Journal of Affective Disorders 167 (2014) 56–63

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research report

Efficacy of an outpatient treatment for prolonged grief disorder: A randomized controlled clinical trial

Rita Rosner [a,b,*], Gabriele Pfoh [a], Michaela Kotoučová [a,1], Maria Hagl [a,1]

[a] Department of Psychology, Ludwig-Maximilian-University of Munich, Germany
[b] Catholic University Eichstätt-Ingolstadt, Ostenstr. 25, D-85071 Eichstätt, Germany

ARTICLE INFO

Article history:
Received 26 March 2014
Received in revised form
20 May 2014
Accepted 22 May 2014
Available online 2 June 2014

Keywords:
Bereavement
Prolonged grief disorder
Complicated grief
Persistent complex bereavement-related disorder
Randomized controlled trial
Psychotherapy

ABSTRACT

Background: Abnormal forms of grief, currently referred to as complicated grief or prolonged grief disorder, have been discussed extensively in recent years. While the diagnostic criteria are still debated, there is no doubt that prolonged grief is disabling and may require treatment. To date, few interventions have demonstrated efficacy.
Methods: We investigated whether outpatients suffering from prolonged grief disorder (PGD) benefit from a newly developed integrative cognitive behavioural therapy for prolonged grief (PG-CBT). A total of 51 patients were randomized into two groups, stratified by the type of death and their relationship to the deceased; 24 patients composed the treatment group and 27 patients composed the wait list control group (WG). Treatment consisted of 20–25 sessions. Main outcome was change in grief severity; secondary outcomes were reductions in general psychological distress and in comorbidity.
Results: Patients on average had 2.5 comorbid diagnoses in addition to PGD. Between group effect sizes were large for the improvement of grief symptoms in treatment completers (Cohen's $d=1.61$) and in the intent-to-treat analysis ($d=1.32$). Comorbid depressive symptoms also improved in PG-CBT compared to WG. The completion rate was 79% in PG-CBT and 89% in WG.
Limitations: The major limitations of this study were a small sample size and that PG-CBT took longer than the waiting time.
Conclusions: PG-CBT was found to be effective with an acceptable dropout rate. Given the number of bereaved people who suffer from PGD, the results are of high clinical relevance.

1. Introduction

Prolonged grief disorder is being proposed as part of the stress related disorders category in the ICD-11; in the DSM-5, "persistent complex bereavement disorder" is classified as a "condition for further study" (American Psychiatric Association, 2013). Despite this discrepancy, many papers on severely impairing forms of abnormal grief have been published in the last few decades. The term "complicated grief" was coined by Horowitz and his colleagues (Horowitz et al., 1997; Prigerson et al., 1995), while "traumatic grief" was used by Prigerson and her colleagues (Jacobs, 1999; Prigerson et al., 1997; Shear et al., 2001). As the concepts evolved, the criteria and definitions for grief varied (for an overview and a comparison of the terminology, see Shear et al. (2011)). However, core symptoms overlap between definitions: for example, intense yearning and preoccupation with the loss, reactive distress symptoms, such as avoidance of memories of the deceased person and emotional numbing, as well as social/identity disruption, such as feeling detached or having difficulties trusting others.

In this manuscript, we are referring to the respective grief condition as prolonged grief disorder (PGD). Estimates regarding the prevalence of PGD vary between studies. While a study from the USA has reported that approximately 10% of the bereaved show symptoms that cause impairment in everyday life (Bonanno et al., 2008; Ott, 2003), European studies have reported prevalence values of 4.2% in a sample of older Swiss (Maercker et al., 2008) and 4% in a German sample (Kersting et al., 2011). In the Netherlands (Newson et al., 2011), a prevalence of 4.8% was found in a sample of 5741 adults aged 55 years and older. For those participants who had experienced a loss, the prevalence of PGD was 25.4%.

PGD has been found to be associated with deteriorated health (Stroebe et al., 2007), increased depression, and suicidality (Boelen and Prigerson, 2007; Latham and Prigerson, 2004). Having a diagnosis of PGD six months after a loss correlated with an increased risk for heart disease, high blood pressure, cancer, and altered eating habits (Prigerson et al., 2008). Furthermore, PGD has

* Corresponding author at: Catholic University Eichstaett-Ingolstadt, Ostenstr. 25, D-85071 Eichstätt, Germany. Tel.: +49 8421 93 1581; fax: +49 8421 93 2033.
E-mail address: rita.rosner@ku.de (R. Rosner).
[1] MK and MH are no longer affiliated with the Ludwig-Maximilian-University

http://dx.doi.org/10.1016/j.jad.2014.05.035
0165-0327/

been effectively differentiated from depression and posttraumatic stress disorder (PTSD) (Boelen and van den Bout, 2005; Boelen et al., 2008). However, PGD is often comorbid with these disorders (Maercker and Znoj, 2010; Simon et al., 2007).

Despite discussions about the precise criteria for PGD, there is an impressive amount of literature on treatment outcomes for bereavement associated problems. In general, meta-analyses evaluating the efficacy of treatments for grief give small (Kato and Mann, 1999: $d=0.11$; Fortner, 2000: $d=0.13$; Rosner et al., 2005: $d=0.20$; Currier et al., 2008: $d=0.16$) to medium (Allumbaugh and Hoyt, 1999: $d=0.43$) effect size (ES) calculations at best. However, studies including only patients with severe grief symptoms showed evidence of larger effect sizes than studies with subjects that did not have substantial grief symptoms: Currier et al. (2008) reported an ES of $d=0.51$, and Rosner et al. (2005) reported an ES of $d=0.27$. The most recent meta-analysis compared preventive and treatment interventions for PGD and found an ES of 0.03 for prevention and 0.53 for treatment interventions (Wittouck et al., 2011).

