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Group-based compassion-focused therapy for prolonged grief symptoms in adults – Results from a randomized controlled trial

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ABSTRACT

Prolonged grief disorder is a debilitating condition, which affects approximately one out of ten who lose a loved one. While existing meta-analyses have synthesized evidence regarding the overall effect of psychological interventions for pathological grief across different types of psychotherapy, it remains clinically relevant to explore whether specific types of psychological interventions are efficacious in the treatment of grief. The present study investigated the efficacy of group-based Compassion-Focused Therapy (CFT) for adults who had lost a spouse or a parent, and who reported clinically relevant levels of prolonged grief symptoms (PGS) at 11 months post-loss. A total of 82 participants were randomized to the CFT group ($n = 42$) or the waitlist control ($n = 40$). Time × group interactions showed no statistically significant effects of the intervention on the primary outcome PGS at post-intervention or 6-month follow-up. Likewise, no statistically significant effects were found for any of the secondary outcomes or process variables, with the exception of posttraumatic stress symptoms and self-reassurance.

Taken together, in the present study group-based CFT did not emerge as an efficacious treatment for PGS. Possible explanations include that CFT may not target core maintaining processes in PGS and that the group-based, 8-week operationalization of CFT may be less than optimal.

1. Introduction

Losing a loved one is a universal experience that most people undergo during a lifetime (Holmes and Rahe, 1967). The majority of bereaved individuals go through a natural mourning process, coping adaptively with the loss over time (Jordan and Litz, 2014; Prigerson et al., 2009; Zisook and Shear, 2009). However, approximately 10% are estimated to develop pathological grief, namely symptoms of Prolonged Grief Disorder (PGD), and continue to suffer from the loss to an extent that interferes with daily functioning (Lundorff et al., 2017). PGD, which was recently accepted as a new diagnostic entity in the International Classification of Diseases 11th Revision (ICD-11) and is, in a slightly different version, planned to be included in the DSM 5 Text Revision, describes a syndrome of significant loss-related distress following the loss of a loved one (Maercker et al., 2013; Prigerson et al., 2009, 2021). Core symptoms of ICD-11 PGD include pervasive yearning or persistent preoccupation with the deceased accompanied with intense emotional pain (WHO 2022). In addition, the symptoms must (i) interfere with the person's ability to function in social, occupational, or other important contexts, (ii) have persisted for minimally 6 months, and (iii) clearly exceed social, cultural, or religious norms (WHO 2022). As PGD is a recent diagnosis, most existing research has investigated *symptoms* of PGD using self-report measures designed to capture prolonged grief symptoms (PGS). Numerous studies have found that PGS are associated with impaired familial, social, and occupational functioning (Boelen et al., 2019; Jordan and Litz, 2014; Prigerson et al., 2009, 2021; Shah and Meeks, 2012). Moreover, a recent meta-analysis reported high levels of psychiatric morbidity between PGS, post-traumatic stress symptoms

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(PTSS), depression, and anxiety (Komischke-Konnerup et al., 2021), and while the causality remains unclear, it points to the need for efficacious treatments.

1.1. Existing research

Given the negative consequences of PGS, numerous studies have investigated psychological treatments for PGS. Synthesizing the existing literature, the most recent meta-analyses report small to moderate positive effects of grief interventions in general (Johannsen et al., 2019; Maass et al., 2020; Wittouck et al., 2011). These meta-analysis pooled effects across different types of treatments, thus precluding conclusions regarding the effect of specific types of psychotherapy. In single randomized controlled trials especially Complicated Grief Therapy (Shear and Gribbin Bloom, 2017) and Cognitive Behavioral therapy for PGD (Boelen et al., 2007; Bryant et al., 2014) have been found efficacious for reducing symptoms of PGD. Yet clinically, it is relevant to explore not only whether psychological treatment in general appear efficacious for PGS, but also whether new and specific types of psychological interventions may be efficacious.

1.2. Compassion-focused therapy (CFT) for PGS

Over the last decade, there has been an increasing interest in studies that have investigated the positive effects of cultivating compassion (Beaumont and Martin, 2015). CFT is one such kind of psychotherapy, which was developed by Paul Gilbert and mainly has its roots in evolutionary psychology, neuropsychology, attachment theory, and Buddhism (Beaumont and Martin, 2015; Gilbert, 2014). CFT defines compassion as a "*sensitivity to suffering in self and others, with a commitment to try to alleviate and prevent it*" (Dalai Lama, 2001). Moreover, CFT conceptualizes compassion as three flows of interactions, namely (i) compassion directed from self to another, (ii) compassion directed from another to self, and (iii) compassion from self to self (Beaumont and Martin, 2015; Craig et al., 2020). A meta-analysis found that fear of compassion was more strongly related to reduced mental health in clinical populations compared to non-clinical populations (Kirby et al., 2019), and thus targeting these processes in therapy may be relevant. CFT aims to facilitate compassion in order to increase psychological well-being (Leaviss and Uttley, 2015). Specifically, CFT focuses on the 'two psychologies' of compassion, namely engagement with and alleviation of suffering (Gilbert, 2009). Engagement activities relate to the development of e.g., sensitivity towards suffering and distress tolerance, while alleviation of suffering relates to the development of skills such as attention training, compassionate imagery, and problem-solving (Craig et al., 2020; Gilbert, 2009).

