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Development and Preliminary Evaluation of a Cognitive-Behavioral Intervention for Perinatal Grief

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Perinatal loss, typically defined as fetal death beyond 20 weeks gestation through infant death 1-month postpartum, is a potentially traumatizing experience for parents occurring in approximately 1% of births in the United States. Although many women recover, 15% to 25% have enduring grief-related symptomatology and functional impairment. Perinatal grief is a unique bereavement experience, but clinical resources for detecting and treating severe perinatal grief are rare and interventions are largely without empirical support. We developed and pilot tested a cognitive-behavioral intervention targeting the psychological and behavioral sequelae of perinatal bereavement. To initially evaluate the feasibility and efficacy of the intervention, 5 women who suffered a perinatal loss were randomized to a 2-week, 4-week, or 6-week baseline period in a multiple-baseline single-case experimental design. In most cases, after the respective baseline periods, there was a steady decline in reported grief symptoms. These gains were largely maintained at a 6-week follow-up assessment. This study provides initial evidence in support of future research and clinical efforts tailoring cognitive behavioral interventions to meet the specific needs of women who experience perinatal loss.

APPROXIMATELY 1% of pregnancies in the United States results in a perinatal loss, typically defined as fetal death beyond 20 weeks gestation through infant death 1-month postpartum (MacDorman, Munson, & Kirmeyer, 2007). Between 10% and 25% of pregnancies may result in a spontaneous abortion (miscarriage) before 20 weeks gestation (National Library of Medicine, 2006). The experience of pregnancy loss or perinatal death can be devastating and potentially traumatizing for some parents regardless of the type of perinatal loss or the gestational age of the child (Berman, 2001; Cote-Arsenault & Mahlangu, 1999; Klier, Geller, & Ritsher, 2002; Vance et al., 1995). Thus, the use of the term perinatal loss in this manuscript is not meant to exclude the experience of women who have a miscarriage before 20 weeks gestation or a neonatal death beyond 1-month postpartum.

Research and clinical reports suggest that the severity of mental health distress generally wanes over the first

year following perinatal loss; however, approximately one-fifth of women continue to experience clinically significant symptoms 12 months after the loss (Boyle, Vance, Najman, & Thearle, 1996; Leon, 2001). Hughes, Turton, Hopper, and Evans (2002) reported that approximately 20% of women who suffer a perinatal loss experience depression or posttraumatic stress disorder (PTSD). The lifetime risk for PTSD from perinatal loss has been estimated to be 29% (Turton, Hughes, Evans, & Fainman, 2001). In another study, Vance et al. (1995) found that perinatally bereaved parents reported significantly greater symptoms of depression and anxiety than parents who experienced a successful pregnancy when assessed 2 months and 8 months after their loss, with a substantial drop in symptoms between these two time points. A number of studies have shown that women who suffer miscarriage are also at increased risk for anxiety and depressive disorders (e.g., Geller, Klier, & Neugebauer, 2001; Klier, Geller, & Neugebauer, 2000; Klier et al., 2002). During the subsequent pregnancy following a loss, approximately 15% to 20% of mothers report a host of mental health symptoms and syndromes, including depression, anxiety disorders, reexperiencing of the prior loss, and/or fear about suffering another loss (Cote-Arsenault & Bidlack, 2001; Geller, Kerns, & Klier,

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2004; Theut, Pedersen, Zaslow, & Rabinovich, 1988; Turton et al., 2001).

It has previously been asserted (Bennett, Litz, Lee, & Maguen, 2005; Bennett, Litz, Maguen, & Ehrenreich, 2008) that prolonged grief disorder (PGD) may best capture the enduring mental health impact of perinatal loss. A rapidly increasing body of strong clinical, biological, and empirical evidence suggests that PGD is distinct from normal grief, PTSD, and depression (e.g., Boelen, van de Schoot, van den Hout, de Keijser, & van den Bout, 2010; Bonanno et al., 2007; Prigerson et al., 1996). PGD is not yet a formal diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994)*; however, provisional diagnostic criteria have long been used in bereavement research (e.g., Horowitz et al., 1997; Prigerson et al., 1999; Stroebe et al., 2000), and revised diagnostic criteria have been proposed for *DSM-5* (Prigerson et al., 2009).

There is evidence from a handful of randomized controlled trials (RCTs) that cognitive-behavioral treatment (CBT) significantly reduces chronic post-loss psychopathology. Shear, Frank, Houck, and Reynolds (2005) conducted a RCT of an intervention designed specifically to target symptoms of complicated grief (as the construct was known at that time). Complicated grief treatment (CGT; Shear et al., 2005) includes education about grief processes and focuses on restoration of a satisfying life through attention to personal life goals. CGT also includes exposure therapy targeting the memories of the deceased and the time of their death. Shear et al. (2005) compared interpersonal psychotherapy ($n=46$) and CGT ($n=49$) over an average of 19 weeks and found that although both groups improved, the response rate was greater for the CGT (51%) than for interpersonal psychotherapy (28%). Other research shows that CBT for complicated bereavement is efficacious when administered in alternate modalities, such as the internet (Wagner, Knaevelsrud, & Maercker, 2006; Wagner, Knaevelsrud, & Maercker, 2007). Boelen and colleagues reported on several factors associated with the efficacy of CBT for complicated grief, and found that individuals who experienced the loss of a partner or child tended to have worse treatment outcomes than those who experienced other types of familial loss (Boelen, de Keijser, van den Hout, & van den Bout, 2010).

