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Self-guided online treatment of disturbed grief, posttraumatic stress, and depression in adults bereaved during the COVID-19 pandemic: A randomized controlled trial

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ABSTRACT

Objective: This randomized-waitlist controlled trial is the first study examining short-term effects of a self-guided online grief-specific cognitive behavioral therapy (CBT) in reducing early persistent complex bereavement disorder (PCBD), posttraumatic stress disorder (PTSD), and depression symptoms in adults bereaved during the COVID-19 pandemic.

Method: Sixty-five Dutch adults, bereaved at least three months earlier during the pandemic, with clinically-relevant PCBD, PTSD, and/or depression symptoms, were allocated to a treatment (n = 32) or waitlist condition (n = 33). Telephone interviews were conducted to assess PCBD, PTSD, and depression symptoms (using validated instruments) at baseline, post-treatment, and post-waiting period. Participants received an eight-week self-guided online grief-specific CBT including exposure, cognitive restructuring, and behavioral activation assignments. Analyses of covariance were performed.

Results: Intention-to-treat analyses indicated that people in the intervention condition showed significantly lower PCBD ($d = 0.90$), PTSD ($d = 0.71$), and depression ($d = 0.57$) symptom-levels post-treatment relative to waitlist controls post-waiting, while taking baseline symptom-levels and use of professional psychological co-intervention into account.

Conclusions: The online CBT proved to be an effective intervention, reducing PCBD, PTSD, and depression symptoms. Pending replication of these findings, early online interventions may be widely implemented in practice to improve treatments for distressed bereaved people.

1. Introduction

On March 11, 2020, the World Health Organization (WHO) assessed the outbreak of coronavirus disease 2019 (COVID-19) as a pandemic. As per April 5, 2022, COVID-19 has caused more than 6,1 million deaths worldwide (World Health Organization, 2022a). In the Netherlands, there are more than 22,000 registered COVID-19 deaths at that time (World Health Organization, 2022b). After losing a loved one, bereaved people commonly experience acute grief reactions involving separation distress (e.g., longing for the person who died), and emotional (e.g., feeling sad), cognitive (e.g., thoughts about self-blame), and behavioral (e.g., avoidance of places, objects, or thoughts related to the loss) symptoms. The majority of bereaved people is able to integrate the loss into their lives and do not need professional help during the grieving process (Bonanno & Malgaroli, 2020; Lenferink et al., 2020a; Nielsen et al., 2019). However, about 10% of people bereaved by a natural cause (Lundorff et al., 2017) and 50% of people bereaved by an unnatural cause (Djelantik et al., 2020) develop persistent and intense grief symptoms associated with significant distress and disturbance of daily functioning.

Persistently distressing and disabling grief symptoms are referred to as persistent complex bereavement disorder (PCBD) in the fifth edition

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of the Diagnostic and Statistical manual of Mental disorders (DSM-5; APA, 2013). PCBD is included in section III of the DSM-5 as a disorder for further study. PCBD can be diagnosed if one experiences persistent yearning for the deceased, symptoms of reactive distress and social/-identity disruption, after the loss of a loved one at least twelve months earlier. In the recent text-revision of the DSM-5 (DSM-5-TR; APA, 2022), PCBD is replaced by prolonged grief disorder (PGD) and included in the main text (Section II). A diagnosis of PGD as per DSM-5-TR may apply if someone experiences separation distress, and multiple accompanying distressing symptoms (e.g., intense loneliness, anger) at least twelve months post-loss. Furthermore, a diagnosis of PGD is included in the eleventh edition of the International Classification of Diseases (ICD-11; World Health Organization, 2018). PGD as per ICD-11 is characterized by distressing and disabling longing for the deceased and/or preoccupation with the deceased, combined with feelings of guilt, anger, and other symptoms reflecting intense emotional pain, after the loss of a loved one at least six months earlier. In this study, the term "disturbed grief" is used as an umbrella term for disordered grief reactions. Although disturbed grief is often associated with symptoms of post-traumatic stress disorder (PTSD) and depression (Komischke-Konnerup et al., 2021), studies showed that these disorders are distinct (Boelen et al., 2010; Djelantik et al., 2017; Lenferink et al., 2017, 2020a, 2021; Malgaroli et al., 2018; O'Connor et al., 2010).

Losing a loved one during the COVID-19 pandemic is considered a potentially traumatic loss, likely resulting in high rates of symptoms of disturbed grief, PTSD, and depression (Eisma et al., 2020; Kokou-Kpolou et al., 2020). Indeed, preliminary results of several studies have confirmed that the prevalence of disturbed grief is relatively high in people (recently) bereaved during the COVID-19 pandemic (Breen et al., 2022), compared to people bereaved before the COVID-19 pandemic (Downar et al., 2022; Eisma & Tamminga, 2020). The elevated risk of psychopathology following the loss of a loved one during the COVID-19 pandemic might be explained by several stressors that may apply to all people bereaved during the pandemic, including being unable to engage in traditional grieving rituals and/or social deprivation due to quarantine measures (cf., Boelen et al., 2006; Brooks et al., 2020; Cao et al., 2020; Lobb et al., 2010). Some potential stressors are specific to COVID-19 deaths, such as experiencing multiple deaths in a short period of time and/or feeling responsible for having infected the deceased (cf., Erlangsen et al., 2017; Hengst et al., 2018).

Given the potentially traumatic characteristics of deaths during the COVID-19 pandemic and the large numbers of deceased, it is likely that there is a growing need of bereavement care (Eisma et al., 2020; Kokou-Kpolou et al., 2020). Face-to-face cognitive behavioral therapy (CBT) is the treatment of choice for bereaved people with disturbed grief symptoms (Boelen & van den Bout, 2017; Boelen, Lenferink, & Spuij, 2021; Boelen & Smid, 2017a; Doering & Eisma, 2016; Rosner et al., 2015; Shear et al., 2005). This treatment encompasses exposure and behavioral activation to decrease avoidance behaviors, and cognitive restructuring to alter dysfunctional cognitions.