According to CFT, humans have three emotion regulation systems which was developed during evolution to avoid harm (the threat system), seek out resources (the drive system), and take care of offspring (the soothing system) (Craig et al., 2020; Gilbert, 2014, 2009). The threat system is developed to react when the individual is in danger and motivates the fight/flight/freeze response together with emotions of fear, anger, and disgust (Craig et al., 2020; Gilbert, 2014, 2009). The drive system motivates striving and seeking out resources and is associated with emotions of joy and excitement (Craig et al., 2020; Gilbert, 2014, 2009). The soothing system is based on attachment experiences, motivates caregiving, and is characterized by a sense of calmness and affiliation (Craig et al., 2020; Gilbert, 2014, 2009). In therapy, the overall aim is to increase psychological well-being by balancing activity in the three emotion regulation systems, often with particular focus on up-regulating the soothing system (Craig et al., 2020; Leaviss and Uttley, 2015). The focus of CFT is facilitation of the three flows of compassion by means of practices such as 'soothing rhythm breathing', compassionate thinking and -imagery (Beaumont and Martin, 2015; Craig et al., 2020). During the last decade, the number of studies investigating the efficacy of CFT has increased. This growing body of literature has been synthesized in several systematic reviews, which generally conclude that CFT appears efficacious in treating a range of clinical populations, although the existing studies vary considerably in terms of study quality and content of the therapeutic intervention and -format (Beaumont and Martin, 2015; Craig et al., 2020; Leaviss and Uttley, 2015). The studies included in these reviews found significant effects of CFT on psychological distress such as symptoms of depression and anxiety in different groups including clients with trauma symptoms, brain injury, eating disorders, personality disorders, schizophrenia-spectrum disorder, chronic mental health problems and psychosis, eating disorders, depression, and opioid use disorder both within groups and during one-to-one therapy (Beaumont and Martin, 2015; Craig et al., 2020; Leaviss and Uttley, 2015).

PGD can, with its core symptoms of separation distress, be defined as an attachment related disorder (Maccallum and Bryant, 2013; WHO, 2022). Especially high levels of attachment anxiety is related to PGD (Meier et al., 2013). Without the deceased to soothe, encourage, and calm the bereaved person, the world can become a frightening place with no sense of an available secure base. The bereaved person needs to find a footing in the world without the deceased and new ways to soothe and calm themselves. As CFT aims to activate and enable the soothing system (i.e. attachment system) in order to balance emotion regulation and facilitate compassion (i.e. sensitivity towards suffering and an aim to reduce this suffering) from self to others, others to self, and self-to-self (Gilbert, 2014).Therefore, the focus and techniques used in CFT aimed at activating the soothing system might be particularly relevant in a bereaved population where the loved person (i.e., soothing source) has definitively gone. As bereaved individuals often feel desolate and lonely after their loss (Hansson and Stroebe, 2007), grief therapy delivered in a group format may be particularly relevant, as patients may discover that they are not alone in their suffering.

However, no studies are currently available on CFT for PGD.

1.3. Study aim

Taken together, the primary aim of the present study is to investigate the efficacy of group-based CFT for PGS after bereavement in adulthood. Specifically, we hypothesize that group-based CFT will be more efficacious in reducing PGS compared to a waitlist control. Moreover, we expect that other complicated grief reactions (e.g., depression, PTSS) as well as putative change processes (e.g., fear of compassion) will change in a positive direction following CFT compared to waitlist.

2. Methods

The present study was originally designed as a three-arm trial, comparing CFT and Mindfulness-Based Cognitive Therapy (MBCT) both with each other (non-inferiority) as well as with the waitlist control. Due to recruitment challenges, it was decided to exclude the MBCT-arm, and thus the present study was carried out as a two-arm RCT, investigating the efficacy of group-based CFT with a waitlist control group. The study was registered under Aarhus University's agreement with the Data Protection Agency (registration no.: 2015-57-0002), approved by the Regional Ethics Committee (registration no.: 1-10-72-176-7), and pre-registered on clinicaltrials.gov (NCT03384615).

2.1. Procedure

Participants were recruited from The Aarhus Bereavement study (TABstudy; NCT03049007), which is a longitudinal cohort study following participants over time, investigating natural and pathological grief reactions [psy.au.dk/grief]. For a detailed description of the recruitment procedures from the TABstudy, see Lundorff et al. (2021). In the TABstudy, participants who had lost either a spouse or a parent completed multiple questionnaires throughout the first year after the loss. Participants who scored ≥25 on the Prolonged Grief-13 (PG-13)

(Prigerson et al., 2009) at 11 months after the loss were asked if we could contact them and inform them about the intervention study. Participants who consented to be contacted, were screened for eligibility and received oral and written information by research assistants. If they agreed to participate, they were invited to an interview where they met the therapist, were introduced to the content of the CFT program, and could ask questions.

In the present RCT, participants completed a baseline questionnaire (T1), a post-intervention questionnaire (T2), a 3-month follow-up questionnaire (T3), and a 6-month follow-up (T4) questionnaire. The CFT group completed session-by-session measures, while the control group completed a mid-therapy questionnaire (session 4) only. All questionnaires were in Danish language. Questionnaires were collected using the Research Electronic Data Capture (REDcap) tool, which complies with the rules of the European General Data Protection Regulation (GDPR) (Harris et al., 2009), hosted by Aarhus University, Denmark. In case participants preferred paper-and-pen versions of the questionnaires, they were sent using postal service.

2.1.1. Participants

Participants were eligible for inclusion in the present study if they were (i) aged between 18 and 85 years at the time of death of the deceased; (ii) resident in the central region of Denmark, (iii) spouse or child of the deceased, and (iv) showed clinically significant grief symptoms at 11 months post-loss ($\geq$25 on the PG-13). Exclusion criteria were (i) insufficient ability to communicate in Danish, (ii) serious psychiatric disease hindering participation in the project (e.g., current psychosis), (iii) serious cognitive impairment (e.g., dementia), and (iv) current treatment for serious disease (e.g., cancer treatment).