There are a number of factors that make grief specific to perinatal loss (referred to as perinatal grief) unique from grief related to the loss of other important attachment figures (see Bennett et al., 2005, for a review), thus potentially warranting a more specific treatment model. For example, parents have not had the opportunity to “know” their child for very long and have few positive shared experiences with the lost person-to-be. Thus, they mourn “what could have been” in the future,

rather than “what was” in the past. Parents may feel as though the love, energy, time, and physical, psychological and sometimes financial commitments expended to bring the child into the world were largely unrewarded. Parents may have to face the task of explaining what happened to family and friends, when they themselves may not fully understand what happened, as often there is no identified cause for the loss (Nikcevic, Kuczmierczyk, Tunkel, & Nicolaides, 2000). Further, a perinatal loss can leave a woman feeling as though something she did caused the death of her child, as though her own body has betrayed her, that she is “unfit” to be a mother, or that there is something wrong with her womanhood, all contributing to self-blame and guilt (Barr, 2004; Cote-Arsenault & Mahlangu, 1999). In addition to the acute psychological consequences of perinatal loss, women sometimes experience physical trauma as well when the consequences of pregnancy loss and/or pre-term delivery require an invasive medical procedure or threaten the life of the mother.

Unlike other losses, where bereavement rituals are well established, extended family and friends often do not know how to react or provide support following perinatal loss. Some may even view this loss as insignificant, believing the parents can just “try again,” which leaves parents feeling extremely alone and invalidated in their grief (Janssen, Cuisinier, & De Graauw, 1997; Lasker & Toedter, 1991). Turton et al. (2001) found that perceived insufficient or uncertain support from family members following a perinatal loss was associated with greater PTSD symptom severity. Inversely, Toedter, Lasker, and Janssen (2001) reported the convergent evidence from eight studies that indicated the perception of strong support from friends and family was consistently related to lower grief scores. However, perinatal loss has been called a “silent loss,” particularly because others do not know what to say or believe it will upset the parents to bring up the loss, increasing parents’ perceptions that others would feel uncomfortable talking about the loss (Leon, 2001).

Bennett et al. (2008) conducted prior research on the psychological needs of women who suffered a perinatal loss and the deficits that may contribute to the development of pathological symptomatology in the post-loss interval. Ninety-one women who experienced a perinatal loss within the past 5 years at one of four Boston area hospitals participated in this exploratory study. Using hierarchical regression analyses, Bennett et al. (2008) found that maladaptive coping strategies, such as avoidance, suppressing emotions, or accepting responsibility for the loss were generally associated with adverse outcomes, including increased reports of complicated grief (Std. $\beta = .322$, $p = .024$), PTSD (Std. $\beta = .348$, $p < .002$), anxiety (Std. $\beta = .720$, $p < .001$), and depression

(Std. $\beta = .763$, $p < .001$) symptomatology. Increased use of adaptive coping strategies, such as seeking social support, problem solving and positive reappraisal, was predictive of increased reports of posttraumatic growth (Std. $\beta = .433$, $p = .005$). Keeping in mind the internal and external validity flaws inherent in retrospective reports of a self-selected sample, these results suggested potential for a skills-based early intervention aimed at improving the coping capacity of women who suffer this type of loss to have a therapeutic benefit for this population.

The needs of many parents who experience perinatal loss and the potential for research and clinical impact within this population are both great. Thus, the aims of this investigation were to develop and preliminarily evaluate the utility of a cognitive-behavioral intervention targeting the unique sustained psychological and behavioral sequelae of perinatal bereavement. To accomplish this goal, we developed and manualized a treatment based on extant intervention models and our research on the unique phenomenology of perinatal loss (Bennett et al., 2008).

Method

Research Design

This investigation utilized a single-case, multiple-baseline across subjects design (Barlow, Nock, & Hersen, 2009; Kazdin, 2003) to evaluate the efficacy of the proposed intervention in decreasing reported grief symptoms in a small sample of women who recently experienced a perinatal loss. Participants were randomly assigned to a 2-week, 4-week, or 6-week waitlist condition to allow for the collection of baseline data prior to the start of treatment. The baseline phase consisted of weekly visits with the study therapist to collect assessment data and offer a supportive check-in session, which provided a control condition by which the subsequent effects of the weekly cognitive behavioral intervention sessions could be compared. This design allows for assessing changes in rate of symptom improvement during treatment relative to baseline within and between subjects, as well as the extent of symptom change with the implementation of specific treatment components (Barlow & Nock, 2009).

Participants

The study participants were five women who suffered a perinatal loss within 1 to 3 months prior to their recruitment into this investigation (mean length of time since loss=6 weeks). Women who had experienced a spontaneous abortion, perinatal loss, or infant death between 8 weeks gestation and 3 months postpartum were potentially eligible for participation in this investigation. These broad inclusion criteria were chosen given the empirical evidence that mental health distress is not

dependent of gestation age at the time of loss (as described in the literature review above). Further, given the pilot study stage of this research, learning who presented for participation was a variable of interest. Women recruited to the study were seen for their initial assessment at least 1 month after their loss to allow for natural decreases in acute symptoms that typically occur within the first month following a traumatic event (i.e., Bryant, 2003; Bryant, Creamer, O'Donnel, Silove, & McFarlane, 2008). Following this initial assessment, women who scored at or above the clinical cutoff of 91 on the Perinatal Grief Scale (Toedter, Lasker, & Alhadeff, 1988) were eligible to participate in the intervention.

Exclusion criteria consisted of co-occurring conditions or situational variables that posed a strong likelihood of adversely impacting a woman's ability to complete this treatment protocol or for which the utility of the proposed intervention was highly questionable at the time of her assessment (e.g., acute mania, suicidality, or psychosis). None of the women assessed for this study met criteria for these conditions; however, a referral plan was in place to guide women toward appropriate treatment in their local community should they need to be excluded from this study for any reason. The same referral plan was set up in case a participant requested, or her clinician suggested, additional treatment following participation in the study intervention. This was the case for one participant, and referrals were provided based on her presenting problem, geographic location, and preferred payment plan (self-pay vs. insurance). None of the women recruited were taking psychiatric medications at the time of their participation, so medication stabilization was not an issue. The five women who participated in the investigation were ethnically diverse, well-educated (four with graduate degrees, one completing her bachelor's degree), and all were of a relatively high socioeconomic status (income above \$100,000 per year). Demographic information for these participants is presented in Table 1.