In recent years, an accumulating number of studies has demonstrated the effectiveness of online CBT for various mental health conditions, with treatment effects equivalent to face-to-face CBT (Carlbring et al., 2018). Online CBT for bereaved people might offer important benefits over face-to-face CBT for several reasons. First, online CBT may overcome transportation problems or difficulties in scheduling therapy sessions (Lenferink et al., 2020b; Lichtenthal et al., 2015). Second, online CBT is more affordable, making treatment accessible to bereaved people who need professional grief support (Boelen, Eisma, et al., 2021). Third, online treatment may decrease stigma and might therefore decrease barriers for seeking treatment (Wagner et al., 2020).

Yet, research into the effectiveness of online CBT for bereaved people is scarce. To date, only five randomized controlled trials (RCTs) examined the effectiveness of online grief-specific CBT (Eisma et al., 2015; Kersting et al., 2013; Litz et al., 2014; Treml et al., 2021; Wagner et al., 2006), but several gaps in the literature remain. In particular, these studies were exclusively aimed at recently (Litz et al., 2014), suicidally (Treml et al., 2021), or perinatally bereaved persons (Kersting et al., 2013), relied on relatively small samples (Eisma et al., 2015; Wagner et al., 2006), or had significant dropout rates (Eisma et al., 2015). Moreover, separate components of CBT were offered (e.g., providing exposure or behavioral activation only), restricting generalizability of the studies (Eisma et al., 2015; Kersting et al., 2013; Treml et al., 2021; Wagner et al., 2006). Hence, it is imperative that more research is conducted into the effectiveness of online grief-specific CBT to improve treatment options for people at risk for persistent distress following the death of a loved one during the COVID-19 pandemic.

Currently available grief-specific intervention studies are mostly focused on people who lost loved ones on average 36 months ago (Johannsen et al., 2019). Thus, little research is available into the effectiveness of early interventions to prevent disturbed grief symptoms. Offering early treatments for disturbed grief is relevant for several reasons. First, research has shown that acute grief, PTSD, and depression symptoms in the early months after a loss are one of the strongest predictors for clinically relevant disturbed grief, PTSD, and depression levels later in time (Boelen & Lenferink, 2020, 2022; Bonanno & Malgaroli, 2020; Kristensen et al., 2020; Lenferink et al., 2020a; Nielsen et al., 2019; Sveen et al., 2018). For instance, Boelen and Lenferink (2022) found that people who met (versus did not meet) probable PGD criteria 4 months post-loss were 32 times more likely to meet probable PGD criteria 1 year later. Second, several studies indicated that changes in disturbed grief symptoms precede changes in PTSD and depression symptoms following bereavement and not vice versa (Djelantik et al., 2018; Lenferink et al., 2019; O'Connor et al., 2015; but see Glad et al., 2022). Lastly, Litz et al. (2014) showed that an intervention for bereaved people who experienced clinically relevant disturbed grief at three to six months post-loss yielded significant reductions in disturbed grief at later points in time. Altogether, these findings suggest the relevance of an early intervention targeted at disturbed grief symptoms, which may ameliorate considerable grief-related distress and functional impairment in the early months after a loss.

The aim of the present study was to evaluate the short-term effectiveness of an early self-guided online CBT compared to a waitlist control condition in reducing disturbed grief, PTSD, and depression symptoms for adults who lost a loved one during the COVID-19 pandemic. This study is part of an ongoing study consisting of two parts; the study protocol is described in (Reitsma et al., 2021). In the current study, the results of part 1 are presented. In part 2, we will examine the short-term and long-term effectiveness of guided grief-specific online CBT (vs. self-guided online grief-specific CBT (from part 1)) in reducing disturbed grief, PTSD, and depression symptoms in adults bereaved during the COVID-19 pandemic.

In line with the study protocol, we expected that people in the self-guided online CBT condition show lower symptom-levels of disturbed grief, PTSD, and depression immediately after treatment compared to people allocated to the waitlist control condition post-waiting period, while taking baseline symptom-levels and the use of professional psychological co-intervention into account.

2. Method

2.1. Design

A mono-center RCT was conducted in the Netherlands. Eligible participants were randomized to the online CBT condition or waitlist control condition using a random-number service (www.random.org). A blocking randomization procedure was carried out by the first author. Participants were allocated using a 1:1 ratio. Telephone interviews were conducted by the first author at pre-treatment or pre-waiting period (T1), and post-treatment or post-waiting period (T2). Supplementary Fig. 1 illustrates the design of the study. The present study was approved by the Medical Ethics Committee at the University Medical Center

Utrecht in the Netherlands (NL74518.041.20) and has been registered in the Netherlands Trial Register (NL8993).

2.2. Participants

The sample consisted of Dutch speaking adults who lost a spouse, family member, or friend due to various causes, at least three months earlier during the COVID-19 pandemic. This three-month time criterion was based on research by Litz et al. (2014), which demonstrated the effectiveness of an early intervention for clinically relevant grief symptoms. An additional inclusion criterion was experiencing clinically relevant early PCBD, PTSD, and/or depression symptom-levels based on telephone interviews. People were excluded from the study when they did not master Dutch, had no Internet access, had ever been diagnosed with a psychotic disorder (i.e., assessed with one item during T1), and/or reported high suicidal ideation. Suicidal ideation was assessed with one item during T1 (i.e., "Over the past two weeks, how often have you been bothered by thoughts that you would be better off dead, or thoughts of hurting yourself in some way?"). In case a participant answered 1 ("several days"), 2 ("more than half the days"), or 3 ("nearly every day"), a suicide protocol was conducted that included follow-up questions, such as: "Over the past four weeks, have you considered ending your life?" and "Over the past four weeks, have you made a plan to end your life?". Participants were recruited through advertisements on social media and Google Ads, via media attention, and a website specifically created for this study (www.rouwencorona.nl). The inclusion period was between October 2020 and February 2021.