2.1.2. Sample size and randomization

Sample size was calculated to detect an effect size (ES) of Cohen's *d*: 0.65, which is the median between a medium to large effect size. Using a pre-post repeated-measures design, a sample size of 2 × 38 would enable the detection of a difference of Cohen's *d*: 0.65 between CFT compared with the waitlist control group with a two-sided alpha of 0.05, a pre-post correlation (Rho) of 0.5, and a statistical power of 0.90. While this ES is larger than the pooled ESs found in previous meta-analyses, this was chosen as previous studies have generally found large effects of psychological interventions for PGS which includes cognitive techniques, with Cohen's *d* ranging from 0.80 to 1.36 compared with wait-list controls (Boelen et al., 2007; Rosner et al., 2015; Supiano and Luptak, 2014). On this background, an intervention with a small ES would be questionable in terms of clinical utility.

Randomization was conducted in a 1:1 allocation ratio. The randomization was carried out using the REDcap randomization module. The allocation sequence was generated by an external biostatistician not otherwise involved in the project. No other blinding procedures were applied as, given the nature of the psychological intervention and the control group, it was not possible to blind study participants or the therapists.

2.3. Measures

2.3.1. Sociodemographic information

Socio-demographic information was collected during the TABstudy at 2 months post loss (i.e., 9 months prior to enrollment in the present study), and included information regarding gender, age, and loss-related information (e.g., cause of death).

2.3.2. Primary outcome

The primary outcome was PGS, measured by a Danish version of the Prolonged Grief-13 (PG-13) (Prigerson et al., 2009) applied and validated in a Danish context (Lundorff et al., 2021; Vang et al., under review). The PG-13 consists of 13 items and measures symptoms of prolonged grief, using a 5-point Likert scale to indicate how disturbing or frequent a symptom is. The total score ranges from 11 to 55, with higher scores indicating more grief symptoms.

2.3.3. Secondary outcomes and process measures

Secondary outcomes included different types of complicated grief reactions that have been shown to co-occur, but not overlap completely, with PGS (Komischke-Konnerup et al., 2021). Depression was measured using the Center for Epidemiologic Studies Short Depression Scale (CES-D 10; Radloff, 1977). The CES-D consists of 10 items measuring depressive symptoms, using a 4-point Likert scale. The total score ranges from 0 to 30, with higher scores indicating more depression symptoms. PTSS were measured using the posttraumatic stress disorder (PTSD) Checklist for Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (PCL-5; Ashbaugh et al., 2016; Weathers et al., 2013), using a 5-point Likert scale. The total score ranges from 0 to 80, with higher scores indicating more PTSS. In the present study, we replaced the word 'stressful event' with 'the death' to capture bereavement-specific PTSS. Anxiety symptoms were measured using the 7-item Generalized Anxiety Disorder questionnaire (GAD-7; Spitzer et al., 2006). The total score ranges from 0-21, with higher scores indicating more anxiety symptoms. Well-being was measured using the WHO Well-Being Index (Bech et al., 2001; Bonsignore et al., 2001), consisting of 5 items. Items are rated on a 6-point Likert scale. Scores are standardized and converted to range from 0 to 100, where higher scores yield more well-being.

Participants in the CFT group were asked to report whether they conducted their home practice during the previous week (yes/no) at T2-T4. They were also asked to indicate their overall satisfaction with the group therapy on a 5-point Likert scale ("Very dissatisfied" to "Very satisfied") at T2-T4. For all scales validated Danish versions were used.

Of the putative change processes during therapy, we measured fear of compassion, self-criticism, experiential avoidance, and rumination. Fear of compassion was measured using the 38-item Fear of Compassion Scale (FCS; Gilbert et al., 2011), consisting of three subscales (i) fear of compassion from others (FCS-FO) (range: 0–52); (ii) fear of compassion towards others (FCS-TO) (range: 0–40), and (iii) fear of compassion towards self (i.e., self-compassion; FCS-SC) (range: 0–60). Items are rated on a 5-point Likert scale, with higher scores indicating more fear of compassion. Self-criticism was measured by the Forms of Self-Criticizing/Attachment and Self-Reassuring Scale (FSCRS; Gilbert et al., 2004). The FSCRS consists of 22 items, rated on a 5-point Likert scale. The FSCRS consists of three subscales (i) inadequate self (IA) (range: 0–36), (ii) hated self (HS) (range: 0–20), and (iii) reassuring self (RS) (range: 0–32). Higher scores on the IA and HS subscales reflect more self-criticism, while higher scores on the RS subscale indicate more self-reassurance. Back-translated Danish versions of these scales were used in the present study. Experiential avoidance was measured using the Brief Experiential Avoidance Questionnaire (BEAQ; Gámez et al., 2014). BEAQ consists of 15 items rated on a 6-point Likert scale (range: 15–90), with higher scores indicating more experiential avoidance. Finally, rumination was measured using the rumination subscale from the Rumination Reflection Questionnaire (RRQ; Trapnell and Campbell, 1999). The rumination subscale consists of 12 items, rated on a 5-point Likert scale (range: 12–60), with higher scores reflecting more rumination. Validated Danish versions of these scales were used.

2.4. The study conditions

2.4.1. Group-based CFT for PGS

The group-based CFT program for PGS was developed and manualized by the second author (CS). The groups in the present study were facilitated by the first (MJ), second (CS), and last (MOC) authors of the study. All therapists were psychologists, who received formal CFT-training and supervision during the data collection. The program consisted of 8 group sessions of 2 h and 15 min duration, including a 15-min break. Each session consisted of psychoeducation, an experiential exercise, group discussions, and introduction to home practice. See Table 1

Table 1
Overview of session content in group-based compassion-focused therapy (CFT) for grief.

