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Interpersonal Psychotherapy (IPT) for Major Depression Following Perinatal Loss: A pilot randomized controlled trial

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Abstract

Purpose.—This randomized controlled pilot trial examined the feasibility, acceptability and preliminary efficacy of an adapted Interpersonal Psychotherapy (IPT) for major depressive disorder (MDD) following perinatal loss (miscarriage, stillbirth, or early neonatal death).

Methods.—Fifty women who experienced perinatal loss within the past 18 months, whose current depressive episode onset during or after the loss, were randomized to group IPT adapted for perinatal loss¹, or to group Coping with Depression (CWD), a cognitive-behavioral treatment which did not focus on perinatal loss nor social support. Assessments occurred at baseline, treatment weeks 4 and 8, post-treatment, and at 3 months and 6 months after treatment ended.

Results.—IPT was feasible and acceptable in this population. Although some participants were initially hesitant discuss their losses in a group (as occurred in IPT but not CWD), end of treatment satisfaction scores were significantly ($p = .001$) higher in IPT than in CWD. Confidence intervals around between-groups effect sizes favored IPT for reductions in depressive symptoms during

¹The Group IPT for Major Depression Following Perinatal Loss manual developed for this study is available at no cost by contacting either of the first two authors.

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treatment, as well as for improvement in mode-specific targets (social support, grief symptoms) and recovery from posttraumatic stress disorder over follow-up.

Conclusions.—This group IPT treatment adapted for MDD after perinatal loss is feasible, acceptable, and possibly efficacious.

Keywords

depression; major depressive disorder; spontaneous abortion; stillbirth; perinatal death; posttraumatic stress disorder

Perinatal loss includes early (before 20 weeks; miscarriage) and late (after 20 weeks; stillbirth) fetal death and the death of a liveborn neonate in the first 28 days after birth (neonatal death; Armstrong, 2002). For many women, perinatal loss constitutes a traumatic event representing the death of a future child, disruption of reproductive plans, and doubts about procreative competence (Neugebauer et al., 1997). Despite medical advances, miscarriages occur in 10–15% of recognized pregnancies (Petrozza, 2006), stillbirths in 1 in 160 live births (CDC, 2007) and neonatal death in an additional 1 in 168 live births (CDC, 2015). About 650,000 women in the United States experience perinatal loss each year (American Pregnancy, 2008).

Perinatal loss increases women's risk for major depressive disorder (MDD; see Klier et al., 2002 for a review). For example, the most rigorous case-controlled study to date (Neugebauer et al., 1997) assessed 229 women who had experienced perinatal loss (before 28 weeks of gestation) and 230 matched community controls. This study found that 11% of women with perinatal loss experienced a major depressive episode in the 6 months following the loss, compared with only 4% of community women. Among women with perinatal loss, 72% of cases of MDD began within the first month after loss; only 20% of community cases started during the comparable period. Among women with a history of MDD, 54% experienced a recurrence of MDD following the loss. Studies of depression following stillbirth or early neonatal death (versus miscarriage) have also documented increased depressive symptoms following the loss (Carrera et al., 1998; Clarke and Williams, 1979; Klier et al., 2002). One study (Boyle et al., 1996) found that mothers who experienced a stillbirth or early neonatal death had higher rates of psychological distress (including depressive symptoms) for at least 30 months after their loss than did mothers of living infants. Other research has concluded that “pregnancy loss is... a stressful life event that can give rise to a marked deterioration in a woman's mental health” (Janssen et al., 1996 p. 226; see also Cordle and Prettyman, 1994).

Despite high prevalence of MDD and associated impairment among women who have experienced perinatal loss, no previous randomized studies have evaluated the efficacy of any treatment (psychological or pharmacological) for MDD following perinatal loss. Only one study selected women based on elevated depressive symptoms: Neugebauer et al. (2006) compared telephone interpersonal counseling (IPC), a short, highly scripted version of interpersonal psychotherapy (IPT), to community treatment as usual among 19 women who had recently miscarried. Results favored IPC for decline in depressive symptoms, but women in the IPC arm still had elevated depressive symptoms at the end of treatment.

Although indicating promise for IPT-based interventions for depressive symptoms following miscarriage, this study lacked follow-up data and excluded participants who met full MDD criteria. A few other randomized studies (Kersting et al., 2011; Kersting et al., 2013; Swanson, 1999; Swanson et al., 2009) have found brief, 3–5 session counseling interventions to reduce distress, including depressive symptoms, among general (rather than clinical) populations of women with perinatal loss. However, none of these studies enrolled samples selected for MDD or elevated depressive symptoms. In fact, the Kersting et al. studies excluded individuals with likely MDD or who had suicidal ideation. Research on effective treatments for perinatal loss related clinical disorders, especially MDD (which may include suicidal ideation), is needed.