Studies based exclusively on patients meeting the criteria for PGD are still rare. There are three successful randomized controlled trials investigating individual treatment for PGD in terms of overall ES: (1) a trial with two active conditions comparing complicated grief treatment with interpersonal therapy (Shear et al., 2005); (2) a trial comparing an internet-based intervention with an untreated control (Wagner et al., 2006); and (3) a trial comparing cognitive behavioural therapy (CBT) with supportive counselling (Boelen et al., 2007). Because two of the studies compared active treatments (Boelen et al., 2007; Shear et al., 2005), it is reasonable to use the pre- to post-treatment effect sizes to compare the respective treatment protocols. Boelen et al. (2007) reported an ES of 1.36 for the combination of cognitive restructuring followed by exposure and an ES of 1.80 for the combination of exposure followed by cognitive restructuring. Shear et al. (2005) reported an ES of 1.63, and Wagner et al. (2006) reported an ES of 1.41 (the combined result for posttraumatic symptoms and symptoms of dysfunctional adaptation to grief). All reported ES values are based on completer analyses.

In all treatment protocols, patients with severe comorbid disorders were excluded. Boelen et al. (2007) excluded severely depressed patients, as well as patients with substance use disorders, and provided no further information on additional diagnoses. Shear et al. (2005) excluded patients with substance abuse, psychosis, and bipolar disorder. However, 45% of patients in their complicated grief treatment group met criteria for a current depressive episode, and 49% of patients met criteria for PTSD. An effectiveness study based on patients seeking inpatient treatment showed an even wider range and higher number of comorbid disorders (Rosner et al., 2011b). Therefore, under clinical conditions, a high number of comorbid diagnoses should be expected. The reduction of comorbid symptoms has not yet been covered in depth. In regards to the studies mentioned above, Boelen et al. (2007) reported an ES of 1.18 measuring overall psychological distress with the Dutch version of the SCL-90-R (Derogatis, 1977) for the cognitive restructuring followed by exposure condition and an ES of 1.15 for exposure followed by cognitive restructuring. Shear et al. (2005) reported an ES of 1.22 for depression and 0.82 for anxiety.

To develop a successful intervention, we reviewed studies that reported positive outcomes regarding their specific therapeutic interventions. We also performed a meta-analysis on therapeutic interventions by correlating them with symptom severity (Rosner et al., 2005; Rosner and Hagl, 2007) to estimate the contribution of PGD status to outcome. The most promising treatment strategies were the following: psycho-education about normal and prolonged grief processes, exposure elements relating to the most painful aspects of the loss, and transformation of the loss to enable change. The study by Boelen et al. (2007) was not published at the time our manual was developed. Furthermore, we identified other promising interventions in our literature review, such as grief resolution in a publication by Melges and DeMaso (1980) and Rando's (1993) description of Gestalt and psychodrama interventions. We decided to use exposure and cognitive interventions similar to those described in two PTSD interventions: Ehlers's manual on the treatment of PTSD in adults (Ehlers, 1999) and Cohen and coworkers' manual (2006) on the treatment of PTSD and grief in children. We included these elements in our newly developed intervention for inpatients. The resulting structure and selected interventions were then adapted for different settings. An inpatient group treatment based on our manual showed a large pre- to post-treatment ES of 1.21 for inpatients with comorbid complicated grief (Rosner et al., 2011b).

Hence, the primary goal of this study was to evaluate the efficacy of a specific individual outpatient treatment manual for PGD, named integrative cognitive behaviour therapy for prolonged grief (PG-CBT), in terms of improving patients' grief severity compared to a wait list control group. Secondary goals were to test whether PG-CBT is more effective in improving general distress symptoms and comorbid symptoms compared with a wait list control group.

2. Methods

2.1. Procedure

The study was approved by the university's ethics committee and has been registered with Clinical Trials (Identifier: NCT01433653). Pilot patients were seen in 2005. Randomization began in October 2006. The last patient finished therapy in June 2011. The study design is a stratified randomized controlled trial. We stratified our sample according to the patient's relationship to the deceased, namely, a child or other form of kinship, and according to the type of death, namely, a natural or non-natural death. A stratified randomization list was electronically produced and provided by the university's Department of Statistics; then it was transferred into four groups of envelopes (according to type of death × type of kinship) that contained group allocation. Allocation was not disclosed to patients or project workers before the end of baseline assessment.

The control condition was a wait list. The waiting period was set at four months or longer. This shortest possible waiting period of four months was chosen for ethical reasons to avoid unnecessary suffering on the patients' part as well as for practical purposes to ensure treatment adherence. Once a month during the waiting period, patients met with the diagnostician, who had assessed the patients' baseline, for ethical and safety reasons. These interim sessions did not include any treatment; rather, these sessions consisted of informal safety check-ups, such as inquiring about possible intentions of self-injurious behaviour or suicidal ideations. None of the participants had to be excluded from wait list because of respective clinical reasons. Treatment was offered as soon as a therapist was available, but not before the minimum waiting period of four months. On average, patients in the wait list control group were re-assessed by their respective diagnostician after six months of waiting ($M=6.04$; $SD=1.36$). Patients in the treatment group were assessed at baseline by a diagnostician, while later assessment was conducted by their respective therapist. During the treatment, but not during the wait list period, symptom questionnaires (PG-13 and SCL-90-R, see Measures section below) were administered three times (along with additional process measures): (1) between sessions 5 and 7,