Measures

Prior to the initiation of the baseline phase of the investigation, participants took part in an initial assessment consisting of self-report questionnaires and a semistructured interview (described below) to determine their eligibility for study participation. The Perinatal Grief Scale, was administered each week during the baseline and intervention phases of the study. Treatment evaluation and adherence measures were also administered each week during the intervention phase of the study. The full assessment battery was administered a four time points: prebaseline, postbaseline/pre-treatment, immediately post-treatment, and at 6-weeks post-treatment.

Table 1
Participant Demographic Characteristics.

Variable	P1	P2	P3	P4	P5
Age	32	42	29	33	38
Marital status	M	N	M	M	M
Ethnic/Cultural Background	Russian-American	Caucasian-American	Subcontinental Indian-American	Chinese-American	Mexican-American
Education	Ph.D.	J.D.	R.N.	M.A.	SC
Occupation	Post-doctoral fellow	Attorney	Nurse	Pediatric Physical Therapist	Student
Annual Income	>100 K	>100 K	>100 K	>100 K	>100 K
Loss Status	34 weeks	10 weeks	twins at 21 and 22 weeks	8 weeks	twins at 20 and 22 weeks
Time Since loss	1st loss 8 weeks	2nd loss 4 weeks	1st loss 5 weeks	3rd loss 5 weeks	1st loss 6 weeks

Note. P=participant; N=never married; M=married; C=Caucasian; SC=some college.

Perinatal Grief Scale (PGS; Toedter et al., 1988)

Total score on the PGS was the primary dependent measure of interest for this study and a score of 91 or above on this measure was the primary inclusion criteria for participation in the intervention. Responses are given using a 5-point Likert-type scale and include items regarding sadness, missing the baby, crying for the baby, functional impairment in daily activities, withdrawal from others, feelings of worthlessness, and despair. This questionnaire also served as a weekly screen for suicidal ideation with an item addressing this concern. In a meta-analysis of 22 studies using this measure, totaling nearly 2,500 participants, Toedter et al. (2001) found that the internal reliability of the measure was high, with Cronbach's Alpha ranging from .92 to .96 for these studies. The authors calculated the standard error of the mean (SEM) for normative purposes across studies and found that the SEM equaled 3.08 for the total scale with 2,243 participants. In addition, they found that 95% of the time the PGS total score fell between 78 and 91, with the upper bound 95% confidence interval suggesting that 97.5% of a perinatal bereaved sample will score below 91 on this measure. Thus, a score above 91 can be considered to represent a clinically significant level of grief. Potvin, Lasker, and Toedter (1989) calculated the test-retest reliability for this measure and found that the correlations ranged from .59 to .66 ($p < .001$).

Anxiety Disorders Interview Schedule for DSM-IV: Lifetime and follow-up versions (ADIS-IV-L & ADIS-IV-F; DiNardo, Brown, & Barlow, 1994)

Shortened versions of the ADIS-IV-L and ADIS-IV-F were used to assess pretreatment and posttreatment levels of anxiety and depressive disorders, respectively. Participants were assigned a clinical severity rating (CSR) on a scale from 0 (*no symptoms*) to 8 (*very disturbing/disabling symptoms*) for each disorder believed to be present at the

end of the interview (CSR of 4 or above indicates marked impairment and suggests need for clinical intervention). Diagnostic reliability for anxiety and mood disorders ranges between $k = .61$ and $k = .81$, with the exception of dysthymia ($k = .36$) (Brown, DiNardo, Lehman, & Campbell, 2001).

Ways of Coping Questionnaire (WOC; Folkman & Lazarus, 1988)

This 67-item questionnaire is used to assess individuals' coping styles and has been found to be highly reliable across samples (Vitaliano, Russo, Carr, Mauiro, & Becker, 1985). It was utilized in this investigation to assess change in frequency of maladaptive and adaptive coping strategies. The Escape/Avoidant Coping subscale of this measure was used specifically to assess for frequency of avoidant coping techniques reportedly utilized (e.g., try to make myself feel better by eating, drinking, smoking, using drugs or medication; avoid being with people in general) given the previous finding that avoidant coping was associated with greater reported symptomatology (e.g., Bennett et al., 2008). The reliability for this subscale with a larger sample of perinatally bereaved women was good ($\alpha = .81$; Bennett et al.). The standard error of the mean for this subscale equaled 2.22.

End-of-Session/End-of-Treatment Questionnaires

Brief End-of-Session and End-of-Treatment questionnaires were created for the purposes of this investigation to assess participants' degree of engagement in the intervention and satisfaction with the intervention process. Participants were invited to rate each session on a scale from 1 to 5 (where 5 = *extremely helpful*). Participants were also invited to provide qualitative responses indicating aspects of the session/treatment that they found helpful, neutral, or unhelpful, and to provide suggestions for revisions to the protocol. Responses on these measures

were utilized to inform review and refinement of the treatment.

Intervention

Intervention components by session are provided in Table 2. The intervention components were influenced by the prior research findings of Bennett et al. (2008) and utilized source material from The Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (Barlow et al., 2010; Wilamowska et al., 2010). In recent years, Barlow and colleagues have developed this transdiagnostic approach to treating emotional disorders, which we argue has relevance to targeting perinatal loss and the affective state of grief. This treatment approach is based, in part, on the theory that individuals with a variety of psychological disorders may experience and respond maladaptively to a range of emotion states in similar ways (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010). That is, regardless of the type of problem, individuals with significant psychological disorders are less able to tolerate and cope with a broad range of negative affective states, though they experience these negative mood states more frequently and more intensely than those without anxiety and mood disorder diagnoses (Fairholme, Boisseau, Ellard, Ehrenreich, & Barlow, 2010). Given that many women who experience perinatal loss will not necessarily meet criteria for an existing mental health diagnosis, we believed that using a broad, transdiagnostic approach to promote adaptive coping and emotion regulation would be helpful for the varied emotional experiences that may impair functioning in the wake of a perinatal loss.