Session	Content	Home practice
1. Introduction and goal setting	• Establishment of group rules • Psychoeducation: The dual process model of coping with bereavement • Psychoeducation: Tricky brain • Group discussion: Tricky brain and grief • Personal goal setting • Exercise: Mindfulness (attention training)	Daily mindfulness exercise
2. The three affect regulation systems and grief	• Repetition of group rules • Recap of homework • Psychoeducation: The three affect regulation systems • Group discussion: The three affect regulation systems and grief • Exercise: Soothing rhythm breathing	Daily soothing rhythm breathing exercise
3. Establishing a compassion focus and Compassion towards self	• Repetition of group rules • Recap of homework • Psychoeducation: What is compassion, compassion towards self • Group discussion: Fear of self-compassion, using the tricky brain to visualize yourself as an ideal helper • Exercise: Visualizing a safe place and yourself as an ideal helper	Daily soothing rhythm breathing exercise Visualizing a safe place and yourself as an ideal helper exercise min. 2 times
4. Compassion towards others	• Repetition of group rules • Recap of homework • Psychoeducation: Compassion towards others • Group discussion: Fear of compassion towards others • Exercise: Visualizing a safe place and yourself as an ideal helper for others	Daily soothing rhythm breathing exercise Visualizing a safe place and yourself as an ideal helper for others exercise min. 2 times
5. Recognizing the threat system and Compassion from others	• Repetition of group rules • Recap of homework • Psychoeducation: Understanding grief as a trigger of the threat system • Group discussion: Self-protective strategies • Exercise: Visualizing a safe place, yourself as an ideal helper, and receiving compassion from an ideal helper	Daily soothing rhythm breathing exercise Visualizing a safe place, yourself as an ideal helper, and receiving compassion from an ideal helper exercise min. 2 times
6. Self-criticism and compassion-based problem-solving	• Repetition of group rules • Recap of homework • Psychoeducation: Understanding self-criticism • Group discussion: Functional analysis of self-criticism and development of compassion-based problem-solving • Exercise: Visualizing yourself as an ideal helper, compassion towards self and self-criticism, compassion-based problem-solving	Daily soothing rhythm breathing exercise Visualizing a safe place and yourself as an ideal helper exercise min. 2 times Compassion-based problem-solving
7. Introducing multimind	• Repetition of group rules • Recap of homework • Psychoeducation: Understanding emotions and the different version of ourselves	Daily soothing rhythm breathing exercise Visualizing a safe place and your ideal helper exercise min. 2 times Compassion-based problem-solving
8. Future wishes and closing	• Group discussion: What do we need when we are sad, afraid, and angry? • Exercise: Visualizing as safe place and development of ideal helper • Repetition of group rules • Recap of homework • Psychoeducation: The three flows of compassion (recap) • Group discussion: Being human, grief, and what we need • Evaluation of personal goals • Exercise: Compassionate letter to self	

for a detailed overview of the session content.

2.4.2. Waitlist control group

The waitlist control group was not offered treatment or other types of support during the waiting period. Due to ethical considerations, there were no constraints regarding self-sought support and/or professional help. The waitlist control group was offered to participate in a CFT group upon completion of the data collection.

2.5. . Analytical strategy

All analyses were conducted using IBM SPSS Statistics v. 27 and v. 28 (IBM, Chicago, IL). The longitudinal effect of group (i.e., CFT versus Control) was analyzed using Mixed Linear Models (MLM). Compared to repeated measures ANOVA, this is a flexible and appropriate method for analysis of longitudinal data, where missing data is tolerated, and thus MLM does not unnecessarily compromise statistical power (Singer and Willett, 2003). All models were run using maximum likelihood estimation and were based on the intent to treat sample. Data was nested in two levels, with Time at level 1 nested within Person at level 2. Time was entered as days since the Baseline (T1) assessment. Fixed effects were estimated for intercept, time, group, and time × group interaction. Random intercept and random slope were added in a stepwise fashion one by one, and were kept if fit improved as evaluated by AIC (Singer and Willett, 2003).

An intervention effect was seen if the interaction between time and group was significant at $p<.05$. Effects sizes were expressed using Cohen's *d*, calculated from the F test using the formula $2\cdot\sqrt{\frac{F}{df}}$.

3. Results

3.1. Participant characteristics

A total of 352 participants scored ≥ 25 on the PG-13, corresponding to 32.4% of all screened participants. Of the 352, 36.4% did not wish to be contacted regarding the present study. Of the remaining 224 eligible participants, a total of $N = 82$ participants agreed to participate and were randomized to the CFT ($n = 42$) and waitlist control group ($n = 40$). See Fig. 1 for a detailed study diagram.

