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Change in Avoidance and Negative Grief-related Cognitions Mediates Treatment Outcome in Older Adults with Prolonged Grief Disorder

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Abstract

Objective: The present study investigated the role of the two theoretically derived mediators in the treatment of Prolonged Grief Disorder (PGD). Mediators were changes in avoidance and maladaptive cognitions. An additional hypothesis tested whether these candidate mediators are specific to CBT-based Complicated Grief Treatment (CGT) compared to Interpersonal Therapy (IPT).

Method: We performed secondary analyses with assessment completers (n = 131) from a randomized-controlled trial with older adults with PGD. Patients received 16 sessions of CGT or IPT. Outcomes were treatment response and reductions in grief symptoms and grief-related related impairment.

Results: Reductions in avoidance between baseline and week 16 mediated reductions in grief symptoms and grief-related impairment. Reductions in maladaptive grief-related cognitions over the same period mediated treatment response, reductions in grief symptoms and grief-related impairment. There were no significant treatment-mediator interactions. We could not establish that mediators changed before the outcomes.

Conclusion: Results are consistent with theoretical models of PGD, including the CGT treatment model. Despite different therapeutic procedures, we found no significant interaction

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effect, but CGT produced larger effects. Future research needs to establish a timeline of change through the use of multiple measurements of mediators and outcomes. (clinicaltrials.gov identifier NCT01244295)

Keywords

avoidance; complicated grief/prolonged grief disorder; maladaptive cognitions; mediation; older adults; treatment

Despite the vast number of studies that have shown that psychotherapy is effective, there is still less insight into *how* therapy works (Cuijpers et al., 2019). Identifying so-called mechanisms of change can make psychotherapy more efficacious and cost-efficient: It can clarify which strategies drive change, find the most suitable treatment for a patient, and bring order and parsimony to treatment (Kazdin, 2007, 2009).

Mechanisms of change are often categorized into specific and common factors (Cuijpers et al., 2019; Lambert, 1992; Wampold, 2001). Common factors are factors that all therapies share (e.g., alliance) and specific factors pertain to a particular form of psychotherapy or a specific disorder. To get to mechanisms, studying mediators is the first step (Kazdin, 2007). While mechanisms are the processes that are responsible for the change, mediators are defined as intervening variables that may account (statistically) for the relationship between the independent and dependent variables (Kazdin, 2009). Mediation analysis was initially described by Baron and Kenny (1986) and the McArthur criteria are a useful modification when studying mediation in clinical research (Kraemer et al., 2008). In this approach, mediation is established when there is either a main effect of the mediator or an interaction between mediator and treatment (Kraemer et al., 2008). The interaction indicates whether a mediator plays a larger role in one treatment compared to another.

One condition that is relatively new to psychotherapy research is prolonged grief disorder (PGD). No prevalence studies have been published to date using official diagnostic criteria. However, among bereaved individuals, PGD prevalence of 11% derived from a meta-analysis (Lundorff et al., 2017) is probably the best estimate to date. The World Health Organization (2019) recently included an official diagnosis of PGD in the ICD-11 (PGD_{ICD-11}). The guideline for this disorder includes pervasive intense yearning or longing, or persistent preoccupation with the deceased that persists at least six months after bereavement. This is accompanied by other evidence of emotional pain, such as sadness, guilt, anger, denial, blame, difficulty accepting the death, feeling one has lost a part of one's self, an inability to experience positive mood, emotional numbness, or difficulty in engaging with social or other activities (World Health Organization, 2019; https://icd.who.int/browse11/l-m/en). The American Psychiatric Association has also approved a diagnosis of Prolonged Grief Disorder (personal communication).

Several CBT-based treatments have shown efficacy in the treatment of PGD (Johannsen et al., 2019). Building on this evidence, it is now essential to move to the identification of potential mechanisms of change in these treatments (Doering & Eisma, 2016; Johannsen et al., 2019). It is the aim of the present study to examine the role of candidate mediators in Complicated Grief Treatment (CGT) and Interpersonal Therapy (IPT) for PGD.

CGT is the first and best-studied treatment for PGD (Shear et al., 2005; Shear et al., 2016; Shear et al., 2014). It has roots in Prolonged Exposure for posttraumatic stress disorder (PTSD; Foa, 2011) and incorporates elements of other evidence-based psychotherapies. IPT is an efficacious treatment for depression (de Mello et al., 2005) that has a grief focus and has recently been adopted for treatment of other disorders (Lipsitz & Markowitz, 2013). In an initial randomized-controlled trial (RCT), CGT was compared to IPT with a grief focus (Shear et al., 2005). The response rate was significantly higher for CGT than IPT, and CGT led to greater reductions in grief symptom severity and grief-related impairment. These positive effects of CGT were replicated in a RCT comparing CGT to IPT among older adults aged 50–91 (Shear et al., 2014) and in a study of citalopram with or without CGT (Shear et al., 2016).

The CGT model proposes a number of impediments to adaptation following loss that can result in PGD (Shear & Gribbin Bloom, 2017; Shear et al., 2007). Initially, acute grief is the natural response to learning of the death of a close attachment (Shear & Shair, 2005). Over time, a process of adaptation usually occurs and includes accepting the reality of the loss including the changes it brings, as well as restoring a sense of wellbeing. As a result, grief is transformed and integrated. The CGT model further posits that certain kinds of cognitions, such as maladaptive grief-related cognitions, behaviors such as avoidance, difficulty with emotion regulation, or severe social problems can interfere with adapting to the loss. As a result, acute grief symptoms can intensify and persist in the form of PGD (Shear et al., 2007).