Instilling adaptive emotion regulation skills and facilitating adequate social support were key goals of the intervention because these variables were strongly related to mental health problems following perinatal loss in our prior research (i.e., Bennett et al., 2008). Increasing awareness, tolerance and effective regulation of emotions were also important factors for increasing women's feelings of self-efficacy in managing intense grief experiences. This was done through the practice of adaptive coping skills, such as pleasant events scheduling, mindfulness, and cognitive reappraisal, which were taught in early sessions and practiced throughout treatment. Various "emotion exposures" were the primary vehicle to access in session the difficult emotions women were confronted with in their daily lives (e.g., grief, anger, shame, guilt, anxiety). The participants were then supported by the therapist in identifying the emotions, tolerating the experience, and ultimately gaining more control over the regulation of their emotional experiences through the use of adaptive coping skills. A general "mindful awareness of thoughts and feelings" exercise was practiced during the second session to facilitate present-focused, nonjudgmental awareness of emotions, and additional exercises were provided for practice at home. Cognitive reappraisal techniques were taught and practiced in Session 3 to help women restructure unhelpful cognitions, such as those focused on self-blame.

Prior to initiating emotion exposure practices, time was spent identifying sources of emotional and logistical support that participants could utilize for social support during treatment, for assistance in exposure practices, and/or in managing day-to-day tasks. Emotion exposure

Table 2
Intervention Content.

Session	Primary Goal	Content
1	Psychoeducation	Education about common reactions to perinatal loss and emotions, including relationship between emotions, cognitions, physiology, and behavior. Describe treatment model and rationale for emotions exposure. Homework: monitor emotions throughout week.
2	Emotion regulation skill building	Pleasant Events Scheduling. Mindfulness practice. Homework: practice these skills throughout week.
3	Emotion regulation skill building	Cognitive Reappraisal Homework: practice cognitive reappraisal and other skills
4	Social Support enhancement	Review the impact of grief on relationships and vice versa. Build a social support inventory to identify people who can provide emotional and/or logistical support. Homework: utilize an identified support person.
5	Exposure	Emotion exposure (general, imaginal, in vivo, narrative) as appropriate. Homework: practice exposure, continue skill practice
6	Exposure	Continue targeted exposure practices (in vivo, narrative, imaginal) as appropriate. Homework: practice exposure, continue skill practice
7	Exposure	Emotion exposure practice via revision of loss narrative incorporating cognitive reappraisal where appropriate, or other exposure practice options (in-vivo, imaginal). Homework: practice exposure, continue skill practice
8	Review and plan for future	Review psychoeducation and skills learned. Review revised loss narrative. Make plan for continued practice.

practices were done gradually according to a predetermined hierarchy of perceived emotional difficulty, thus providing women with control over the pace and intensity of exposure practices. Emotion exposure targets included all types of exposure practices including situational exposure (e.g., visiting the hospital room, going to the baby section of Target), imaginal exposure (e.g., imagining traumatic moments of the pregnancy or birth, imagining a more desired outcome), and/or narrative exposure (e.g., speaking or writing about the perinatal loss experience) according to the needs and abilities of each participant. General emotion-inducing stimuli were also used (e.g., songs, movie clips), often early in the treatment process, to generate particular emotions without specific loss related content. These practices were done in order to provide participants with opportunities to practice tolerating and regulating their emotions in session, with the goal of decreasing behavioral or cognitive avoidance related to reports of functional impairment in their daily lives.

Procedure

Approval for this research study was obtained from the human subjects research Internal Review Board at participating institutions. Following a perinatal loss, it is standard practice for women to be informed of all options for psychosocial treatment by their primary physician, Obstetrician/Gynecologist (OB/Gyn), or hospital social worker, should they be interested in seeking professional assistance in coming to terms with and processing their loss. Participation in this intervention research study, called The Coping With Perinatal Loss Program (CPLP), was included among these options at collaborating hospitals. If a woman was interested, she was given a pamphlet with information about the intervention and proposed research project before leaving the hospital, or at a follow-up appointment. Women then contacted the primary investigator (SMB) for more information and/or to schedule an initial assessment appointment. An informed consent form was read, discussed, and signed before beginning the initial assessment and a copy of this consent form was given to the participant for their records. Women were told they could opt to include their partners in treatment sessions if they wished, and some expressed interest in this option, but no participants followed through with having her partner involved in the therapy sessions, either due to scheduling conflicts or personal preferences.

Twelve women made initial contact for more information about the study, and of these, 7 presented for an initial assessment. Of the 5 who chose not to participate, 2 indicated they pursued another type of care instead (standard couples counseling and a loss support group)

and the remaining 3 reported they chose not to seek services at this time. Of the 7 women who presented for an initial assessment, 1 did not meet criteria for enrollment in the study because too much time had passed since her loss, and thus she was provided with referrals for standard outpatient therapy. Six women enrolled in the study, and 1 woman dropped out after Session 3 because she became pregnant and no longer wished to participate in the study.

Following the initial assessment, women who scored a 91 or above on the PGS were randomly assigned to a 2-, 4-, or 6-week baseline period. Check-in sessions were scheduled once a week during baseline to collect paperwork, monitor participant functioning, and to serve as an active waitlist control condition. Following the baseline period, women entered the intervention phase, which consisted of eight weekly sessions lasting approximately 60 minutes. The therapist was the lead investigator of this study (SMB) who was a senior graduate student at the time of data collection. A licensed clinical psychologist familiar with the intervention protocol and trained in bereavement-related care provided weekly supervision. As stated above, women completed the PGS weekly during the baseline and intervention periods, and participated in the full assessment battery at four time points: prewaitlist, postwaitlist, postintervention, and 6-week follow-up. An independent evaluator conducted the postintervention and 6-week follow-up assessments.