Participant characteristics are summarized in Table 2. The mean age of the sample was 60.5 years (SD: 13.4; range: 23–83). Of the 82 participants, 82.9% was a spouse to the deceased. In the spousal sample, the mean number of years of cohabitation was 36.9 years (SD: 13.8; range: 2–62). Cancer was the most common cause of death (54.9%). The majority of the sample was female (67.1%). At T1, 56.1% of the participants reported that they had received some sort of psychosocial support since the loss (i.e., from psychologist, psychiatrist, counselling, social support groups outside the research project), with no difference between the

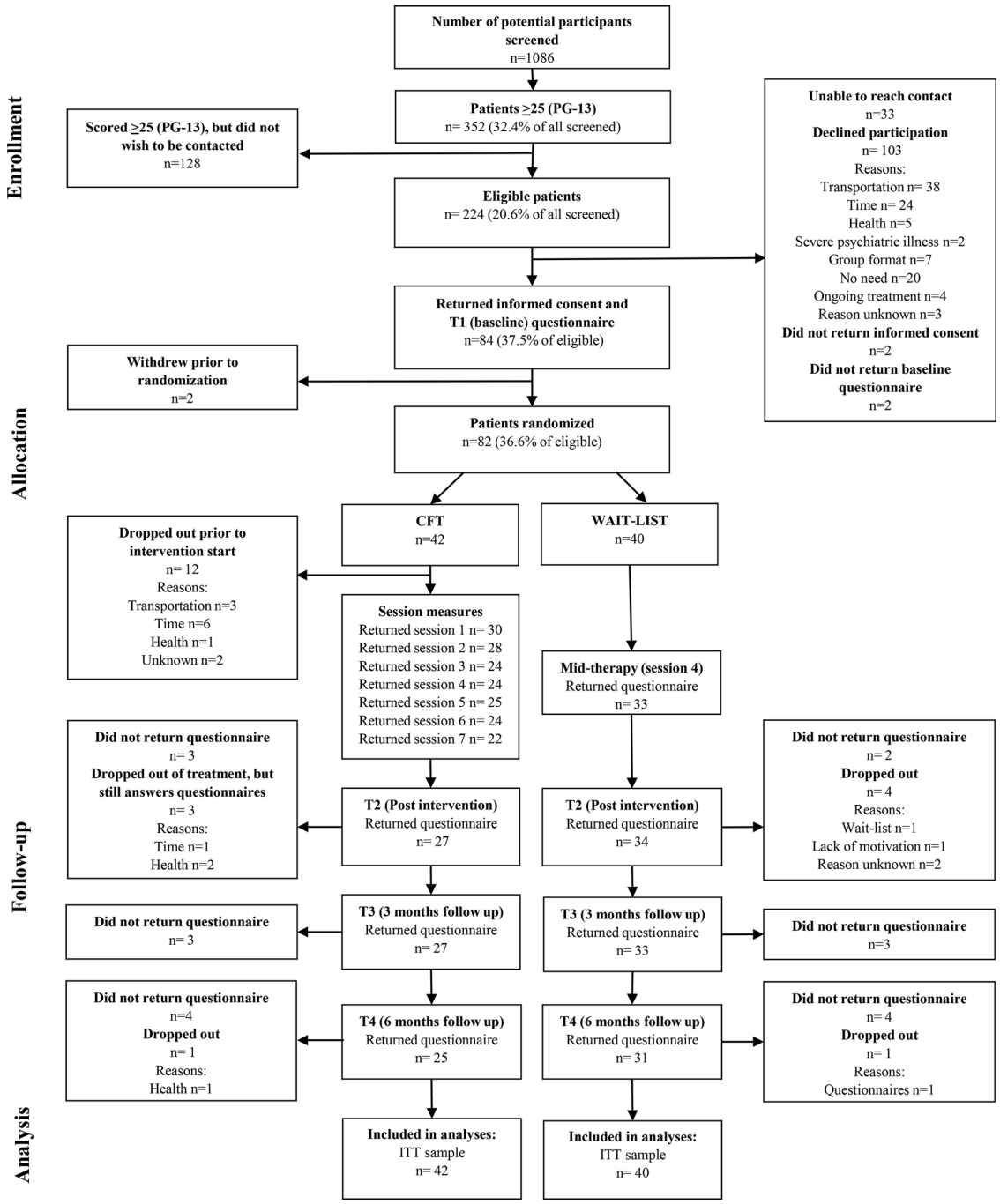

Fig. 1. Study flow diagram.

intervention and control group (p = .34). No psychosocial support except for the CFT program was delivered within the research project. At T2, 15.0% of the participants in the waitlist control group had received psychosocial support, decreasing to 12.5% and 7.5% at T3 and T4, respectively.

Of the 82 participants, 4.9% at T2, 7.3% at T3, 9.8% at T4 did not return questionnaires (i.e., non-returners). A total of 25.6% (38.1% in the CFT group; 12.5% in the control group; $p = 0.008$) proclaimed that they no longer wished to participate in the study (i.e., dropouts) during the study period (T1-T4).

We tested whether dropouts differed from study completers on socio-demographics, loss-related characteristics, as well as primary and secondary outcomes, using chi square and t tests. Dropouts only differed significantly from study completers regarding higher anxiety scores (p = 0.03), just like a larger proportion of dropouts were female ($p = 0.008$). While we did not find that dropouts and study completers differed on PGS severity, we also tested whether baseline PGS predicted dropout during the study, which was not found to be the case (Odds Ratio: 1.03, p = .041).

3.2. *Efficacy of CFT on the primary outcome*

The mean level of satisfaction with the CFT program at T2 was 4.2 (SD: 1.25; range: 1–5). The mean number of sessions attended was 6. On average, the participants in the CFT group conducted home practices 2.56 days (SD: 1.19) per week over the 6-month follow-up period.

Results are summarized in Table 3. No statistically significant time × group interactions were found for PGS at post-intervention (T1-T2;

Table 2
Participant characteristics.