2.3. Procedure

After informed consent was obtained, T1 was scheduled and participants were screened for eligibility. Next, eligible participants were randomized to the online CBT condition or to the waitlist control condition. Results of the randomization procedure were communicated to participants through e-mail. People allocated to the online CBT condition started with treatment within one week after randomization. People in the waitlist control condition started with treatment after a waiting period of eight weeks. In case people were still in need of professional psychological support after treatment completion, they were referred to their general practitioner or to one of the collaborating mental health care institutes. People who were not eligible for participation were referred to their general practitioner. Participants did not receive financial compensation and there were no costs for participating in the study.

2.4. Materials

2.4.1. Primary outcome

The primary outcome was early PCBD symptom severity, in accord with the DSM-5 criteria (APA, 2013), since the DSM-5 was most commonly used in the Dutch mental health care system at the time of conducting this study. Early PCBD symptoms were measured with 16 items from the 22-item Traumatic Grief Inventory-Clinician Administered (TGI-CA; Lenferink et al., preprint). The TGI-CA is the interview version of the Traumatic Grief Inventory-Self Report Plus (TGI-SR+). The 22-item TGI-SR+ is a reliable and valid instrument to assess PCBD symptoms (Lenferink et al., 2022). The TGI-CA assesses PCBD symptoms according to DSM-5 criteria (APA, 2013), and PGD symptoms in compliance with the ICD-11 (World Health Organization, 2018) and DSM-5-TR (APA, 2022). Participants report how often they are affected by each symptom in the past month (e.g., "In the past month, how often have you been bothered by experiencing intense emotional pain, sadness, or pangs of grief?") on a 5-point Likert scale ranging from 1 = never, through 5 = always. The instruction of the original questionnaire has been modified from "the death of your loved one" to "the death of your loved one(s) during the COVID-19 pandemic". In accord with the DSM-5 diagnostic scoring rule (APA, 2013), participants were regarded to have clinically relevant early PCBD symptom-levels when they scored at least 3 (sometimes) on at least one of the B-cluster symptoms (representing separation distress), six C-cluster symptoms (representing reactive distress and identity or social disruption), and the D-cluster symptom (representing functional impairment) (Boelen & Smid, 2017b). Based on a recent validation study on the TGI-SR+ (Lenferink et al., 2022), a score of $\geq$53 was used as a cut-off for clinically significant early PCBD symptoms, based on the 16 PCBD items as described in the TGI-SR+ (instead of using a cut-off score of $\geq$54 as described in the study protocol (Reitsma et al., 2021)). In this study, Cronbach's alpha for the PCBD items in the TGI-CA showed a good internal consistency at baseline ($\alpha = 0.81$).

2.4.2. Secondary outcomes

PTSD *severity*. PTSD symptoms were measured with the 20-item PTSD Checklist for DSM-5 (PCL-5; Blevins et al., 2015; Boeschoten et al., 2014). Participants indicate to what extent they are affected by each symptom during the past month on a 5-point Likert scale ranging from 0 = not at all, through 4 = extremely. The formulation of the instruction and the items of the original questionnaire were changed from the "stressful experience" to the "death of your loved one(s) during the COVID-19 pandemic". Moreover, because items were administered in a telephone interview, formulation of the items as presented in the original questionnaire were altered from statements into questions (e.g., "In the past month, how much were you affected by repeated, disturbing dreams of the death of your loved one during the COVID-19 pandemic?"). The PCL-5 is a psychometrically sound measure of PTSD symptoms (Blevins et al., 2015). Any item rated as at least 2 (moderate) is considered an endorsed symptom. In accordance with the DSM-5 diagnostic rule (APA, 2013), participants are assumed to report clinically relevant PTSD symptoms when they endorsed at least one cluster B item (representing intrusive memories), one cluster C item (representing avoidance), two cluster D items (representing negative cognitions and mood), and two cluster E items (representing hyperarousal), and/or register a total score of at least 31 (Weathers et al., 2013). The PCL-5 demonstrated a good internal consistency in this study at baseline ($\alpha = 0.82$).

Depression severity. Depression symptoms were measured with the 9-item Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001). Participants rate how often they are bothered by each symptom during the past two weeks on a 4-point Likert scale (0 = not at all, through 3 = nearly every day). Formulation of the items in the original questionnaire have been changed from statements into questions (e.g., "Over the past two weeks, how often have you been bothered by having little interest or pleasure in doing things?"). The PHQ-9 is a psychometrically sound measure of depression symptoms (Kroenke et al., 2001). Based on Kroenke et al. (2001), a total score of at least 10 was used as a cut-off for clinical depression. The PHQ-9 had a relatively low, yet acceptable internal consistency in this study at baseline ($\alpha = 0.61$).

2.4.3. Other measures

Participant characteristics (i.e., gender, age, educational level, country of birth), characteristics of the deceased (i.e., age, date of death), and the loss (i.e., relationship to deceased, time since loss, cause of death) were registered. Further, corona-related stressors (i.e., funeral attendance, experiencing multiple losses) were recorded. In case a participant indicated to have experienced multiple losses since the outbreak of the pandemic during T1, the interview was solely focused on what the participant considered to be the most significant loss. In addition, the use of professional psychological interventions during participation was registered with one dichotomously (yes/no) scored item during T2 (i.e., "During the past 8 weeks did you receive additional psychological professional support from a psychologist, therapist, or psychiatrist for dealing with your emotional problems with regard to the deceased?").

2.5. Intervention

The early self-guided online CBT treatment contains eight distinct weekly sessions that had to be completed within a period of maximum twelve weeks. The treatment is based on the face-to-face treatment protocol including exposure and cognitive restructuring that was developed and evaluated by Boelen et al. (2007) and expanded by an online protocol addressing behavioral activation (drawing from, e.g., Eisma et al. (2015) and Papa et al. (2013)). The treatment protocol has already been used in a prior online treatment described in the TrafVic study protocol (see Lenferink et al., 2020c). A notable difference with the TrafVic protocol is that we tailored the treatment to the specific circumstances of a loss during the COVID-19 pandemic (e.g., the absence of traditional grieving rituals, lack of physical social support).