Sessions were videotaped and just over 10% (5 of 40 session tapes) were picked at random for viewing by an independent rater highly trained in the CBT and the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders to ensure adherence to the intervention protocol. Adherence to the intervention manual was rated via a checklist of predetermined goals addressed in each session, and was determined to be very good (95%).

Analytic Strategy

Given the choice of a multiple baseline design in this investigation the primary data analysis strategy used was visual inspection, as is standard practice in most single-case research designs (Hayes, Barlow, & Nelson-Gray, 1999; Kazdin, 2003). Changes in symptomatology and functioning over time were examined by visually inspecting patterns of change in the level, slope, and stability of the PGS scores. Changes that are large in magnitude, temporally related to the baseline-to-intervention phase change, consistent throughout the intervention phase, and similar across participants allow for the strongest conclusions to be drawn about the relationship between the intervention and reported symptomatology (Barlow,

Nock, & Hersen, 2008; Hayes et al., 1999). A reduction below the suggested clinical cutoff of 91 on the PGS increased the inferred efficacy of the intervention. Further, large magnitude changes were examined relative to their temporal relationship to particular intervention components in order to infer relative efficacy of intervention parts. Replication of these differences across subjects and baseline conditions increases the likelihood that reported improvements are due to the efficacy of the proposed intervention as opposed to other variables.

A reliable change index score (RCI) was also calculated to determine the significance of change in the PGS and WOC scores during the waitlist and intervention phases above and beyond that of normal measurement variance and/or change due to the passage of time. Waitlist RCI scores were also compared to intervention RCI scores to determine if reported changes were more significant during the intervention period. To calculate the RCI, the posttreatment score is subtracted from the pretreatment score and this result is divided by the standard error of the differences (Ferguson, Robinson, & Splaine, 2002). If the product is larger than the z-score level of significance, in this case 1.96 ($p < .05$), then the change can be considered to be beyond that of chance variation. The formula uses the SEM, which is calculated using standard deviations and reliability coefficients of normative samples, all of which are statistically sound for the PGS and WOC.

Diagnostic status and clinical severity ratings as assessed by the ADIS-IV were also examined for all participants across primary assessment points to determine whether a change in the presence or severity of a diagnosis was related to the study phase (see Table 3). These analyses were conducted in an exploratory manner, highlighting components of the intervention that were reported to be particularly useful. Participants' names have been replaced with participant numbers to protect anonymity and confidentiality.

Results

Participant 1 (P1)

On the PGS (see Fig. 1), P1's score increased during her 2-week baseline period, reflecting a moderate worsening of grief symptoms in the absence of intervention. Immediately following the baseline-to-intervention phase change, a downward level shift of moderate magnitude was observed. Following some variability during the early weeks of intervention, P1's scores trended steadily downward to the postintervention assessment. However, her PGS score increased at the 6-week follow-up assessment and never fell below the cutoff score of 91. The RCI for the waitlist period was -1.61 (see Table 4), which represents a trend toward significantly worsening symptoms. From pretreatment to posttreatment the RCI was 1.61, which is nonsignificant but represents a trend toward significant improvement in symptomatology. P1's scores on the Escape/Avoidance scale (EAS, see Table 4) showed a notable change. Her scores remained constant during the baseline period (RCI=0), then decreased following the intervention and postintervention periods (RCI=0.45). The intervention RCI was not significant; however, it appears the intervention may be related to a decrease in P1's use of some avoidant emotion-regulation coping strategies. This participant did not meet diagnostic criteria for an Axis I disorder at any time point. P1 completed the End-of-Session questionnaire after six of the eight sessions. Her mean and modal session satisfaction score was a 4 out of 5 (5 = *extremely helpful* and 1 = *not at all helpful*). She reported one session to be a 3 out of 5.

Participant 2 (P2)

P2's scores on the PGS (see Fig. 1) decreased significantly during her 2-week baseline phase (RCI=2.52, see Table 4) and continued to trend downward, with some variability, during the intervention phase until Session 7. Her scores increased slightly toward the end of the

Table 3
Participant Diagnostic Status and Clinical Severity Ratings.

Participant	Intake	CSR Post-BL/		CSR Post-TX		CSR 6-WK		CSR
	DX	Pre-TX	Diagnosis	DX	DX	FU	DX	
P1	None	NA	None	NA	None	NA	None	NA
P2	None	NA	BN	4	BN	4	BN	4
P3	GAD	4	GAD	4	Adj disorder w Anxiety	3	MDD	3
						4	PDA	3
P4	None	NA	None	NA	None	NA	None	NA
P5	SP (high way driving)	4	SP (highway driving)	5	SP (highway driving)	3	SP (highwaydriving)	4

Note. P=Participant; CSR=Clinical Severity Rating; NA=not applicable; BN=Bulimia Nervosa; GAD=Generalized Anxiety Disorder; Adj=adjustment; MDD=Major Depressive Disorder; PDA=Panic Disorder with Agoraphobia; SP=Specific Phobia.