Other models have also conceptualized avoidance and maladaptive cognitions as key mechanisms of PGD. Boelen et al. (2006) propose negative global beliefs and misinterpretations of grief reactions and avoidance strategies as two of three core processes in the development and maintenance of PGD. In the cognitive attachment model (Maccallum & Bryant, 2013), avoidance restricts engaging in activities that facilitate a self-identity independent from the deceased. An independent self-identity is posited to be associated with a lower risk for the development of PGD than a self-identity merged with the deceased. A merged identity is further proposed to be associated with maladaptive appraisals. These fuel distress, negatively impact emotion regulation strategies, and interfere with participating in adaptive activities.

Based on these theoretical perspectives, changes in avoidance and maladaptive cognitions are candidate mechanisms of change. Excessive avoidance behavior, such as avoiding to visit the grave or dealing with the belongings of the deceased, avoiding activities associated with the person, or avoiding own thoughts and emotions is frequent in patients with PGD (e.g., Boelen & van den Bout, 2010; Eisma & Stroebe, 2020; Shear et al., 2007). Maladaptive cognitions regarding the form and function of grief, self-blame, or judging one's grief reaction as either too excessive or as the only tie to the deceased, are also common (e.g., Boelen et al., 2006; Skritskaya et al., 2017).

All three theoretical models suggest that changing maladaptive cognitions and resolving avoidance strategies during treatment would be associated with better outcomes. In CGT, avoidance behavior is targeted by a procedure for living with reminders that is similar to

in-vivo exposure. Acceptance of the reality of the loss and overcoming avoidance is further targeted by repeatedly telling the story of learning of the death. There is evidence that CGT successfully reduces avoidance (Glickman et al., 2016a; Shear et al., 2016; Shear et al., 2014). Each of seven CGT procedures also provides an opportunity to identify and address maladaptive thinking, and maladaptive grief-related cognitions have been found to decrease significantly among CGT responders (Skritskaya et al., 2020).

IPT focuses on the interpersonal context and works on one or more of four central interpersonal problems that it seeks to resolve. These include interpersonal dispute, grief, role transition, or interpersonal deficit. To achieve this aim, the therapist works to enhance social support and decrease interpersonal stress, which also entails processing emotions and improving interpersonal skills (Lipsitz & Markowitz, 2013).

In a preliminary examination of mediators of CGT, Glickman et al. (2016b) identified reduction in avoidance, guilt and self-blame, and negative thoughts about the future as possible mediators of CGT outcomes. Change in avoidance was the strongest mediator for responder status, PGD symptoms, and grief-related impairment. Early change in avoidance also predicted subsequent reduction in grief-related impairment, suggesting there might be a causal relation. This analysis had, however, methodological limitations and it also remained unclear if the mediators were specific to CGT or the treatment of PGD in general.

Aims of the present study

It is an important next step to expand on the initial findings on mediators of PGD treatment. It was the main aim of the present study to examine whether reductions in avoidance and maladaptive cognitions mediate treatment outcome and may be candidates for specific factors in the treatment of PGD. The guiding hypotheses were (1) reduction in avoidance partially mediates reductions in other grief symptoms, grief-related impairment, and treatment response and (2) reduction in maladaptive cognitions partially mediates reductions in grief symptoms, grief-related impairment, and treatment response. We further investigated whether the relationship between treatment outcome and change in avoidance and maladaptive cognitions differs between CGT and IPT. We expected mediation effects of these variables for CGT but not IPT because CGT explicitly targets avoidance and maladaptive cognitions whereas IPT targets interpersonal functioning. Both Kazdin (2007) and Kraemer et al. (2008) emphasized the importance of demonstrating that the mediator changes before the outcome (i.e., temporal precedence). We therefore conducted analyses to examine whether early reduction in the potential mediators would be associated with later reduction in the outcomes.

Method

Procedure

The present study was a secondary analysis of data from a previously published RCT that investigated the efficacy of CGT in older adults (see Shear et al., 2014 for a detailed description). Participants were included if they were 50 years or older. They scored 30 or higher on the Inventory of Complicated Grief (ICG; Prigerson et al., 1995) and confirmed on

clinical interview to have grief as their primary problem. We later confirmed that these cases can also be identified by the ICD-11 guideline for PGD (Mauro et al., 2018). Exclusion criteria were: current substance use disorder or bipolar I disorder, active suicidality, lifetime history of psychotic disorder, significant cognitive impairment, pending lawsuit or disability claim related to the death, concurrent psychotherapy. Eligible participants were randomized to receive either CGT or IPT.

Sample characteristics

The original study sample consisted of 151 participants (see Shear et al., 2014 for a description). Due to missing data on variables of interest in the present study (see below), we used data from 131 participants (CGT: n = 64, IPT: n = 67; see Table 1). As in the full sample, incidence of current PTSD was higher in the CGT group than in the IPT group ($\chi^2[1] = 6.986$, p = 0.008). There were no other statistically significant differences between groups (all p > .05).