In Session 1, information is offered about normal and disordered responses to loss and different factors affecting these responses. Attention is paid to so-termed "corona-related factors" hindering processing, including limitations in social support and the ability to perform leave-taking rituals. As a rationale for applying exposure, cognitive restructuring, and behavioral activation, it is explained that three tasks have to be achieved to come to terms with loss: (1) Facing the loss and pain that follow after bereavement, (2) Keeping confidence in yourself, other people, life, and the future, (3) Engaging in helpful activities that promote adjustment to the new situation without the deceased. Sessions 2, 3, and 4 are focused on exposure (Task 1). It is explained that different forms of avoidance block recovery from the loss; through writing assignments participants are encouraged to share the story of the loss, with a focus on the most painful elements. Then, to foster exposure to the reality of the loss, they are instructed to write about the things missed most, since their loved one died. Sessions 5 and 6 include cognitive restructuring. These sessions are focused on identifying and altering maladaptive thoughts and helping participants to maintain an adaptive view on themselves, their lives, and the future (Task 2). To this end, participants complete cognitive diaries and engage in behavioral experiments to test maladaptive and strengthen adaptive cognitions. Sessions 7 and 8 are spend on helping participants to re-engage in activities that were valued before the loss (Task 3) by formulating goals and steps to achieving these goals. Information and assignments during the sessions are presented in writing and explained by a therapist in pre-recorded video messages. Participants can select either a male or female video therapist at the start of treatment, both presenting the same information. Communicating with the video therapists is not possible. Participants spend about 2 h working through each lesson and are allowed to shape these 2 h to their own preference. Parallel to the eight sessions, participants complete writing assignments to confront painful memories of the events surrounding the loss (e.g., by writing detailed accounts of specific circumstances), to elaborate on the implications of the loss (e.g., by writing to the deceased what is missed most), to obtain a different perspective on maladaptive cognitions (e.g., by writing a supportive letter to a hypothetical friend), and to consolidate lessons learned (e.g., by writing a summary of what they learned that may be used when the emotional pain returns; Cummings et al., 2014; Wagner et al., 2006).

The first author checked participants' compliance to the treatment protocol by collecting log data from the participants, including the total number of lessons completed. In case a participant was falling behind in treatment, the first author sent an encouragement by email to the participant to proceed with treatment without offering therapeutic assistance. Treatment content was presented through a secured website. All participants were permitted to obtain any other form of psychosocial support during participation in the study.

2.6. Data analyses

As reported in the study protocol, an a priori sample size calculation indicated that a sample of 52 participants was sufficient to find a large difference between the online CBT and waitlist control condition (Reitsma et al., 2021). For the intention-to-treat (ITT) sample, statistical analyses were conducted with MPlus, version 8.3 (Muthén & Muthén, 1998-2021). Missing data were addressed with multiple imputation. T2 data from 15 out of 65 participants (23.1%) were imputed. In accord with procedures proposed by Graham et al. (2007) and Little et al. (2014), a number of 100 imputed datasets were created. For the completers sample, statistical analyses were performed using SPSS, version 27.0 (IBM Corp., 2020). The significance level was set at $\alpha = 0.05$.

Differences between the online CBT and waitlist control condition in terms of age (in years), time since bereavement (in days), and baseline PCBD, PTSD, and depression symptoms were evaluated using independent samples t-tests and Mann-Whitney U tests. Chi-square tests and Fisher's exact tests were used to examine group-differences in gender (0 = male, 1 = female), educational level (0 = primary, secondary or vocational, 1 = college/university), kinship to deceased (0 = spouse or child, 1 = other), number of losses (0 = one loss, 1 = multiple losses), and cause of death (0 = illness, 1 = other). The same statistical analyses were conducted to compare differences between treatment completers and non-completers on sociodemographic characteristics, loss-related variables, and baseline PCBD, PTSD, and depression symptoms. Participants who completed less than six treatment sessions were regarded as non-completers.

Treatment effects were evaluated on both the ITT and completers sample using three separate analyses of covariance (ANCOVAs). Dependent variables were mean symptom-levels of PCBD, PTSD, or depression at post-treatment/post-waiting period. The independent variable was condition (online CBT vs. waitlist control condition). Covariates were baseline symptom-levels of PCBD, PTSD, or depression, and the use of professional psychological support during participation (0 = no, 1 = yes).

Based on the recent changes in the DSM-5-TR, replacing PCBD with PGD, we repeated the analyses for the primary outcome using the PGD DSM-5-TR[1] items of the TGI-CA. Effect sizes (Cohen's *d*) were computed for within-group and between-group differences (Feingold, 2009). In the ITT sample, within-group differences were tested using Wald test of Parameter Constraints (Muthén & Muthén, 2010). In the completers sample, similar within-group differences were tested using paired sample t-tests. Within-group effect sizes were calculated by dividing the difference between the post-treatment or post-waiting period score, and pre-treatment or pre-waiting period score by the pooled standard deviation of the pre-treatment/pre-waiting period score. Between-group effect sizes were calculated by dividing the unstandardized beta by the pooled standard deviation of the pre-treatment/pre-waiting period score (Feingold, 2009). Effect sizes can be interpreted as small (Cohen's $d \geq 0.2 \leq 0.49$), medium (Cohen's $d \geq 0.5 \leq 0.79$), and large (Cohen's $d \geq 0.8$) (Cohen, 1988). Furthermore, reliable change indices (RCIs) were computed on the completers sample, to determine clinically significant changes from pre-treatment/pre-waiting period to post-treatment/post-waiting period for symptom-levels of PCBD, PTSD, and depression per individual. The formula of Jacobson and Truax (1991) was used for calculating the RCIs:

$$\mathrm{RCI} = \frac{\mathrm{X2} - \mathrm{X1}}{\sqrt{\mathrm{Sdiff}}}$$

[1] PGD criteria as per DSM-5-TR include the following items in the TGI-CA: at least one of the two Criterion B symptoms (representing separation distress; item 1 and 3), at least three of the eight Criterion C symptoms (representing cognitive, emotional, and behavioral symptoms), and the Criterion D symptom (representing functional impairment; item 13). All Criterion C symptoms are reflected by one of the TGI-CA items (items 6, 9, 10, 11, 18, 19, and 21), except for one symptom (C4 criterion; representing intense emotional pain related to the death), which is captured by two TGI-CA items (items 2 and 8). The highest score on one of these two items is used to represent the C4 criterion.