Characteristic[a]	Total sample (*n* = 82)	CFT (*n* = 42)	Waitlist (*n* = 40)
Age, mean (SD)	60.49 (13.64)	61.40 (13.62)	59.53 (13.76)
Gender n (%)			
Female	55 (67.1)	30 (71.4)	25 (62.5)
Male	23 (32.9)	12 (28.6)	15 (37.5)
Children, n (%)			
Yes	66 (80.5)	33 (78.6)	33 (82.5)
No	12 (14.6)	9 (21.4)	6 (15.0)
Education[b], n (%)			
Primary education	37 (45.0)	21 (50.0)	16 (40.0)
Secondary education	42 (51.3)	19 (45.2)	23 (57.5)
Source of income[c], n (%)			
Salary	26 (31.7)	12 (28.6)	14 (35.0)
Pension	38 (46.3)	23 (54.8)	15 (37.5)
Out of employment	7 (8.4)	3 (7.1)	4 (10.0)
Other	8 (9.8)	3 (7.1)	5 (12.5)
Relationship to the deceased, n (%)			
Spouse	68 (82.9)	35 (83.3)	33 (82.5)
Child	14 (17.1)	7 (16.7)	7 (17.5)
Years of cohabitation[d], mean (SD)	36.86 (13.81)	36.12 (14.05)	37.72 (13.71)
Illness prior to death, n (%)			
Yes	56 (68.3)	31 (73.8)	25 (62.5)
No	23 (28.0)	9 (21.4)	14 (35.0)
Cause of death, n (%)			
Cancer	45 (54.9)	21 (50.0)	24 (60.0)
Other (e.g., cardiovascular disease, old age, dementia)	20 (24.4)	12 (28.6)	8 (20.0)
Time since loss (months), mean (SD)	11.06 (0.45)	11.11 (0.43)	11.01 (0.47)
Previous use of psychosocial support[e] at T1, n (%)	46 (56.1%)	26 (61.9%)	20 (50.0%)

Notes
[a] Numbers may not add up to 100% due to missing observations
[b] Educational attainment was categorized as (1) primary education (primary school, high school, vocational training) and (2) secondary education (college, university)
[c] Source of income was categorized as (1) salary for those holding a job, (2) pension for those on early voluntary retirement and those receiving self-financed or government-assisted pension, and (3) out of employment (including unemployment benefits, government-sponsored support, social security payments due to sickness)
[d] Only spousal sample
[e] Psychosocial support included contacts with a psychiatrist, psychologist, counselling (e.g., patient organizations), and social support groups

Cohen's *d*: .29, $p = 0.24$) or over time (T1-T4; Cohen's *d*: .13, $p = 0.59$), with correspondingly small effect sizes. The analyses were re-run including the session-by-session data for the primary outcome PGS, which did not substantially change the results (data not otherwise shown). As the analyses did not reveal a statistically significant effect of CFT on the primary outcome (i.e., PGS), no mediator or moderator analyses were conducted.

3.3. Efficacy of CFT on secondary outcomes and process variables

There was no statistically significant time × group interaction for any of the secondary outcomes over time (T1-T4) (see Table 3). The only exception was for PTSS where CFT showed a statistically significant positive effect compared with the waitlist control group ($p = .04$), corresponding to a medium size effect (Cohens *d*: 0.49).

No statistically time × group interactions were found for the proposed process variables at post-intervention (T2), with the exception of RA which yielded a large effect size (Cohen's *d*: 0.81, $p < 0.001$) (Table 3).

4. Discussion

To our knowledge, the present study is the first RCT to test the efficacy of group-based CFT for PGS in a bereaved adult population. Based on our results, we did not find support for CFT as an efficacious psychological treatment of grief after losing a spouse or a parent in adulthood. While statistically significant effects were found for PTSS and the process variable 'reassuring self', these outcomes were secondary, and given the number of analyses conducted without correcting for type-I error, these findings appear less than robust.

Our results are not in line with existing meta-analyses finding small to medium effects of psychological treatments for PGS *across* different therapeutic approaches (Johannsen et al., 2019; Wittouck et al., 2011). Of relevance, the meta-analysis by Johannsen et al. (2019), found indications of publication bias. Importantly, this finding suggests there may be a bias towards studies reporting null-findings, which may not be as easily published, possibly leading to overestimated effects.

One possible explanation for our results is that CFT may not have adequately targeted previously proposed core processes in pathological grief in the ways as expected when designing the study. Proposed core maintaining mechanisms in prolonged grief disorder are i) the inability to integrate the reality of the loss in autobiographical memory (i.e., lack of acceptance of the loss), ii) avoidance behavior (e.g., social withdrawal, avoidance of situations that trigger feelings about the loss), and iii) negative loss-related cognitions (e.g., catastrophic misinterpretations) (e.g., Boelen et al., 2006; Boelen and Lenferink, 2020). This cognitive-behavioral model has received some empirical support. Studies have shown that negative loss-related cognitions and avoidance behaviors are related to complicated grief reactions, including PGS (e.g., Boelen et al., 2003a, 2003b; Boelen and Lenferink, 2020; Boelen and Van Den Hout, 2008). This literature suggests that the maintaining mechanisms as proposed in the model may be specifically well targeted by cognitive-behavioral interventions. Indeed, studies suggest that Cognitive Behavioral Therapy (CBT), and in particular exposure-based approaches, which are congruent with the cognitive-behavioral model, seem particularly efficacious in reducing PGS, yielding large effect sizes (Boelen et al., 2007; Bryant et al., 2014; Rosner et al., 2015). Likewise, Complicated Grief Treatment (CGT; Shear et al., 2005), which also includes cognitive treatment components, found large, positive effects of CGT on PGS (Shear et al., 2016; Supiano and Luptak, 2014). In our study, the CFT program focused mainly on the three flows of compassion and on self-criticism. Correspondingly, we did not find a significant change in experiential avoidance, an indicator of exposure (Cohen's *d*: .05, $p = 0.83$). In contrast, our secondary analyses showed a large effect of the intervention on the process measure 'reassuring self'. However, when we conducted an explorative correlation analysis between PGS and 'reassuring self' at baseline, we found that they were not significantly correlated (r=-0.17, $p = 0.15$), further suggesting that the ability to self-reassure might not be a key mechanism in prolonged grief.