Treatment conditions

Both treatment arms are described in more detail in Shear et al. (2014). CGT was delivered in 16 weekly sessions that each included a focus on loss and on restoring wellbeing. During sessions 1 to 3, the therapist focuses on understanding the loss in the context of the patien's biography, gives information on PGD and CGT, introduces daily grief monitoring, begins to work on aspirational goals, and holds one session with a significant other. Sessions 4 to 9, the core revisiting sequence, includes imaginal and situational revisiting procedures, and introduction to memories work. Session 10 is a midcourse review and sessions 11 to 16 comprise the closing sequence, including an imaginal conversation with the deceased, continued situational revisiting and aspirational goals work, and preparation for treatment termination.

IPT was delivered in 16 sessions according to Hinrichsen and Clougherty (2006) and had a grief focus as well as a second focus on role transition or interpersonal disputes if indicated. The effect of bereavement and other interpersonal events on depressed mood was discussed, along with some discussion of the relationship with the deceased, circumstances of the death, and encouragement and support for satisfying relationships and activities in the present.

Measures

The number of participants who completed each instrument is presented in Table 2.

Potential mediators.

Avoidance.—The Grief-related Avoidance Questionnaire (GRAQ; Baker et al., 2016; Shear et al., 2007) measures avoidance with 15 items such as "Do you avoid rooms or places you associate with the person who died?" that participants are asked to rate on a scale from 0 (never) to 4 (always). Internal consistency in the present sample was excellent (Cronbach's $\alpha = .90$). The GRAQ was administered at baseline, week 8, and week 16.

Maladaptive cognitions. —Maladaptive grief-related cognitions were measured with the Typical Beliefs Questionnaire (TBQ; Skritskaya et al., 2017). It consists of 25 items (e.g., "You should have done something to prevent this death or make it easier") and participants are asked to rate how strongly they believe each statement on a scale from 0 (not at all) to 4 (strongly). The total score was used in the present study. Internal consistency in the present sample was good (Cronbach's $\alpha = .83$). The instrument was administered at baseline, week 8, and week 16. The validated version of the TBQ was introduced during the clinical trial and administered at baseline to 74.8% (n = 113) of participants.

Outcomes.

Responder status.—Treatment response was the main outcome of the clinical trial. A rating of responder was determined by an independent evaluator rating of 1 or 2 on the grief-anchored Clinical Global Impression Scale (CGI; Guy, 1976; Shear et al., 2016) corresponding to "much improved" or "very much improved". Non-responders were given a rating of 3 or greater on this scale. Interrater reliability of the CGI (Cohen's $\kappa = 0.68$; Shear et al., 2014) can be considered as substantial (McHugh, 2012). Ratings were obtained at week 20.

PGD symptoms.—Prolonged grief symptoms were also assessed with the ICG (Prigerson et al., 1995). This self-report measure includes 19 items (e.g., "I think about this person so much that it's hard for me to do the things I normally do") that are rated on a scale from 0 (never) to 4 (always). The ICG is one of the most widely used measures of PGD and a cut-off score of 30 has been used to reliably identify cases of PGD (Simon et al., 2011). Internal consistency in the present sample was satisfactory (Cronbach's $\alpha = .78$). The instrument was administered at baseline, week 8, and week 20.

Grief-related impairment.—Grief-related impairment in functioning was measured with a grief-focused version of the Work and Social Adjustment Scale (WSAS; Mundt et al., 2002). The WSAS measures grief interference with functioning in five areas: Work, home management, private leisure, social leisure, and family relationships on a nine-point scale ranging from 0 (not at all) to 8 (severe interference). Internal consistency was excellent (Cronbach's $\alpha = .89$). The WSAS was administered at baseline, week 8, and week 20.

Statistical Analysis

Data were analyzed with R version 3.5.1 (R Core Team, 2018) and Mplus Version 7.3 (Muthén & Muthén, 2012). Each analysis was conducted with those participants who had completed measurements on the mediator and outcome.

Responder status was based upon the CGI rating obtained at week 20. Change in ICG and WSAS was calculated by subtracting the score at week 20 from the score at week 1. Change in each potential mediator was operationalized by subtracting the score at week 16 from the score at week 1, since no measurements were collected at week 20. Mediators were centered to zero. Type of treatment was included as a binary treatment variable (0 = IPT, 1 = CGT).

In a mediation model (see Figure 1), path a represents the effect of the treatment variable on the mediator and path b represents the effect of the mediator on the outcome. The product of the coefficients a*b is the indirect effect or mediation effect. It represents the effect the treatment has on the outcome via the mediator. Path c represents the effect of treatment on the outcome when effect of the mediator is accounted for (i.e., direct effect). The sum of indirect effect and direct effect comprises the total effect (path c). The mediators were first investigated in separate models and then combined in multiple mediator models to control for possible covariance between them.

Single mediation analysis was conducted using the *mediation* package for R (Tingley et al., 2014). The package uses a quasi-Bayesian Monte Carlo method based on normal approximation to estimate the direct (c'), indirect (ab), and total effects (c) from regression models for paths a, b, and c'. Logistic regression was used for responder status and linear regression for the remaining outcomes and mediators. Each mediation model included the treatment variable, a single mediator, and the outcome (see Figure 1a). Number of simulations was set to 1000. To determine significance, 95% confidence intervals (CI) were used for the indirect effect. A value can be considered statistically significant if the CI does not contain zero. As a measure of effect size, the proportion mediated was calculated as (total effect – direct effect)/total effect. Adjusted R-squared ranged between .095 and .305 which is typical for multiply determined psychological phenomena (e.g., Gignac & Szodorai, 2016).