X2 represents a participant's post-treatment/post-waiting period score, whereas *X1* represents a participant's pre-treatment/pre-waiting period score. *Sdiff* represents the standard error of the difference on the TGI-CA, PCL-5, or PHQ-9. An RCI $>|1.96|$ demonstrates that the change is unlikely due to chance ($p < .05$) (Jacobson & Truax, 1991). Next, the number of participants were counted that exhibited reliable change on the outcome variables (both for the online CBT and waitlist control condition). Then, the percentage of reliable change was calculated. Fisher's exact tests and chi-square tests were performed to compare differences between the two conditions in percentages of participants demonstrating reliable change in PCBD, PTSD, and depression symptoms from baseline to post-treatment/post-waiting period. Lastly, changes in percentages of people scoring above the cut-off for PCBD, PTSD, and depression were reported at pre-treatment versus post-treatment or pre-waiting versus post-waiting. It was reported whether participants recovered (i.e., symptoms exceeded cut-off score (s) at T1, while at T2 symptoms were below cut-off score(s)), deteriorated (i.e., symptoms were below cut-off score(s) at T1, while at T2 symptoms exceeded cut-off score(s)), or showed no change (i.e., no change in T1 and T2 cut-off score(s)).

3. Results

3.1. Sample characteristics and preliminary analyses

In total, 73 people filled in the informed consent form and were invited for T1. For four people (5.5%), no telephone interview was conducted, because the deceased had died less than three months earlier. Of the remaining 69 people who completed T1, four people (5.8%) were excluded from participation because they reported non-clinically relevant PCBD, PTSD, and depression levels. A total of 65 people were randomized to the online CBT condition (n = 32) or the waitlist control condition (n = 33). The majority of participants (86.2%) were recruited via announcements on (social) media channels. Fig. 1 illustrates the flow of participants through the study.

The age of participants ranged from 26 through 80 (M = 53.82, SD = 12.91) years. The majority of participants were born in the Netherlands (90.8%), were female (84.6%), and had a college/university degree (52.3%). Most participants lost a parent (43.1%) or spouse (36.9%), mostly due to illness (not related to COVID-19; 61.5%). The age of the deceased ranged from 29 to 92 (M = 69.51, SD = 15.71). Four participants (6.2%) could not attend the funeral of the deceased. Three participants (5.8%) received concurrent professional psychological support during participation. Table 1 displays socio-demographic characteristics, loss-related variables, and symptom-levels of PCBD, PTSD, and depression at baseline for participants in the two conditions; none of these variables differed between the two conditions (see Supplementary Table 1).

In the online CBT condition, 13 of all 32 participants (40.6%) were considered non-completers. For one participant, administration of the T2 measures was terminated early due to high levels of suicidality. In the waitlist control condition, 1 of all 33 participants (3.0%) dropped out during waiting period. This implies an overall dropout rate of 14 of all 65 (21.5%) participants in the current study. Reasons for dropout are illustrated in Fig. 1. Baseline characteristics and PCBD, PTSD, and depression symptoms of completers and non-completers are presented in Supplementary Table 2. These characteristics and symptom-levels did not differ between completers and non-completers, except for kinship. In the completers group, there were significantly more participants who had lost a spouse or child (vs. other relative) than in the non-completers group (see Supplementary Table 3). The mean number of completed sessions for the ITT sample was 5.88 (SD = 2.50), and the mean number of completed sessions for the completers sample was 7.68 (SD = 0.67).

3.2. Differences in early PCBD, PTSD, and depression symptoms between the online CBT and waitlist control condition

ITT analyses indicated that symptom-levels of PCBD,[2] PTSD, and depression were significantly lower for participants in the online CBT condition post-treatment, compared to waitlist controls post-waiting, when taking baseline symptoms and the use of professional psychological support during participation into account. Between group effect sizes were $d = 0.90$ for PCBD, $d = 0.71$ for PTSD, and $d = 0.57$ for depression symptoms. In Table 2 the descriptive statistics and within- and between-group effect sizes are displayed for all outcomes. Table 3 shows the parameter estimates for the ANCOVAs including condition, baseline symptoms, and concurrent use of professional psychological support on all outcomes. Completers analyses revealed similar results for PCBD and PTSD symptoms. However, in the completers analyses, no significant difference was found in depression symptoms between the two conditions (see Supplementary Tables 4 and 5). In addition, for the ITT sample, significant within-group effects were found for PCBD, PTSD, and depression symptoms in the online CBT condition, while no significant within-group effects were detected in the waitlist control condition (see Table 2; see Supplementary Table 4 for significant within-group effects for both conditions in the completers sample).

3.3. Clinically relevant changes in early PCBD, PTSD, and depression symptoms from baseline to post-treatment or post-waiting

RCIs indicated that, in the online CBT condition, 33.3%, 50.0%, and 26.3% of the participants demonstrated clinically relevant changes in PCBD, PTSD, and depression symptoms respectively, from pre-treatment to post-treatment. In the waitlist control condition, RCIs indicated that 6.1%, 18.2%, and 3.0% of the people reported clinically relevant changes in PCBD, PTSD, and depression symptoms respectively, from pre-waiting to post-waiting. (see Supplementary Table 6 for an overview of the RCIs). Significant differences were found between the two conditions in percentages of participants demonstrating clinically relevant change in PCBD ($p = .017$), PTSD (χ^2 (1) = 5.68, p = .017), and depression symptoms ($p = .020$) from baseline to post-treatment or post-waiting.