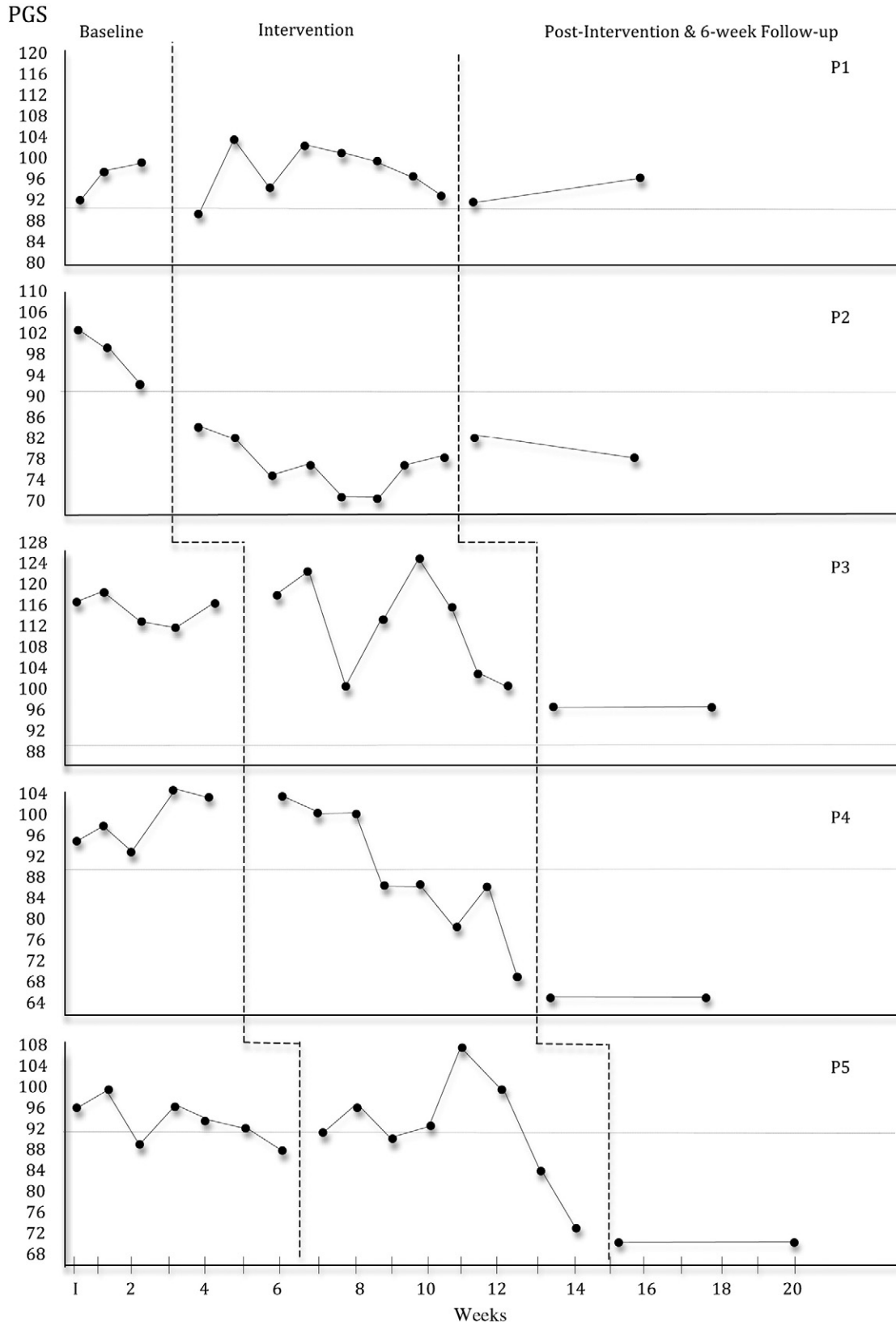


Figure 1. Weekly Perinatal Grief Scale (PGS) scores across baseline (2-, 4-, or 6-weeks), intervention, and postintervention phases to 6-week follow-up for all participants.

Table 4
Participant Scores for Outcome Measures across Study Phases.

Measure	Treatment Phase	Participant (baseline)				
		P1 (2 wk)	P2 (2 wk)	P3 (4 wk)	P4 (4 wk)	P5 (6 wk)
PGS	Intake	92	103	117	95	96
	Post-baseline	99	92	117	103	88
	<i>RCI</i>	-1.61	2.52*	0	-1.83	1.83
	Post-intervention	92	82	97	66	72
	<i>RCI</i>	1.61	2.29*	4.59*	8.49*	3.67*
	6-week follow-up	97	78	97	66	78
WOC-EA	Intake	5	15	12	6	9
	Post-baseline	5	15	12	9	7
	<i>RCI</i>	0	0	0	-1.35	0.90
	Post-intervention	4	12	6	1	6
	<i>RCI</i>	0.45	1.35	2.70*	3.60*	0.45
	6-week follow-up	3	7	7	3	7

Note. P=participant; PGS=Perinatal Grief Scale; WOC-EA=Ways of Coping, Escape/Avoidance Scale; wk=week; RCI=reliable change index; * $p < 0.5$.

intervention phase, but remained well below the clinical cutoff of 91 for this measure and decreased again at the 6-week follow-up assessment. From pretreatment to post-treatment, the RCI was also significant ($RCI=2.29$); however, the impact of the intervention on P2's grief scores was inconclusive because the downward slope during the baseline phase precludes the possibility of determining improvements related to the intervention beyond the impact of time. The impact of the intervention appears to be noteworthy for her scores on the Escape/Avoidance scale of the WOC (EAS, see Table 4), which remained constant during the baseline phase ($RCI=0$), and decreased following the intervention phase ($RCI=1.35$), a change that approached statistical significance and was maintained at the postintervention assessment. This observation suggests that participation in the CBT intervention coincided with reported decreases in avoidant coping relative to no reported change during the baseline phase. P2 reported no current DSM-IV diagnoses on the ADIS-IV at the intake assessment (see Table 3). However, at the postbaseline/pretreatment assessment, she reported that she had three episodes of bingeing and purging behavior during the previous week. She agreed to monitor the frequency of the binge/purge behavior on a weekly basis during the course of the intervention, and found that the frequency of this behavior decreased steadily throughout the intervention period as she acquired more adaptive skills for regulating her emotions. At her postintervention assessment, the independent evaluator assigned a diagnosis of bulimia nervosa at a clinical severity rating of four out of eight. This clinical severity rating remained unchanged at the 6-week follow-up assessment, although P2 reported no

disordered eating behavior at this assessment and reportedly had not engaged in bingeing or purging at all over the prior 2 weeks. P2 completed the End of Session questionnaire after six of the eight intervention sessions. Her mean and modal rating of the helpfulness of the intervention was a 5 out of 5, where 5 equals *extremely helpful*. She rated one session as a 4 out of 5.