Multiple mediation analysis was conducted using Mplus and the indirect effect was estimated via a bias-corrected bootstrap procedure. Number of bootstrap samples was set to 10000. This analysis yields specific indirect effects for each mediator and a total indirect effect, composed of specific indirect effects of all mediators. Mediation models were estimated for each of the three outcomes and included the treatment variable, both mediators, and the respective outcome. R-squared ranged between .208 and .303. Due to the models being saturated, commonly used fit indices for these models were not available.

Following the McArthur criteria (Kraemer et al., 2008), the single mediator models were then repeated with the interaction term between treatment and mediator included in the regression models for path c'. This approach allowed us to determine whether the treatment condition influences the relationship between mediator and outcome. Indirect effects for each treatment group were estimated using the *mediation* package and the statistical significance of the differences between these effects was tested using t-tests.

In order to explore whether we could detect treatment-related change in mediators that occurred prior to change in outcomes, we conducted further mediation analyses (see Figure 1b). We investigated temporal precedence by examining early change in GRAQ and TBQ scores as mediators. The analyses are considered preliminary since we had only one midtreatment score at week 8. We did not have CGI improvement ratings prior to week 20. We computed two change scores: For the *early change* score, week 8 scores were subtracted from week 1 scores, and for the *late change* score, week 20 scores were subtracted from week 8 scores. Early change in the outcomes was included as an additional predictor. The indirect effect of early change in GRAQ and TBQ scores was inspected as a primary test

of mediation effects. We also tested whether change between weeks 1 and 8 in the potential mediators predicted change between weeks 8 and 16 in the outcomes.

As a sensitivity analysis, ICG item 12 which assesses avoidance was omitted and models investigating avoidance as a mediator were repeated. No adjustments were made to control for multiple testing (Bender & Lange, 2001), because the analyses constituted exploratory analyses.

Results

Scores at baseline, week 8, and treatment endpoint are displayed in Table 2. Sample sizes for the mediation models varied because, as noted, the final version of the TBQ was administered to only 75% of participants and because some participants failed to complete forms. As a result, the sample size varied between n = 114 (CGT: n = 56, IPT: n = 58) for analyses with the GRAQ as the mediator and responder status as the outcome, and n = 89 (CGT: n = 42, IPT: n = 47) for analyses with the TBQ as the mediator and the ICG as the outcome.

Total effects and relationship between treatment groups and changes in potential mediators

Table 3 presents coefficients for all paths in the single mediation models. In line with results of the main outcome paper (Shear et al., 2014), there were significant total effects on all outcomes. Rate of response at week 20 was higher for CGT than for IPT and CGT led to greater reduction on the ICG and WSAS at week 20 than IPT (path *c*). Treatment groups also differed regarding changes in the potential mediators at week 16 (path *a*). Those in the CGT group had greater reductions in both GRAQ and TBQ scores.

Mediation effects

Avoidance.—Reduction in avoidance mediated reduction on the ICG (ab = 1.823, 95% CI [0.190, 3.770]) and WSAS (ab = 1.474, 95% CI [0.138, 3.340]). Avoidance accounted for an estimated 26.3% (95% CI [3.3, 56.0]) of the treatment effect on ICG scores and an estimated 28.3% (95% CI [3.1, 100.0]) of the treatment effect on WSAS. Although technically non-significant, the lower boundary of the CI for the indirect effect on responder status was very close to zero (ab = 0.040, 95% CI [-0.001, 0.11], estimated proportion mediated 10.4 %, 95% CI [-0.3, 0.32]).

Maladaptive cognitions.—Reduction in maladaptive grief-related cognitions mediated CGI responder status (ab = 0.101, 95% CI [0.018, 0.200], estimated proportion mediated 25.2 %, 95% CI [6.1, 54.0]), reduction on the ICG (ab = 2.050, 95% CI [0.431, 4.190], estimated proportion mediated 27.7 %, 95% CI [6.5, 58.0]), and reduction on the WSAS (ab = 1.866, 95% CI [0.314, 3.76], estimated proportion mediated 32%, 95% CI [6.3, 98.0]).

Multiple mediation.—Mediators were moderately correlated (r = 0.41). There were total indirect effects on change on the ICG (ab_{total} = 2.854, 95% CI [0.830, 5.268]) and WSAS (ab_{total} = 1.881, 95% CI [0.431, 4.147]), but not on CGI responder status (ab_{total} = 0.087, 95% CI [-0.001, 1.185]). Specific indirect effects (Table 4 in the Supplement) confirmed

the results of the single mediator models with one exception: There was no specific indirect effect of reduction in avoidance on improvement on the WSAS ($ab_{GRAQ} = 0.569$, 95% CI [-0.233, 2.661]). Estimates for indirect effects were larger for changes in maladaptive grief-related cognitions than for changes in avoidance.