3.4. Percentages of people scoring above the cut-off for early PCBD, PTSD, and depression

Changes in percentages of people scoring above the cut-off for clinically relevant PCBD, PTSD, and depression were reported at pre-treatment versus post-treatment or pre-waiting versus post-waiting. In the online CBT condition, 8 participants (44.4%), 14 participants (77.8%), and 10 participants (52.6%) recovered in terms of scoring below the cut-off for PCBD, PTSD, and depression at post-treatment versus pre-treatment, respectively. In contrast, in the waitlist condition, 1 participant (3.1%), 13 participants (40.6%), and 8 participants (25.0%) recovered in terms of scoring below the cut-off for PCBD, PTSD, and depression at post-waiting versus pre-waiting, respectively (see Supplementary Table 7 for an overview).

4. Discussion

The effectiveness of online CBT-based interventions in reducing symptom-levels of disturbed grief has been investigated in several RCTs, showing promising results (Eisma et al., 2015; Kersting et al., 2013; Litz et al., 2014; Treml et al., 2021; Wagner et al., 2006). However, these studies had several limitations which impede generalizability of the

[2] Treatment effects for early PGD symptoms according to DSM-5-TR criteria showed similar results to treatment effects for early PCBD symptoms in accordance with DSM-5 criteria.

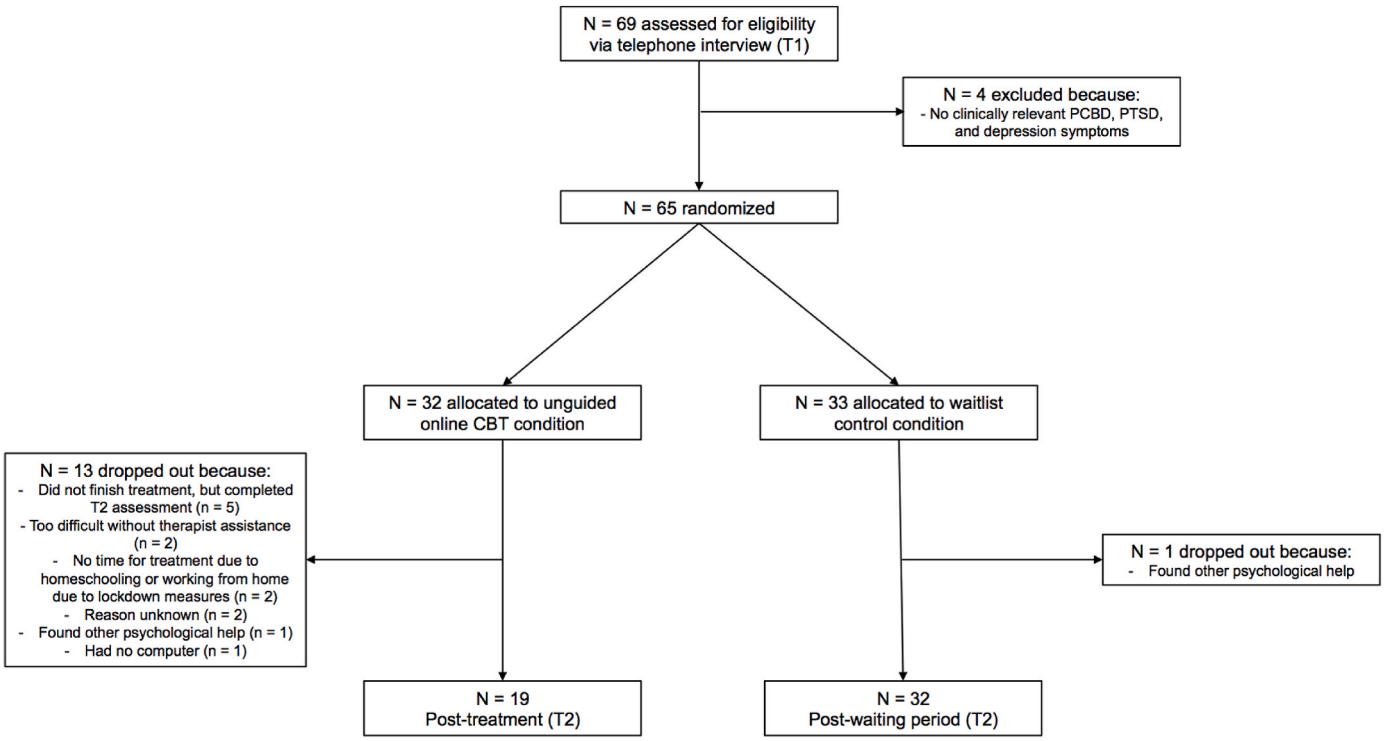

Fig. 1. *Flowchart of Participants*
Note. CBT = cognitive behavioral therapy; PCBD = persistent complex bereavement disorder; PTSD = posttraumatic stress disorder; T1 = pre-treatment or pre-waiting assessment; T2 = post-treatment or post-waiting assessment.

results. Only two of these prior studies were conducted among recently bereaved people using online guided therapy (Kersting et al., 2013; Litz et al., 2014). Accordingly, the aim of this RCT was to assess the effectiveness of an early self-guided online CBT in decreasing disturbed grief, PTSD, and depression levels in adults who lost loved ones during the COVID-19 pandemic.

The most important finding was that ITT analyses showed that online CBT led to significant lower symptom-levels of disturbed grief, PTSD, and depression compared to waitlist controls. The online CBT yielded large between-group effects for reductions in disturbed grief symptoms, and moderate between-group effects for PTSD and depression symptoms. These findings are in line with prior RCTs demonstrating that online grief-specific CBT-based interventions lead to a significant decrease in disturbed grief, PTSD, and depression symptoms relative to waiting for treatment (Eisma et al., 2015; Kersting et al., 2013; Litz et al., 2014; Treml et al., 2021; Wagner et al., 2006). The current RCT was the first to evaluate effects of a self-guided online CBT for disturbed grief and it was the first to examine treatment effects in adults bereaved during the COVID-19 pandemic. In addition, this is the first RCT in which an online grief-specific CBT was offered consisting of all three elements central to CBT for disturbed grief symptoms (i.e., exposure, cognitive restructuring, and behavioral activation), while in previous research the investigational online treatment consisted of different or separate elements of CBT (e.g., exposure, behavioral activation, or writing assignments alone (Eisma et al., 2015; Kersting et al., 2013; Wagner et al., 2006)).