Another possible explanation for our finding relates to the 'dose' and delivery format of the CFT program. A systematic review published after initiation of the present study found that the efficacy of CFT was associated with the number of treatment sessions, namely that minimally 12 sessions seemed to be required to achieve positive change across various populations (Craig et al., 2020). As such, it may be that our treatment program could have benefited from increasing the 'dose' (i.e., number of sessions). Of note, established CBT (e.g., Boelen et al., 2007; Bryant et al., 2014) and CGT (e.g., Shear et al., 2016) programs for pathological grief consists of ≥ 12 sessions, further indicating that a higher number of sessions may be required in the treatment of PGS. Originally, this study was designed as a three-armed trial comparing MBCT and CFT for PGS with a randomized control group. MBCT is an 8-week program (Segal et al., 2013) that has shown promising effects for complicated grief reactions in broader sense, i.e., not restricted to PGD, but also loss-related depression (O'Connor et al., 2014). Therefore, we developed and pilot tested our CFT program to match this 8-session format. Due to

Table 3
Descriptives and main effect results.

	Baseline (T1)		Postintervention (T2)		3-month follow-up (T3)		6-month follow-up (T4)		Time × Group Interaction *F, P* (Cohen's *d*)[a,b]
	CFT	Control	CFT	Control	CFT	Control	CFT	Control	
Primary outcome	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	*Mean (SD) [N]*	
Prolonged grief symptoms (PG-13)	32.12 (6.77) [42]	30.84 (7.64) [40]	29.41 (6.98) [27]	29.63 (7.67) [34]	29.02 (7.60) [27]	28.54 (7.33) [32]	28.58 (7.71) [25]	28.24 (7.41) [31]	.3, .589 (.13)[c]
Secondary outcomes[d]									
Depression (CES-D)	14.44 (4.27) [41]	13.16 (5.83) [37]	11.54 (5.73) [27]	12.19 (5.55) [34]	10.65 (5.25) [26]	12.27 (5.51) [32]	11.90 (6.15) [25]	10.95 (6.05) [30]	1.3, .252 (.30)
Anxiety (GAD-7)	8.56 (4.35) [41]	6.79 (4.62) [38]	7.07 (5.52) [27]	6.41 (4.76) [34]	5.58 (3.81) [26]	5.84 (4.55) [32]	6.07 (3.21) [25]	5.23 (3.59) [30]	2.1, .145 (.21)
Posttraumatic stress symptoms (PCL)	25.58 (11.05) [40]	21.42 (11.31) [38]	18.53 (10.77) [27]	19.18 (11.62) [33]	17.07 (10.16) [26]	20.06 (11.88) [30]	17.42 (10.72) [25]	17.30 (9.53) [28]	**4.4, .040 (.49)**
Well-being (WHO-5)	40.50 (17.69) [40]	44.51 (22.12) [39]	50.07 (21.91) [27]	45.53 (23.49) [34]	49.38 (23.73) [26]	47.55 (23.81) [33]	48.00 (24.85) [25]	47.59 (22.82) [30]	1.5, .218 (.18)
Process variables[e]									
Fear of compassion to others (FCS-TO)	9.52 (9.05) [42]	9.03 (7.14) [39]	7.64 (6.58) [26]	9.88 (8.71) [33]	7.93 (7.62) [26]	9.26 (9.18) [33]	7.08 (6.40) [25]	7.00 (7.27) [30]	2.9, .10 (.44)
Fear of compassion from others (FCS-FO)	11.93 (11.32) [39]	12.05 (11.67) [40]	10.08 (9.88) [26]	12.25 (11.66) [33]	9.67 (9.80) [26]	12.52 (13.30) [33]	8.72 (6.67) [25]	9.06 (9.94) [30]	.00, .84 (.05)
Fear of self-compassion (FSC-SC)	17.48 (11.51) [39]	14.88 (13.34) [40]	13.95 (11.93) [26]	15.45 (12.97) [33]	8.79 (8.40) [26]	14.64 (14.39) [31]	9.82 (8.41) [25]	12.84 (13.75) [30]	2.7, .10 (.41)
Self-criticism; inadequate self (FSCRS-IS)	14.20 (5.72) [39]	13.70 (7.52) [38]	12.07 (6.57) [27]	12.91 (9.16) [33]	11.00 (7.02) [25]	14.69 (8.74) [32]	11.78 (5.29) [25]	11.62 (8.36) [29]	1.4, .24 (.31)
Self-criticism; hated self (FSCRS-HS)	4.00 (3.32) [39]	4.68 (3.99) [38]	3.20 (2.94) [27]	4.08 (5.40) [33]	3.78 (4.77) [25]	4.75 (4.49) [32]	3.72 (3.37) [25]	4.34 (4.27) [29]	.40, .55 (.15)
Self-criticism; reassuring self (FSCRS-RS)	13.29 (4.75) [39]	13.99 (6.38)[38]	17.09 (5.69) [27]	13.81 (6.94) [33]	15.16 (7.00) [25]	13.08 (6.47) [32]	15.40 (5.02) [25]	14.34 (6.60) [29]	**11.4, .001 (.81)**
Rumination (RRS)	39.18 (7.51) [40]	40.00 (8.65) [38]	38.00 (8.17) [27]	38.67 (11.64) [33]	36.31 (7.36) [25]	39.23 (10.28) [31]	38.17 (6.49) [25]	37.42 (11.60) [28]	.00, .94 (.02)
Experiential avoidance (BEAQ)	46.83 (10.48) [40]	50.85 (13.80) [40]	44.99 (13.90) [27]	49.96 (13.62) [33]	44.00 (14.24) [24]	48.92 (12.07) [31]	45,78 (13.61 [25]	46,89 (13.50) [28]	.05, .83 (.05)