Interaction between mediators and treatment type

Including the interaction between the treatment variable and reductions in avoidance and maladaptive grief-related cognitions in the regression models confirmed the mediation effects of the single mediator models. No significant differences were detected on indirect effects between treatment groups in all models (all p > .05, Table 5 in the Supplement).

Temporal precedence of the mediators

Change in avoidance from week 1 to week 8 did not show a mediation effect on change in ICG from week 8 to week 20 (ab = -0.056, 95% CI [-0.768, 0.600], estimated proportion mediated -0.8%, 95% CI [-26.2, 15.0]); nor on change in WSAS from week 8 to week 20 (ab = 0.300, 95% CI [-0.570, 1.350], estimated proportion mediated 8%, 95% CI [-45.8, 62.0]). Early reduction in avoidance significantly predicted later reduction on the WSAS ($B_b = 0.314$, SE = 0.108, p = 0.004). This reduction did not differ between treatment groups ($B_a = 0.969$, SE = 1.418, p = 0.496).

Early reduction in maladaptive grief-related cognitions at week 8 also did not significantly mediate later reduction on the ICG (ab = 0.115, 95% CI [-0.393, 0.770], estimated proportion mediated 1.5%, 95% CI [-15.7, 20.0]) or WSAS (ab = 0.115, 95% CI [-0.393, 1.310], estimated proportion mediated 12.5%, 95% CI [-50.2, 54.0]). Early reduction on the TBQ predicted later reduction on the ICG ($B_b = 0.208$, SE = 0.086, p < 0.001). This reduction did not differ between treatment groups ($B_a = 2.228$, SE = 2.310, p = 0.337).

Sensitivity analyses

Results did not differ when the avoidance item was omitted from the ICG.

Discussion

This study explored change in avoidance and maladaptive cognitions as potential mediators in the treatment of PGD in a study comparing CGT and IPT. We derived our mediation hypotheses from theoretical models of PGD and from the model used in designing CGT (Shear & Gribbin Bloom, 2017). Change in avoidance mediated change in grief symptoms and grief-related impairment at week 20. Change in maladaptive grief-related cognitions mediated responder status at week 20 and change in grief symptoms and grief-related impairment. The CI for the mediation effect of change in avoidance on responder status included the effect size found in the previous investigation by Glickman et al. (2016b) (proportion mediated 32%), although this effect was not significant in the present study.

Multiple mediator models that control for shared variance between variables pointed towards change in maladaptive cognitions as the more important mediator. This is in line with the proposition that avoidance behavior is often the result of maladaptive cognitions regarding

the grief reaction (Boelen et al., 2006; Maccallum & Bryant, 2013). However, we cannot rule out other possibilities for these results. From a clinical standpoint, we suggest that addressing both cognitions and avoidance is important.

Differences between CGT and IPT in parameter estimates for indirect effects were negligible and non-significant. It is therefore possible that the relation between change in avoidance and cognitions and outcomes did not differ between CGT and IPT. As this study was not designed and powered to detect mediation by treatment interaction, these results should be interpreted cautiously. However, our results resemble those of a study comparing mediators of CBT and IPT in the treatment of depression (Lemmens et al., 2017).

While statistical associations of mediators show the relation between treatment and outcome (Kazdin, 2009), it is essential for the identification of mechanisms to understand the procedures through which change comes about. In CGT, the procedure called situational revisiting directly addresses avoidance of reminders of the loss. This intervention resembles in-vivo exposure used for anxiety disorders and PTSD that successfully reduces avoidance behaviors (e.g., Deacon & Abramowitz, 2004). Additionally, by repeatedly revisiting and reflecting on the story of how they learned of the death, patients have the opportunity to reduce avoidance of thinking about the death. This may help them grow in acceptance of the reality, an important component of adaptation to the loss. Additionally, therapeutic work throughout the treatment aims to resolve maladaptive thinking.

In IPT, improving interpersonal relations and re-engaging in social relationships that are often avoided by people with PGD may have had some effect on avoidance behavior. This would, however, be indirect and less structured than in-vivo exposure and not a regular target of the therapy. Discussion of the relationship with the deceased and possible review of circumstances of the death might have led to changes in maladaptive cognitions.

Our results regarding mediation provide support for the findings of our previous exploratory investigation into mediators of CGT (Glickman et al., 2016b). Results are also consistent with findings obtained in previous studies with a range of non-grief disorders. The above mentioned study by Lemmens et al. (2017) also found support for change in dysfunctional cognitions as a mediator in the treatment of depression with CBT and IPT. Change in cognitions has also emerged as a mediator in treatment outcome for PTSD (Brown et al., 2018). Change in avoidance behaviors has received less attention as a specific mechanism, but there is evidence for its importance (Bonnert et al., 2018).

It is a shortcoming of many mediation studies to date that they only inspect concurrent changes (Lemmens et al., 2016). Establishing mechanisms requires demonstration that the mediator changed before the outcome (Kazdin, 2007; Kraemer et al., 2008). In line with Glickman et al. (2016b), we found that early reductions in avoidance and also maladaptive cognitions predict later reductions in PGD symptoms and impairment. This finding points to a temporal relationship, but our statistical model did not indicate mediation effects at midtreatment. It should, however, be noted that CIs for both mediation effects on grief-related impairment included the effect sizes that were found for change until week 16 in our own and (for change in avoidance) the previous investigation by Glickman et al. (2016b).