Completers analyses affirmed treatment effectiveness for disturbed grief and PTSD, but not for depression. There are at least three possible explanations for this inconsistency between ITT and completers analyses in treatment effects for depression. A first possible explanation is that in the waitlist control condition, within-group effects were largest for depression (compared to disturbed grief and PTSD), resulting in a non-significant between-group effect for depression. A second possible explanation may be related to power problems. In the completers sample, statistical analyses examining treatment effects for depression were run on a relatively small number of participants (n = 51) and, therefore, lacks sufficient power that was needed to test our hypothesis. A third possible explanation is that the online CBT is less suitable in reducing depression symptoms, compared to disturbed grief and PTSD.

Our second main finding was that the percentage of participants who experienced clinically relevant improvements was highest in the intervention condition on all outcomes. Yet, in the waitlist control condition, some participants showed clinically relevant improvements on disturbed grief, PTSD, and depression symptoms too. Clinical improvements were highest for PTSD, compared to disturbed grief and depression in both conditions. Reliable changes in the waitlist control condition may be due to natural remission after the loss of a loved one (Ott & Lueger, 2002; Sveen et al., 2018). These findings suggest that PTSD symptoms show a stronger natural decline compared to disturbed grief symptoms, emphasizing the importance of an early intervention for disturbed grief.

Furthermore, in the completers sample, significant within-group effects were found in the waitlist control condition for disturbed grief, PTSD, and depression symptoms. Significant improvements in disturbed grief, PTSD, and depression symptoms in people waiting for treatment have been shown previously (e.g., Lenferink et al., 2020d), and may be explained by people showing natural remission. That said, improvements in disturbed grief and PTSD symptoms (but not for depression) were larger, which is represented by the moderate to large between-group effect sizes.

Several strengths of this study can be noted. One strength is that our findings are not only relevant for people bereaved during the pandemic, also non-pandemic bereaved people could benefit from this treatment because all psychoeducation and assignments related to exposure, cognitive restructuring, and behavioral activation are applicable to non-pandemic bereaved people too. Furthermore, in contrast to previous studies in which the majority of participants were highly educated (Eisma et al., 2015; Kersting et al., 2013; Litz et al., 2014; Treml et al.,

Table 1
Baseline characteristics and PCBD, PTSD, and depression symptoms of participants (N = 65).

Characteristic	Total sample		Online CBT condition (*N* = 32)		Waitlist control condition (*N* = 33)	
Gender, *N* (%)						
Female	55	(84.6)	29	(90.6)	26	(78.8)
Male	10	(15.4)	3	(9.4)	7	(21.2)
Education, *N* (%)						
College/ University	34	(52.3)	16	(50.0)	18	(54.5)
Vocational education	21	(32.3)	10	(31.3)	11	(33.3)
Primary school	1	(1.5)	0	(0)	1	(3)
Secondary school	9	(13.8)	6	(18.8)	3	(9.1)
Age (in years), *M* (*SD*)	53.82	(12.91)	53.34	(10.62)	54.28	(14.96)
Days since bereavement, *M* (*SD*)	179.83	(76.04)	188.94	(84.97)	171.00	(66.37)
Deceased is …, *N* (%)						
Parent	28	(43.1)	14	(43.8)	14	(42.4)
Spouse	24	(36.9)	11	(34.4)	13	(39.4)
Sibling	4	(6.2)	1	(3.1)	3	(9.1)
Child	3	(4.6)	2	(6.3)	1	(3.0)
Grandparent	2	(3.1)	1	(3.1)	1	(3.0)
Friend	2	(3.1)	1	(3.1)	1	(3.0)
Grandchild	0	(0.0)	0	(0.0)	0	(0.0)
Other	2	(3.1)	2	(6.3)	0	(0.0)
Number of losses during the pandemic, *N* (%)						
One	45	(69.2)	21	(65.6)	24	(72.7)
Two	13	(20.0)	8	(25.0)	5	(15.2)
Three	3	(4.6)	2	(6.3)	1	(3.0)
Four	3	(4.6)	1	(3.1)	2	(6.1)
Five	1	(1.5)	0	(0.0)	1	(3.0)
Cause of death, *N* (%)						
Illness	40	(61.5)	17	(53.1)	23	(69.7)
COVID-19	16	(24.6)	11	(34.4)	5	(15.2)
Suicide	4	(6.2)	2	(6.3)	2	(6.1)
Other or unknown	4	(6.2)	2	(6.3)	2	(6.1)
Accident	1	(1.5)	0	(0.0)	1	(3.0)
Homicide	0	(0.0)	0	(0.0)	0	(0.0)
Symptom-levels, *M* (*SD*)						
TGI-CA (Early PCBD)	50.28	(9.20)	52.34	(7.76)	48.27	(10.13)
PCL-5 (PTSD)	36.94	(11.20)	38.19	(9.40)	35.73	(12.74)
PHQ-9 (Depression)	13.82	(4.14)	14.03	(3.78)	13.61	(4.51)

Note. CBT = cognitive behavioral therapy; TGI-CA = Traumatic Grief Inventory – Clinician Administered; PCL-5 = PTSD Checklist for DSM-5; PHQ-9 = Patient Health Questionnaire-9; PCBD = persistent complex bereavement disorder; PTSD = posttraumatic stress disorder.

2021), our sample was heterogenous with regard to education level enhancing generalizability of the results to the general population.