Participant 3 (P3)

P3's scores on the PGS (see Fig. 1) showed relative consistency throughout the baseline phase ($RCI=0$, see Table 4) and then increased during the first 2 weeks of the intervention. Her reported grief showed a significant drop at Week 3 of the intervention phase, concurrent with the acquisition and practice of cognitive reappraisal skills. Her PGS score increased at Weeks 4 and 5 at the start of exposure practice, and then decreased linearly, steadily, and significantly for the remainder of the intervention phase. Her overall RCI from pretreatment to posttreatment equaled 4.59 (see Table 4), which represents a significant change in reported symptomatology. However, P3's score on the PGS never fell below the clinical cutoff during the baseline, intervention, and postintervention phases.

P3's score on the Escape/Avoidant scale (EAS, see Table 5) remained high and consistent during the baseline phase ($RCI=0$), and then decreased significantly during the intervention phase ($RCI=2.70$). Her score was observed to increase just slightly at the 6-week follow-up. This suggests that participation in the CBT intervention is related to a significant decrease in avoidant coping as compared to the waitlist condition.

P3 met criteria for generalized anxiety disorder (GAD) at a clinical severity rating (CSR) of four out of eight, at the intake and postbaseline/preintervention assessment points (see Table 3). She also reported a significant level of depression symptoms, the onset of which coincided with the death of her babies, thus these symptoms were subsumed under her grief and a diagnosis of major depression was not assigned at that time. At her postintervention assessment, she no longer met criteria for GAD at a clinical level, but her depression symptoms persisted and then met criteria for a diagnosis of major depression of mild severity. At the 6-week follow-up, however, the depression symptoms had improved and thus the independent evaluator indicated that P3 no longer met full criteria for this diagnosis. P3 completed the End-of-Session questionnaire after five of eight intervention sessions. Her mean and modal rating of the sessions was a 3 out of 5.

Participant 4 (P4)

P4's scores on the PGS (see Fig. 1) increased during the waitlist period ($RCI = -1.83$), a change that approached significance and was maintained across the phase change to Session 3. A significant decrease in reported symptoms then occurred between intervention Weeks 3 and 4, after learning and practicing cognitive reappraisal skills, which brought her score below the clinical cutoff score of 91 for this measure. Her scores dropped again between Weeks 5 and 6, increased at Week 7, and then decreased substantially at Week 8. The intervention phase RCI for P4 equaled 8.49, which represents a significant change in symptomatology above and beyond the effects of time and/or measurement variance. Her score decreased slightly again at the posttreatment assessment time point and this change was maintained at the 6-week follow-up assessment point. P4's score on the Escape/Avoidance scale (EAS, see Table 4) increased during the baseline period ($RCI = -1.35$), and then decreased significantly during the intervention phase ($RCI=3.60$), supporting the conclusion that changes on this dependent measure were related to the manipulation on the IV (introduction of the CBT intervention). This participant did not meet diagnostic criteria for an Axis I disorder at any time point. P4 completed the End-of-Session Questionnaire following seven of the eight intervention sessions. Her mean and modal rating of the session helpfulness was 4 out of 5.

Participant 5 (P5)

P5's scores on the PGS (see Fig. 1) showed some variability during her 6-week baseline phase, becoming more consistent during the second half of the baseline phase and across the phase shift. Her RCI during the

waitlist period was -1.83 , representing an increase in symptomatology that approached statistical significance. During the intervention phase, a substantial score increase was observed between intervention Week 4 to Week 5, followed by a steep drop from Week 6 to 7, at which point her score dropped below the clinical cutoff. This increase coincided with the onset of emotionally challenging exposures practices. P5's RCI during the intervention phase was 3.67, representing a significant decrease in reported symptomatology above and beyond the passage of time or measurement variance. Her score showed a slight decrease at the postintervention assessment point and this score was maintained at the 6-week follow-up assessment. P5's score on the EAS subscale of the WOC decreases during both the waitlist ($RCI=0.9$) and intervention periods ($RCI=0.45$), thus it cannot be determined from this measure that a decrease in avoidant coping was related to her participation in the intervention.

At the intake and postbaseline assessments, P5 met criteria for a specific phobia of driving. She had been avoiding highway driving since she became pregnant, following an episode of panic symptoms she experienced while driving, for fear that she could get in a car accident and hurt her babies. During the intervention, P5's avoidance decreased a great deal as she participated in behavioral exposure practices targeting her phobic behavior, and at the postintervention assessment the independent evaluator indicated that P5 no longer met criteria for this diagnosis. Thus, it can be concluded that her change in diagnostic status was related to her participation in the intervention. P5 completed the End-of-Session questionnaire following four of the eight intervention sessions. Her mean and modal rating of session helpfulness was 5 out of 5.

Discussion

In this a preliminary pilot study, we evaluated the feasibility and efficacy of an eight-session cognitive-behavioral intervention for perinatal grief using a single-case, multiple-baseline across subjects design. Several findings emerged. First, the intervention appeared to lead to systematic decreases in grief symptoms for most study participants, relative to various baseline intervals. Regardless of the length of the baseline period (2, 4, or 6 weeks), the dependent variables remained relatively consistent and stable during the baseline period, and then showed a change in level, trend, and slope following the introduction of the independent variable (intervention), typically around Session 3.

For all participants, with the exception of P1, reported grief on the PGS was substantially lower following the intervention period relative to the baseline phase. Although grief scores improved following the intervention, for some participants (e.g., P1 and P3) the PGS score

did not drop below clinical significance, weakening the conclusions that can be drawn about the impact of the intervention, or perhaps suggesting a longer duration of intervention was needed as the RCI's for these participants suggested important change was occurring. For one participant (P2), scores decreased during baseline, precluding what conclusions can be drawn about the impact of the intervention.