The analysis of temporal precedence was limited to a single mid-treatment time point and may have missed a change that took place after this but before the outcome time point. Notably too, work on avoidance does not start until week six or later. Week eight would likely have been too early to detect a meaningful change in avoidance behavior. In an investigation of change mechanisms of a treatment for PTSD, Jensen et al. (2018) found that late reduction in cognitions mediated treatment outcome, but reduction from early to mid-treatment did not. Processes of change are also not necessarily unidirectional and linear. A study with more time points that allow for more advanced statistical methods is needed to better understand the trajectory of change. For example, Kleim et al. (2013) used session-by-session measures and found that change in negative appraisals predicted change in PTSD symptoms in the subsequent session.

Clinical Implications

Our findings support the idea that reduction in avoidance and maladaptive cognitions is likely to mediate a decrease in PGD symptoms (Boelen et al., 2006; Maccallum & Bryant, 2013; Shear et al., 2007). Effectively addressing maladaptive cognitions can reduce PGD symptoms in multiple ways. It can enable an acceptance of the death and changed reality, more effectively manage painful emotions that arise as a result of the cognitions, and foster re-engagement in other areas of life. It can also possibly affect avoidance behavior. Re-engaging in avoided activities often provides new opportunities for enjoyment, as well as access to positive memories of the deceased that are both bittersweet and comforting. Without the constraints of avoidance behavior, patients are more able to fulfill work-related and private roles which reduces grief-related impairment. These changes help to restore a sense of wellbeing, and a reduction in PGD symptoms.

The difference in outcome between CGT and IPT that was found in the present study and reported in the main outcome paper (Shear et al., 2014) as well as a previous study (Shear et al., 2005), strongly suggests that CGT is more effective than standard IPT in treating PGD. While we have not found evidence that positive results from IPT act via a different mechanism, we are not confident in saying that the mechanism is the same. CGT was also significantly more successful at effecting change in the mediators. The likely reason behind this is that CGT aims at changing loss-related maladaptive cognitions and resolving dysfunctional avoidance behavior. Treatment including components that target avoidance and maladaptive cognitions might be preferred for patients with PGD to treatment without such a focus. This is supported by evidence showing that all other treatments to date that successfully reduce PGD symptoms include elements that focus on changing avoidance and maladaptive grief-related cognitions (e.g., Boelen et al., 2007; Bryant et al., 2014; Rosner et al., 2014; Wagner et al., 2006). Clinicians are encouraged to assess these thoughts and behaviors before treatment and to address them during treatment.

Limitations and directions for further research

Although the RCT included an exploratory aim focused on mediators, it was not powered for these analyses. Inspection of the CI for the mediation effect of change in avoidance on responder status supports this assumption, because although this effect did not reach significance the CI included the effect size found in a previous study. There are no previous

studies that report effect sizes for mediation effects at mid-treatment for the purpose of comparison. Mediators explained between 25% and 32% of variance, but the measures included in this study were not comprehensive enough to test a range of mediators that would be consistent with the treatment model. Additionally, mediators were measured infrequently during the 20 week assessment period, a common shortcoming (Kazdin, 2007). Our negative results regarding temporal precedence may therefore be a consequence of low statistical power, insufficient frequency of measurement of mediators, or both.

Future investigations therefore need to be specifically designed to elucidate treatment mediators. They need to study further potential mediator variables derived from theoretical models of PGD (e.g., emotion regulation difficulties, autobiographical knowledge, envisioning a promising future, relationship strength, connection to memories of the deceased) as well as common factors (e.g., alliance, treatment expectations; Wampold, 2015). Dismantling studies would allow for the manipulation of candidate mediators. As mentioned above, the multiple assessment of candidate mediators throughout treatment can provide insight into temporality and directionality of change. The fact that not all possible mediators were included in the present analyses may have influenced our results because it precludes evaluating the role of change in avoidance and maladaptive grief-related cognitions in the context of other mediators.

The use of change scores also constitutes a simplified approach that we chose in part to enable comparisons with the earlier study by Glickman et al. (2016b). Change scores have also been associated with lower statistical power (Vickers, 2001). Depending on the baseline value, a change of, for example, ten points might have a different meaning. Their use is, however, justified in the present analysis, because baseline values did not differ between study groups and correlations between baseline and post-treatment values were high (Vickers, 2001). Our results show that a change in avoidance and cognitions, independent of the range within which that change occurred, appeared to mediate treatment outcome in this study. Future research needs to confirm this finding and to explore the possibility that there is a level of avoidance or cognitions which needs to be endorsed at baseline and/or a level that must be achieved during treatment in order to produce optimal treatment outcomes.

The sample size for several of the analyses of the current study, especially those including the TBQ, was limited by different rates of missing data and may have been too small to detect mediation effects and their differences (Fritz & Mackinnon, 2007). Importantly, we included only assessment completers in the analyses. While inverse probability weighting was used to deal with missing data in the analyses reported in main outcome paper (Shear et al., 2014), mediation models are not well equipped to handle weights. Analyses adjusted for missing data and analyses with assessment completers in the main outcome paper yielded consistent results across outcome measures (Shear et al., 2014). However, we note that we did not correct for multiple testing which leads to a chance for spuriously significant effects. In evaluating the importance of single results, we advise readers to consider effects sizes. Some of the CIs for our measure of effect size are very wide, which is not surprising given that smaller sample sizes tend to generate wider CIs, but needs to be considered when interpreting the size of our effects.