Nonetheless, this study has several limitations. One limitation is that this study suffered from a higher dropout rate than was anticipated. A meta-analysis by Wagner et al. (2020), evaluating the effectiveness of online grief-specific interventions, reported a mean dropout rate of 27.0%, ranging from 10.3% to 58.8% between treatment conditions. In the present study, the dropout rate for participants allocated to online CBT was 40.6%. This is higher than most dropout rates in therapist-assisted interventions reported by Wagner et al. (2020). Yet, compared to a dropout rate of 52.0% in a self-guided online intervention by van der Houwen et al. (2010), the dropout rate in our study was lower. Lack of therapist assistance was indeed one of the most commonly reported reasons for dropout in our study. For instance, some reported that they found the treatment too difficult and emotionally demanding without guidance by a therapist. Accordingly, the effectiveness of therapist-assisted online CBT should be further evaluated. In part 2 of this study, the effectiveness of therapist-assisted CBT will be compared to self-guided online CBT (Reitsma et al., 2021).

A second limitation concerns the fact that although no therapeutic assistance was offered, participants' adherence to the treatment protocol was checked by the first author. Participants who were falling behind in treatment, received an encouragement by mail to continue treatment. This assistance may have been an extra motivation for participants to continue treatment. Accordingly, in clinical practice, more people might discontinue treatment prematurely if no such assistance is offered. A third limitation is that disturbed grief, PTSD, and depression symptoms of participants and the impact of treatment may have been affected by corona-related stressors, such as not being able to engage in traditional grieving rituals or social deprivation due to quarantine measures. However, it was beyond our aim to examine to what extent these factors moderated treatment effects. Another potential limitation is that instruments measuring PCBD (i.e., TGI-SR+), PTSD (i.e., PCL-5), and depression (i.e., PHQ-9) were administered in telephone interviews. There is some evidence that telephone administration of the TGI-SR+

Table 3
Estimated parameters for analyses of covariance comparing the online CBT condition and waitlist control condition in the intention-to-treat sample (N = 65).

	TGI-CA (Early PCBD)		PCL-5 (PTSD)		PHQ-9 (Depression)	
	B	SE	B	SE	B	SE
Intercept	5.64	5.70	0.56	5.13	1.24	1.84
Condition	−8.18***	2.26	−7.93*	3.29	−2.36*	1.02
Baseline symptom-levels	0.81***	0.12	0.82***	0.13	0.73***	0.13
Professional psychological co-intervention	4.51	4.50	10.11	6.62	4.66*	2.28

Note. CBT = cognitive behavioral therapy; TGI-CA = Traumatic Grief Inventory – Clinician Administered; PCL-5 = PTSD Checklist for DSM-5; PHQ-9 = Patient Health Questionnaire-9; PCBD = persistent complex bereavement disorder; PTSD = posttraumatic stress disorder; T1 = pre-treatment or pre-waiting assessment; T2 = post-treatment or post-waiting assessment; B = unstandardized beta; SE = standard error., *p < .05, **p < .01, ***p < .001.

Table 2
Descriptive statistics and effect sizes for the online CBT condition (N = 32) and waitlist control condition (N = 33) in the intention-to-treat sample.

		T1			T2			Cohen's *d* Within groups	Cohen's *d* Between groups
		N	M	SD	N	M	SD		
TGI-CA (Early PCBD)	Online CBT	32	52.34	(7.64)	32	40.09	(9.92)	1.34***	0.90***
	Waitlist control	33	48.27	(9.97)	33	45.08	(11.20)	0.35	
PCL-5 (PTSD)	Online CBT	32	38.19	(9.26)	32	24.16	(13.84)	1.26***	0.71*
	Waitlist control	33	35.73	(12.54)	33	30.35	(15.21)	0.48	
PHQ-9 (Depression)	Online CBT	32	14.03	(3.72)	32	9.27	(4.87)	1.16***	0.57*
	Waitlist control	33	13.61	(4.44)	33	11.44	(4.81)	0.53	

Note. CBT = cognitive behavioral therapy; TGI-CA = Traumatic Grief Inventory – Clinician Administered; PCL-5 = PTSD Checklist for DSM-5; PHQ-9 = Patient Health Questionnaire-9; PCBD = persistent complex bereavement disorder; PTSD = posttraumatic stress disorder; T1 = pre-treatment or pre-waiting assessment; T2 = post-treatment or post-waiting assessment, *p < .05, **p < .01, ***p < .001.

(see Lenferink et al., preprint), the PCL-5 (e.g., Ibrahim et al., 2018; Verhey et al., 2018), and PHQ-9 (e.g., Pence et al., 2012) provides reliable and valid data. However, it is uncertain to what extent the outcomes of this study might have been different if we had used self-reporting only. A related limitation is that probing was conducted throughout the telephone interviews which, in the absence of tests of inter-rater reliability, might raise some concerns with regard to reliability of the measurement. Lastly, women were overrepresented in the current sample, restricting generalizability of the findings. This is, however, a common issue in bereavement research (Johannsen et al., 2019). Nevertheless, this study should be replicated with a sample including more men.

Despite these limitations, early self-guided online CBT is a promising treatment approach for adults bereaved during the COVID-19 pandemic who experience clinically relevant disturbed grief, PTSD, and/or depression symptoms. Since evidence-based online CBT for disturbed grief is not yet widely available, this study contributes to scientific knowledge with regard to the effectiveness of self-guided online CBT. Notwithstanding, the online CBT should be investigated further. As such, long-term effects and the additional effect of therapist-assistance will be examined in two additional studies, once data collection is completed, as stated in our study protocol (Reitsma et al., 2021). The online CBT should be implemented in clinical practice once the findings are replicated, to improve psychological support for recently bereaved adults.

Data statement

Data are only available on reasonable request, since data collection for part 2 of the current study is still ongoing.

Submission declaration

This study was registered in the Netherlands Trial Register (NL8993) and a study protocol has been published (Reitsma et al., 2021). The dataset has not been used before in any publications, nor have manuscripts been submitted using this dataset. The manuscript contains original material and it has not been submitted concurrently to another journal.

Declarations of interest

None.

CRediT authorship contribution statement

L. Reitsma: Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – original draft. **P. A. Boelen:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing – review & editing. **J. de Keijser:** Methodology, Supervision, Writing – review & editing. **L.I.M. Lenferink:** Conceptualization, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – review & editing.

Data availability

Pseudonymized data are available on reasonable request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2023.104286.

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