Notes
Abbreviations: PG-13: the Prolonged Grief-13 questionnaire; CES-D: the Center for Epidemiologic Studies Short Depression Scale; PCL: the PTSD checklist - Civilian Version; GAD-7: the Generalized Anxiety Disorder-7 questionnaire; WHO-5: the WHO Well-Being Index; FCS-FO: the fear of compassion received from others subscale; FCS-TO: the fear of compassion towards others subscale; FCS-SC: the fear of compassion towards self subscale; FSCRS-IS: the Forms of Self-Criticizing/Attachment and Self-Reassuring Inadequate Self subscale; FSCRS-HS: the Forms of Self-Criticizing/Attachment and Self-Reassuring Hated Self subscale; FSCRS-RS: the Forms of Self-Criticizing/Attachment and Self-Reassuring Reassuring Self subscale; RRS: the Rumination Reflection Questionnaire; BEAQ: the Brief Experiential Avoidance Questionnaire
[a] Statistically significant results ($p < .05$) are highlighted in boldface.
[b] All analyses were run using random intercept only, with the exception of the analyses including PGS, depression, and PTSS which were run using random intercept and random slope
[c] Test statistics from the analysis including T1-T4. The result from T1-T2 yielded the following result: F = 1.4, $p = .24$, Cohens $d = .29$.
[d] The analyses for the secondary outcomes were calculated over time (T1-T4)
[e] The analyses for the process variables were calculated from pre- to postintervention (T1-T2)

recruitment difficulties, it was decided to reduce the design to a two-armed randomized controlled trial just before the trial started, comparing CFT and a waitlist control group in order to test whether CFT for grief was efficacious.

Craig et al. (2020) also found more empirical support for group-based CFT compared to individually delivered CFT. This finding is, however, in contrast with a meta-analysis focusing specifically on bereaved populations (Maass et al., 2020). Maass et al. (2020) concluded that the current evidence for efficacious group-based grief interventions is weak with a small effect size at post-intervention and a statistically non-significant effect at follow-up. While we hypothesized *a priori* that a group-based format would benefit the bereaved adults, recent work suggests that this may in fact not be the case.

While we did not find a statistically significant effect of overall CFT, the RCT design used in the present study precludes us from concluding whether individual CFT components in the program were efficacious. In RCTs, treatment components are delivered simultaneously in 'intervention packages', as in the present study. As a consequence, the effect of *individual* treatment components (e.g., psychoeducation, attention training) cannot be singled out (Collins, 2018). As the RCT is not designed to inform about the effects of individual treatment components (Collins, 2018), it remains unclear whether some of the individual components in our CFT treatment program have positive or detrimental effects on PGS, and whether the different treatment components may interact in a positive or negative direction. In future studies, it could be relevant to disentangle the specific efficacy of individual, core CFT components, using methodologies that support that aim, such as the Multiphase Optimization Strategy (MOST) (Collins, 2018).

4.1. Strengths and limitations

Strengths of the present study include a randomized controlled design, with participants recruited from a large representative cohort (Lundorff et al., 2021). Moreover, participants were recruited based on elevated PGS and were 11 months post-loss, thereby meeting the duration criterion as defined in the ICD-11 PGD. Also, we included follow-up assessments to assess the effect of CFT over time. Some limitations should be noted as well.

First, the dropout rate of the study was relatively high, particularly in the intervention group. This may suggest that the intervention in its current form had low acceptability for the participants. Importantly, however, satisfaction with the intervention was high, baseline symptom severity did not predict dropout from the study, and dropouts did not differ substantially from study completers. Second, the majority of participants in the present study had lost a spouse and a smaller proportion of the present sample were adult children to the deceased, and as such, the results cannot be generalized to other types of relationships. Likewise, the majority of the sample had lost their spouse or parent to cancer, implicating that no conclusions can be made regarding the efficacy of CFT for other types of losses. In fact, our results tentatively indicated that CFT may reduce PTSS, which is often seen after violent losses (Djelantik et al., 2020; Kristensen et al., 2009; Raphael et al., 2013). Finally, we calculated statistical power based on a medium-to-large effect size. While this may be considered slightly optimistic given the effect sizes generally seen in psychotherapy research for e.g., depression (Cuijpers et al., 2008), well-established treatment regimens have been documented within the bereavement literature (i.e., CGT and CBT), showing medium-to-large effect sizes. As such, we believe that the effect sizes of newly developed therapies should be benchmarked against current gold standard therapies.

5. Conclusions

PGS are associated with a range of negative outcomes, underlining the need for efficacious treatments. The present study is the first to investigate the efficacy of CFT for PGS in adults. Based on our findings, CFT did not emerge as an efficacious treatment for PGS. Possible explanations include that CFT may not target core maintaining processes in pathological grief and that the group-based, 8-week operationalization of CFT may be less than optimal. Given the design of the present study, however, the efficacy of individual CFT components (e.g., psychoeducation, attention training) remains unclear.

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Author declaration

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Declaration of Competing Interest

None to declare.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2022.114683.

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