Finally, data were collected before the PGD_{ICD-11} guideline was released and patients were not selected based on these criteria. We used a statistical procedure to retrospectively assess whether patients met PGD_{ICD-11} criteria based on available questionnaire data. This procedure differs from making a diagnosis using the PGD_{ICD-11} guideline. However, treatment outcomes in our study are not different using different diagnostic algorithms (Mauro et al., 2018). It is likely that mediators would also be similar.

Conclusion

Results support the idea that resolving avoidance behavior and changing maladaptive grief-related cognitions are partly responsible for reduced PGD symptoms and grief-related impairment, despite inconclusive evidence regarding temporality. Despite different therapeutic procedures used in CGT and IPT, we found no significant interaction effect, but CGT produced significantly larger reduction in PGD symptoms. Knowledge of mediators is important to gain a better understanding of how treatment of PGD works and to optimize treatment. Future research needs to establish the timeline of change by collecting repeated measurements during treatment and inspect further possible specific and common factors of change.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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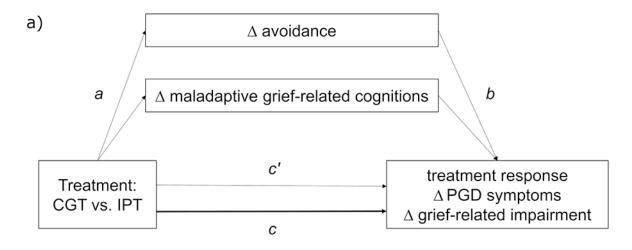
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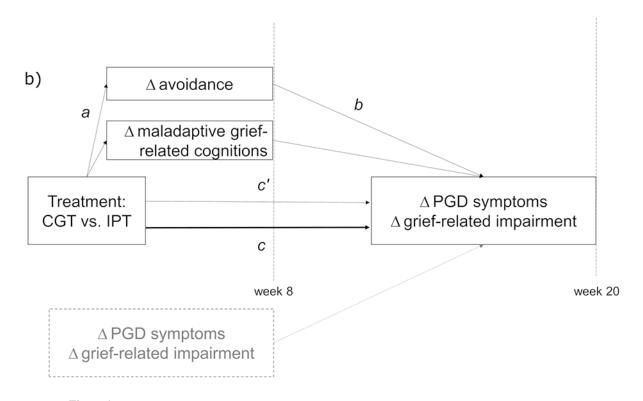


Figure 1. Mediation model for hypotheses 1 and 2 (a; top) and analyses of temporal precedence of the mediators (b; bottom). Path *c* represents the total effect of the treatment on the outcomes. Path *a* presents the effect of the treatment on the mediators. Path *b* represents the effect of the mediators on the outcomes. Path c' represents the effect of treatment on the outcomes when the effect of the mediator is taken into account (direct effect). The indirect effect of

treatment on outcomes via the mediator is represented by the product of the coefficients a and b and noted as ab.

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Table 1

Sample characteristics by treatment group

		Gr	oup		
Characteristic	Total sample (<i>N</i> = 131)	CGT (n = 64)	IPT (n = 67)	Test statistic	p-value
Gender (female), n (%)	107 (81.68)	53 (82.8)	54 (80.6)	$\chi^2(1) = 0.110$	0.743
Age in years, $M(SD)$	65.56 (8.71)	65.5 (8.96)	65.7 (8.52)	t(129) = 0.130	0.896
Race/ethnicity, n (%)				$\chi^2(1) = 1.964^{a}$	0.161
White	114 (87.0)	53 (82.8)	61 (91.0)		
Black/African American	13 (9.9)	9 (14.1)	4 (6.0)		
Asian	2 (1.5)	1 (1.5)	1 (1.5)		
American Indian/Alaska Native	1 (0.7)		1 (1.5)		
Educational level, $n(\%)$				$\chi^2(3) = 7.747$	0.052
High school or less	12 (9.2)	3 (4.7)	9 (13.4)		
Some college	24 (18.3)	17 (26.6)	7 (10.4)		
4-year college	21 (16.0)	9 (14.1)	12 (17.9)		
Post-graduate	74 (56.5)	35 (54.7)	39 (58.2)		
Time since loss, $M(SD)$	6.23 (8.6)	5.89 (8.53)	6.56 (8.78)	t(129) = 0.441	0.660
Violent death, n (%)	18 (13.7)	10 (15.6)	8 (11.9)	$\chi^2(1) = 0.375$	0.540
Current MDD, n (%)	61 (46.6)	32 (50.0)	29 (43.3)	$\chi^2(1) = 0.593$	0.441
Current PTSD, n (%)	18 (13.7)	14 (21.9)	4 (6.0)	$\chi^2(1) = 6.986$	0.008
Person who died, $n(\%)$				$\chi^2(3) = 3.377$	0.337
Spouse/partner	61 (46.6)	28 (43.7)	33 (49.6)		
Parent	38 (29.0)	16 (25.0)	16 (32.8)		
Child	23 (17.6)	14 (21.9)	14 (13.4)		
Relative or friend	9 (6.8)	6 (9.4)	6 (4.5)		

Note. CGT = complicated grief treatment, IPT = interpersonal psychotherapy. Percentages have been rounded and might not add up to 100.

