>	P Value
	All (N = 151)	IPT (n = 77)	CGT (n = 74)		
Age, mean (SD)	66.1 (8.9)	66.5 (8.8)	65.7 (9.0)	0.56	.57
Male sex	28 (18.5)	16 (20.8)	12 (16.2)	0.52	.47
Race/ethnicity					
White	130 (86.1)	68 (88.3)	62 (83.8)	0.65	.42
Hispanic or Latino	12 (7.9)	8 (10.4)	4 (5.4)	1.28	.26
Educational level					
High school or less	16 (10.6)	12 (15.6)	4 (5.4)	7.83	.05
Partial college	28 (18.5)	9 (11.7)	19 (25.7)		
Completed college	28 (18.5)	14 (18.2)	14 (18.9)		
Postgraduate	79 (52.3)	42 (54.5)	37 (50.0)		
Marital status					
Never married	26 (17.2)	13 (16.9)	13 (17.6)	1.18	.76
Married	29 (19.2)	17 (22.1)	12 (16.2)		
Separated/divorced	25 (16.6)	11 (14.3)	14 (18.9)		
Widowed (not remarried)	71 (47.0)	36 (46.8)	35 (47.3)		
Person who died					
Spouse/partner	70 (46.4)	38 (49.4)	32 (43.2)	1.96	.58
Parent	41 (27.2)	22 (28.6)	19 (25.7)		
Child	28 (18.5)	11 (14.3)	17 (23.0)		
Other	12 (7.9)	6 (7.8)	6 (8.1)		
Violent death	20 (13.2)	10 (13.0)	10 (13.5)	0.01	.92
Time since loss, median (range), y	3.2 (0.5-45.3)	2.7 (0.5-38.1)	3.9 (0.5-45.3)	z = 0.39	.69
MDD					
Current	69 (45.7)	33 (42.9)	36 (48.6)	0.51	.48
Lifetime	102 (67.5)	51 (66.2)	51 (68.9)	0.12	.72
Panic disorder					
Current	18 (11.9)	7 (9.1)	11 (14.9)	1.20	.27
Lifetime	28 (18.5)	10 (13.0)	18 (24.3)	3.21	.07
PTSD					
Current	23 (15.2)	7 (9.1)	16 (21.6)	4.59	.03
Lifetime	31 (20.5)	11 (14.3)	20 (27.0)	3.75	.046
Current generalized anxiety	37 (24.5)	20 (26.0)	17 (23.0)	0.18	.67
ICG score, mean (SD) <sup>c</sup>	46.1 (9.4)	46.0 (9.7)	46.1 (9.1)	-0.09	.93
WSAS score, mean (SD) <sup>d</sup>	22.0 (10.3)	21.8 (10.0)	22.3 (10.8)	-0.27	.79
GRAQ score, mean (SD) <sup>e</sup>	23.9 (13.4)	23.9 (14.1)	23.9 (12.7)	-0.02	.99
BDI score, mean (SD) <sup>f</sup>	21.3 (9.0)	20.5 (8.3)	22.4 (9.7)	-1.22	.23
Suicidal thinking since the CG-related death	90 (59.6)	44 (57.1)	46 (63.0)	0.54	.46
CGI severity rating					
Normal	0	0	0	1.93	.59
Borderline ill	0	0	0		
Mildly ill	2 (1.5)	2 (2.9)	0		
Moderately ill	46 (34.8)	23 (33.8)	23 (35.9)		
Markedly ill	78 (59.1)	40 (58.8)	38 (59.4)		
Severely ill	6 (4.5)	3 (4.4)	3 (4.7)		
Antidepressant use	33 (21.9)	15 (19.5)	18 (24.3)	0.52	.47
Anxiolytic use	24 (15.9)	12 (15.6)	12 (16.2)	0.01	.92
Nonpsychotropic prescription medications used, No.					
Mean	2.1	2.1	2.2	-0.16	.87
Median (range)	1 (0-10)	1 (0-8)	2 (0-10)		

(continued)

Table 1. Baseline Comparison of Treatment Groups (continued)