The RCI scores suggested significant symptom reduction during the intervention phase relative to the baseline phase for three of the five participants, and a trend in this direction was identified for a fourth participant. Changes in diagnostic status and clinical severity ratings on the ADIS-IV also suggest that clinical anxiety and depression were much improved following the intervention phase. In addition, one participant's eating disorder symptoms showed considerable improvement, which appeared to be related to components of the intervention. The improvement in comorbid problem areas provides some support for the generalizing impact of the transdiagnostic techniques employed in our treatment (e.g., Barlow et al., 2010).

The intervention also appeared to have an impact on avoidant coping, as reported on the Escape/Avoidance scale of the WOC, relative to baseline. Four of the five participants showed no change in their use of avoidant coping, or reported an increase in avoidant coping, during the baseline period. All participants showed a reported decrease in the use of avoidant coping skills during the intervention phase, and for two participants this change was statistically significant, with a trend in this direction for a third participant. Arguably, given these findings, teaching and practicing adaptive emotion-regulation strategies such as pleasant events scheduling, mindfulness, and cognitive reappraisal helped reduce avoidance strategies during the intervention phase whereas little to no change occurred during the waitlist condition.

The weekly repeated measurement schedule for the PGS allowed for a close look at the relationship between reported symptoms and specific intervention components. Two interesting observations appeared to be present across subjects. Nearly all participants showed two marked decreases in symptoms during the intervention phase. The first occurred around the third session when cognitive reappraisal skills were introduced, and the second was related to participation in emotion exposure exercises during the second half of the intervention. Given this observed pattern, it may be that these are the two most "active" ingredients of the intervention for this sample. It is also of note that before the second observed decrease toward the end of treatment, there was typically a significant increase in reported symptoms. An increase in symptoms at the onset of emotion exposure practice might be concerning to a clinician without sufficient training in exposure therapy. The subsequent decrease

supports the notion that pushing through initial increases in symptoms at the onset in exposure may result in the benefit of significant and stable symptom relief.

Limitations of the intervention were observed as well. Two participants (P1 and P3) did not experience a decline in grief symptoms past the clinical cutoff points on the PGS. There are several factors that may have differentiated why some participants appeared to demonstrate a better response. Individual differences in intervention response did not appear to be related to diagnostic status, gestational age of the child at the time of the loss, or number of prior losses, based on an anecdotal comparison of demographic information (Table 1) and symptom change (Fig. 1, Tables 3 and 4). However, there may be other individual differences and/or nonspecific therapy factors, such as the therapeutic alliance, appropriate intervention length, or client buy-in and practice of intervention components, which may have contributed to differences in the treatment response (e.g., Siev, Huppert, & Chambless, 2009). In addition, the small sample size obviously limits the generalizability of these findings. While the sample was ethnically and culturally diverse, they were similar in SES and education level. This may limit the conclusions that can be drawn about a larger perinatal loss population; however, this demographic may represent a significant subset of the population who are (a) more likely to present for mental health treatment, and (b) more likely to experience losses following the use of fertility services or other assisted reproductive technology.

Regardless, additional research with a larger sample size is necessary to verify the efficacy of this type of intervention for perinatal grief. Accordingly, one of the goals of this intervention development pilot study was to ascertain whether the level of patient interest in the given intervention and the flow of patient recruitment were conducive to future intervention research, such as a randomized controlled trial. Recruitment for this study was quite challenging, and raised implementation issues that should be addressed in future research. We informally surveyed OB/GYN and NICU care providers at participating institutions to better understand how to overcome these barriers. It was universally recommended that mental health care providers interested in this population have an established presence in these departments in order to better identify patients in need and connect them with appropriate mental health care or psychological support services. A simple and standardized system of screening women following a perinatal loss (such as a brief questionnaire of relevant variables) would likely be quite beneficial for connecting women in need with appropriate services. This type of screening system calls for more research on risk factors associated with poor psychological outcome following perinatal loss, such as insufficient social support, avoidant coping strategies, strength of

attachment to the unborn child, number of previous losses, use of fertility or other reproductive services, other trauma/loss history, and mental health history.

Once identified and referred for the study intervention, participants in this study generally reported high satisfaction scores (overall mean of 4.2 out of 5 on helpfulness ratings, and mean of 4.5 out of 5 for overall satisfaction on our intervention satisfaction measures). Common qualitative suggestions for intervention improvement included extending the length of intervention, and including a group component to facilitate connection with other women who have experienced perinatal loss. The most common qualitative reports of what was helpful about the intervention seemed to break down into three categories: having an empathic, nonjudgmental person to talk to about their emotions and experiences surrounding the loss; psychoeducation about emotions and learning their emotional reactions were “normal” following perinatal loss; and the acquisition of concrete emotion-regulation skills in the context of emotion exposure exercises.

Overall, the inferences that can be drawn from these data regarding the specific impact of the cognitive behavioral intervention on outcome, relative to the supportive-care baseline, are moderate, yet promising. For most participants, reductions in reported symptoms appeared to be clearly related to the baseline-to-intervention phase change because distinct changes in the level, trend, and/or stability of the data are observed. Additionally, this intervention appeared to have a significant impact on decreased avoidant coping, perhaps through increased emotion tolerance and regulation, which led to specific improvements in symptoms above and beyond what was observed in the supportive care baseline. Statistically significant symptom improvement during the baseline phase was observed for one participant, yet for the remaining four participants the RCI scores showed significant or near-significant improvement during the intervention, relative to no change, negative change, or nonsignificant change during the baseline phase. However, this was a very small pilot sample; thus, additional research is necessary to confirm the utility of this intervention. Future research is also necessary to improve identification of women in need of psychological support services and access to evidence-based mental health care following a perinatal loss.

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