 $^{{\}it a \atop test was performed for collapsed groups "White vs. Black/Asian/Indigenous" due to small numbers of observations in some cells.}$

Table 2

Baseline and post-treatment scores for treatment groups on mediators and outcomes

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	CGT group	IPT group	Total
Mediator variables			
GRAQ			
week 1, $M(SD)$	23.94 (12.74)	23.90 (14.09)	23.92 (13.41)
	n = 63	n = 68	n = 131
week 8, $M(SD)$	20.59 (11.67)	21.02 (13.57)	20.81 (12.63)
	n = 61	n = 64	n = 125
week 16, M(SD)	15.90 (12.15)	18.55 (12.68)	17.23 (12.44)
	n = 62	n = 62	n = 124
TBQ			
week 1, M(SD)	53.90 (16.31)	54.93 (13.70)	54.45 (14.91)
	n = 50	n = 57	n = 107
week 8, M(SD)	47.98 (18.12)	49.47 (15.06)	48.75 (16.55)
	n = 50	n = 53	n = 103
week 16, M(SD)	39.45 (19.57)	44.65 (17.19)	42.12 (18.48)
	n = 51	n = 54	n = 105
Outcome variables			
CGI responder status week 20 (yes), $n(\%)$	45 (69.23)	23 (33.82)	68 (51.13)
	n = 65	n = 68	n = 133
ICG			
week 1, $M(SD)$	43.09 (10.01)	41.81 (10.55)	42.46 (10.27)
	n = 69	n = 67	n = 136
week 8, M(SD)	35.56 (12.11)	35.67 (11.26)	35.62 (11.64)
	n = 64	n = 66	n = 130
week 20, M(SD)	22.77 (13.07)	28.05 (11.49)	25.45 (12.53)
	n = 64	n = 66	n = 130
WSAS			
week 1, $M(SD)$	22.28 (10.76)	21.81 (9.99)	>22.04 (10.34)
	n = 68	n = 72	n = 140
week 8, M(SD)	17.62 (8.85)	18.75 (9.70)	18.19 (9.27)
	n = 65	n = 67	n = 132
week 20, $M(SD)$	10.70 (9.66)	14.02 (10.09)	12.40 (9.99)
	n = 63	n = 66	n = 129

Note. CGT = complicated grief treatment, IPT = interpersonal psychotherapy, GRAQ = Grief-related Avoidance Questionnaire, TBQ = Typical Beliefs Questionnaire, CGI = Clinical Global Impression Scale, ICG = Inventory of Complicated Grief, WSAS = Work and Social Adjustment Scale. *n* represents number of assessment completers.

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Table 3

Paths in the mediation model

	CGI	CGI responder status	tatus		PGD symptoms: ICG	9.5	Grief-1	Grief-related impairment: WSAS	WSAS
	toti	total effect (path c) $OR = 4.816^{***}$.*		total effect (path c) $B = 6.759$, $SE = 1.793^{***}$,) ****	В	total effect (path c) $B = 4.856$, $SE = 1.850^{**}$	**
Avoidance: GRAO ^a	path a : $B(SE)$	path <i>b</i> : OR	path c : OR	path a: B (SE)	$\begin{array}{l} \text{path } b. \\ B \ (SE) \end{array}$	$\begin{array}{l} \operatorname{path} c \ : \\ B \ (SE) \end{array}$	path a: B (SE)	$\begin{array}{c} \text{path } b: \\ B \ (SE) \end{array}$	path c : B (SE)
Y	3.72 (1.78)* 1.055*	1.055*	4.352 ***	4.01 (1.88)*	4.01 (1.88)* 0.455 (0.082)***	4.934 (1.618)**	4.86 (1.85)**	$4.934 \left(1.618\right)^{**} 4.86 \left(1.85\right)^{**} 0.382 \left(0.090\right)^{***} 3.368 \left(1.756\right)$	3.368 (1.756)
	toti	total effect (path c) OR = 5.558***	(2)		total effect (path c) B = 7.226, $SE = 1.830$ ***	***((;	В	total effect (path c) $B = 5.578, SE = 1.929$ **	**
Maladaptive grief-related cognitions: ${\it TBO}^b$	path a : $B(SE)$	path <i>b</i> : OR	path b : path c : OR OR	path a : $B(SE)$	$\begin{array}{l} \text{path } b. \\ B \ (SE) \end{array}$	path c : B (SE)	path a: B (SE)	path b : $B(SE)$	path c : B (SE)
,	6.55 (2.77)* 1.099***	1.099 ***	5.253 **	7.35 (2.86)*	7.35 (2.86) * 0.278 (0.062) ***	5.183 (1.720)**	7.07 (2.81)*	$5.183 (1.720)^{**} 7.07 (2.81)^{*} 0.265 (0.067)^{***}$	3.708 (1.851)*

Note. GRAQ = Grief-related Avoidance Questionnaire, TBQ = Typical Beliefs Questionnaire, CGI = Clinical Global Impression Scale, ICG = Inventory of Complicated Grief, WSAS = Work and Social Adjustment Scale.

 b Nrange = 89–94.

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

 $^{^{}a}$ Nrange = 108–114,