Characteristic	Group <sup>a</sup>			Test Statistic <sup>b</sup>	P Value
	All (N = 151)	IPT (n = 77)	CGT (n = 74)		
Psychotropic prescription medications used, No.					
Mean	0.7	0.7	0.8		
Median (range)	0 (0-5)	0 (0-5)	0.5 (0-4)	-0.75	.46
Use of psychotropic medicines	67 (44.4)	30 (39.0)	37 (50.0)	1.86	.17
MMSE total score, mean (SD)	28.2 (1.6)	28.1 (1.6)	28.2 (1.6)	-0.23	.82

Abbreviations: BDI, Beck Depression Inventory; CG, complicated grief; CGI, Clinical Global Impression Scale; CGT, CG treatment; GRAQ, Grief-Related Avoidance Questionnaire; ICG, Inventory of Complicated Grief; IPT, interpersonal psychotherapy; MDD, major depressive disorder; MMSE, Mini-Mental State Examination; PTSD, posttraumatic stress disorder; WSAS, Work and Social Adjustment Scale.

<sup>a</sup> Unless otherwise indicated, data are expressed as number (percentage) of patients. Percentages have been rounded and might not total 100.

<sup>b</sup>  $\chi^2$  Tests were used to compare group differences at baseline for categorical outcomes. Two-sample t tests were used for normally distributed continuous outcomes; otherwise, Wilcoxon rank sum tests were used.

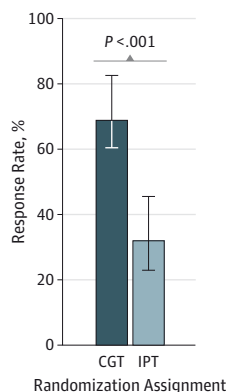
<sup>c</sup> Total score range, 0 to 76.

<sup>d</sup> Total score range, 0 to 40.

<sup>e</sup> Total score range, 0 to 60.

<sup>f</sup> Total score range, 0 to 63.

Figure 2. Response Rates at Week 20 Adjusted for Missing Data by Inverse Probability Weighting



Among those receiving complicated grief treatment (CGT), 52 individuals (70.5%; 95% CI, 60.3%-82.6%) responded compared with 24 (32.0%; 95% CI, 22.7%-45.2%) among those receiving interpersonal psychotherapy (IPT). Whiskers indicate 95% confidence intervals.

33.8% for IPT. Similar findings were obtained in a per-protocol analysis using treatment completers without weighting, with response rates of 69.0% for CGT and 36.1% for IPT.

### Secondary Treatment Outcome Analyses

We found a significant difference in the CGI Severity subscale score between the CGT and IPT treatment groups at week 20 ( $P = .001$ ). Of those in the IPT group, 41 (64.1%) were still at least moderately ill vs 22 (35.2%) in the CGT treatment group.

Longitudinal analysis showed that the rate of improvement in the ICG was 1.05 points per week with CGT compared with 0.75 points per week with IPT ( $t_{633} = 3.85; P < .001$ ), a cumulative difference of 6.10 points during the 20-week study period. Overall mean reduction in ICG score was 21.10 points for CGT and 15.00 points for IPT, and mean ICG scores at week 20 differed significantly ( $t_{633} = 2.58; P = .01$ ). The rate of im-

provement in the Work and Social Adjustment Scale was 0.63 points per week with CGT and 0.39 points per week with IPT ( $t_{503} = 2.87; P = .004$ ); in the Grief-Related Avoidance Questionnaire, 0.56 points per week with CGT and 0.33 points per week with IPT ( $t_{108} = 2.02; P < .05$ ); and in the Beck Depression Inventory, 0.60 points per week with CGT and 0.41 points per week with IPT ( $t_{353} = 2.21; P = .03$ ). Results are summarized in Table 2 and graphically represented in Figure 3.

### Moderator Analyses

We found no statistically significant moderating effects on response by race, age, educational level, sex, time since the loss, relationship to the deceased, violent death, antidepressant or anxiolytic use, presence of current major depression, PTSD, panic disorder, generalized anxiety disorder, or Mini-Mental State Examination total score (eTable in the Supplement).

### 6-Month Follow-up

Assessments by the independent evaluators were obtained for 112 of 151 participants (74.2%). Results revealed that response was maintained for 38 of 38 CGT responders (100.0%) and 19 of 22 IPT responders (86.4%).

## Discussion

Results of this study indicate that CGT is statistically and clinically superior to IPT in ameliorating CG symptoms and impairment and statistically superior in the rate of improvement in depression. Complicated grief treatment was well tolerated, with no discontinuation due to adverse effects and an 18% dropout rate ( $n = 13$ ), which did not differ from the dropout rate for IPT (19% [ $n = 14$ ]). Response was maintained at 6 months for 100.0% of CGT responders and 86.4% of IPT responders.

Interpersonal psychotherapy is a well-established, proven efficacious treatment for depression.<sup>44,45</sup> By contrast, CG response to IPT was low in 2 randomized clinical studies

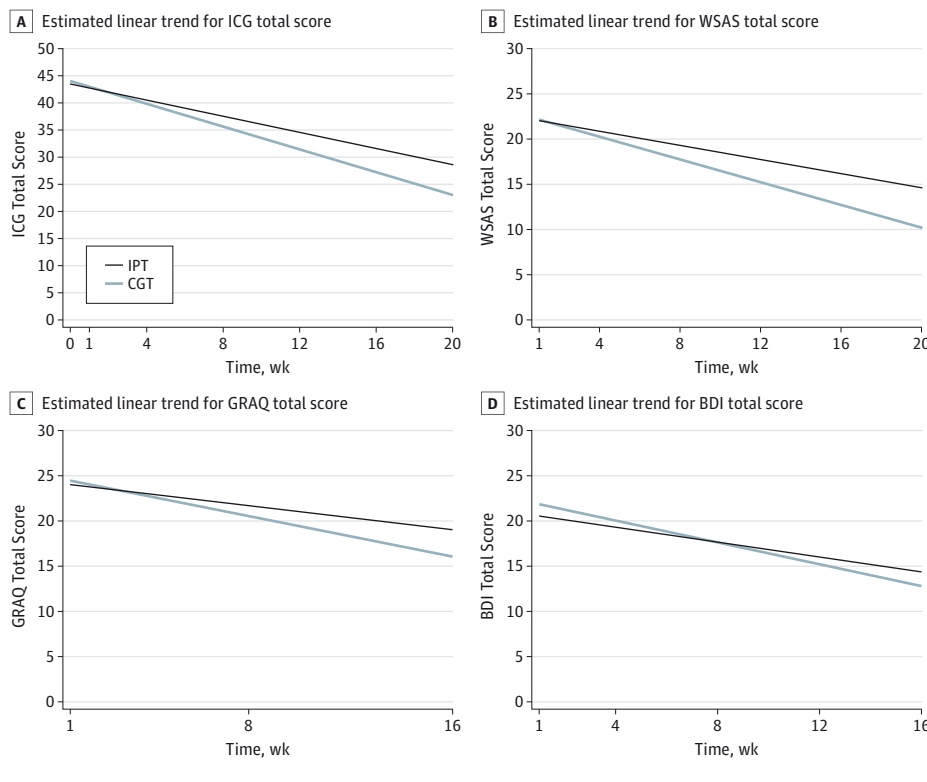
Table 2. Summary of Analyses for Secondary Outcomes

Measure and Treatment Arm	Before Treatment		After Treatment		Estimated Difference Between Arms After Treatment <sup>a</sup>	P Value
	No. of Participants	Observed Score, Mean (95% CI)	No. of Participants	Observed Score, Mean (95% CI)		
ICG						
CGT	74	46.1 (44.0-48.2)	64	22.8 (19.5-26.0)	-5.52	.01
IPT	77	46.0 (43.8-48.2)	66	28.0 (25.2-30.9)		
WSAS						
CGT	68	22.3 (19.7-24.9)	63	10.7 (8.3-13.1)	-4.44	.006
IPT	72	21.8 (19.5-24.2)	66	14.0 (11.5-16.5)		
GRAQ						
CGT	63	23.9 (20.7-27.1)	62	15.9 (12.8-19.0)	-4.04	.09
IPT	68	23.9 (20.5-27.3)	62	18.5 (15.3-21.8)		
BDI						
CGT	62	22.4 (19.9-24.8)	62	13.5 (11.2-15.9)	-2.14	.18
IPT	71	20.5 (18.5-22.4)	65	14.0 (12.0-16.1)		

Abbreviations: BDI, Beck Depression Inventory; CGT, complicated grief treatment; GRAQ, Grief-Related Avoidance Questionnaire; ICG, Inventory of Complicated Grief; IPT, interpersonal psychotherapy; WSAS, Work and Social Adjustment Scale.

<sup>a</sup> Estimated difference between CGT and IPT at week 20 was obtained using a linear mixed-effects model based on longitudinal measurements of each secondary outcome.

Figure 3. Estimated Linear Trends for Symptom and Functioning Measures Based on the Mixed-Effects Model



A, Estimated linear trends for mean total scores on the Inventory of Complicated Grief (ICG) (total range, 0-76). B, Estimated linear trends for mean total scores on the Work and Social Adjustment Scale (WSAS) (total range, 0-40). C, Estimated linear trends for mean total scores on the Grief-Related Avoidance Questionnaire (GRAQ) (total range, 0-60). D, Estimated linear trends for mean total scores on the Beck Depression Inventory (BDI) (total range, 0-63). Scores are totaled by study week for complicated grief treatment (CGT) and interpersonal psychotherapy (IPT) groups in the intention-to-treat sample estimated from a linear mixed-effects model with random intercepts and random slopes.

in different age groups and different cities, underscoring the importance of distinguishing CG from depression.

Complicated grief is a stress response syndrome, and CGT uses revisiting procedures derived from prolonged exposure for PTSD,<sup>20,46</sup> a treatment that has been controversial for elderly patients.<sup>24</sup> Two pilot studies of prolonged exposure in older persons with PTSD show good acceptance and response.<sup>25,26</sup> We also found good efficacy, tolerability, and durability for CGT. Thus, older adults appear to tolerate emotional activation reasonably well and respond to these procedures similarly to younger adults.

Our study population was predominantly female, white, and highly educated. Our results might not generalize to men, nonwhite patients, or less educated individuals or to those groups excluded from the study. However, a prior study<sup>47</sup> found no difference in treatment response among African American compared with white participants. In addition, our participants lost a range of loved ones in many different ways, suggesting that results can be generalized across a wide range of bereavement situations.

Some controversy still exists regarding CG diagnostic criteria, the syndrome name, and the timing of diagnosis. Dif-

ferent criteria produce different population-based rates,<sup>48</sup> and using different criteria might produce somewhat different outcomes than we observed. However, the ICG is a widely used approach to assess this condition and is used throughout the world in a range of settings.<sup>47,49-53</sup> A recent study described it as “the gold standard for measurement of complicated grief in older adults.”<sup>54 (p 232)</sup>

The CGI-I is a single-item Likert rating, which generally is not ideal. However, this scale has been used widely in clinical trials for decades.<sup>55</sup> We documented good interrater reliability. Results for other measures of CG symptoms and impairment were consistent with CGI-I findings. We did not collect systematic data regarding blinding of the independent evaluators; however, the independent evaluators reported instances of unblinding in weekly meetings. Nine such occurrences were documented, with only 2 occurring before the posttreatment assessment.

We used different therapists to administer CGT and IPT, so observed differences might have been confounded by therapist factors. However, clinicians who administered the treat-

ments were well matched with respect to professional education and experience. Interpersonal psychotherapy is not more difficult to learn than CGT, and anecdotally, patients clearly liked their IPT therapists (patient oral communication to M.K.S.). Therapist factors seem unlikely to be confounding our results.

## Conclusions

Complicated grief is an underrecognized public health problem that likely affects millions of people in the United States, many of them elderly. To our knowledge, few treatment studies of this condition and no previous full-scale randomized clinical trial with older adults have been performed. Our sample had a mean age of 66.1 years, with most ranging in age from 60 to 74 years, and 20.5% were 75 years or older. Given a growing elderly population, increased rates of bereavement with age, and the distress and impairment associated with CG, effective treatment should have important public health benefits.

### ARTICLE INFORMATION

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