The current study evaluates the feasibility, acceptability, and preliminary efficacy of a version of interpersonal psychotherapy (IPT) adapted to the needs of women experiencing MDD after perinatal loss. IPT is a front-line treatment for MDD in general (Hollon and Shelton, 2001; National Collaborating Centre for Mental Health, 2010) and perinatal (Clark et al., 2003; Koszycki et al., 2012; O'Hara et al., 2000; Pearlstein et al., 2006; Spinelli and Endicott, 2003) populations. IPT works to increase social support and address interpersonal challenges. Many challenges faced by women experiencing MDD after perinatal loss are interpersonal. For example, because there are few social norms about how to grieve the death of a new infant or a pregnancy loss (Stirtzinger et al., 1999), women may not know how to react or how to ask others to react. Others' avoidance of or discomfort in responding to such an unexpected and sad event may increase women's sense of isolation (Nikcevic, 2003; Stirtzinger et al., 1999). A lack of social support has been associated with greater distress and impairment following perinatal loss (Beutel et al., 1995; Biondi and Picardi, 1996; Swanson, 2003a) and positive social support has been found to be associated with better adjustment to perinatal loss (Abboud and Liamputtong, 2005; Murray and Terry, 1999; Zeanah and Harmon, 1995). IPT can help women identify and request appropriate support.

Perinatal loss can particularly strain couple relationships, increasing emotional and sexual distance (Schaap et al., 1997; Swanson, 2003b), especially if partners deal with the loss differently (Beutel et al., 1996). Women's perceptions of marital difficulties are associated with depression or distress up to a year after miscarriage (Beutel et al., 1996; Forrest et al., 1982; Stirtzinger et al., 1999; Swanson, 2003b). Therefore, addressing the couple relationship as part of IPT's interpersonal focus may be especially important for women experiencing MDD after perinatal loss. Despite the importance of couple functioning issues following perinatal loss, none of the previous intervention studies have reported effects of interventions on couples distress or other interpersonal variables.

This pilot study compares a version of group IPT adapted to treat MDD and associated social and interpersonal challenges following perinatal loss to an un-adapted standard MDD treatment (Coping With Depression, CWD; Lewinsohn et al., 1984). The study examines the feasibility and acceptability of the adapted IPT intervention, and explores preliminary evidence for the following hypotheses:

1. Perinatal-loss specific IPT will be more acceptable to women who experience MDD following perinatal loss than will CWD.
2. Perinatal-loss specific IPT will result in (a) reduced time to recovery from MDD and (b) reduced depressive symptoms relative to CWD.
3. Perinatal-loss specific IPT will result in (a) increased social support and social role functioning, (b) reduced couple distress, and (c) reduced grief relative to CWD.

Methods

Treatments and Treatment Integrity

Both treatments consisted of a pre-group individual session, 12 group sessions, and a 1-month individual booster session (14 sessions total). Groups were slow-open, with group members able to enter the groups every four weeks.

IPT.—IPT identifies a difficult life event or current interpersonal problem and addresses it by helping the individual to improve communication, to change relationship expectations, and/or to build or better utilize her extended social support network. IPT uses education, therapeutic exploration, communication and interpersonal incident analysis, and work on building social support to solve the difficulty that triggered the onset of the depressive episode (Weissman et al., 2000). All three areas in which treatment goals can be set (grief, role transition, interpersonal disputes) can be adapted to address perinatal loss. A specialized treatment manual (Group IPT for Major Depression Following Perinatal Loss) was developed for this study. It is available at no cost by contacting either of the first two authors.

Adaptations. In IPT, a major depressive episode triggered by grief (i.e., bereavement) is typically treated by facilitating the mourning process and by helping patients reestablish interests and relationships that can sustain them (Weissman et al., 2000). One unique feature of perinatal loss is that women often experience it as a “real” loss, but it is not always acknowledged by the culture around them (Gilbert and Smart, 1992). As a result, women experiencing perinatal loss need to learn not only how to deal with their own reactions to the loss, but also to the reactions of other people. Furthermore, losses such as miscarriage, stillbirth, and early neonatal death involve a “unique kind of mourning based on unfulfilled expectations and a loss of the normal order of the life cycle” (Stirtzinger et al., 1999, p. 237). As a result, the death of an infant or end of a pregnancy often raises questions about fault, including what happened to the pregnancy, and questions about meaning, including what this unexpected event means to the woman, means for her relationship with her partner, means about her future, and means about whether or not events are predictable or fair (Gilbert and Smart, 1992). Finally, some women feel guilty or feel like they are losing their connection to the baby as they begin to re-engage in other activities and think less about the loss. In this study, the IPT goal of facilitating the mourning process and re-establishing social contacts was adapted to help women: (1) cope with others’ reactions to the loss, including questions about the baby from acquaintances and cultural attitudes which minimize or ignore the

impact of perinatal loss; (2) address issues of fault and meaning; and (3) find ways to maintain a sense of connection to their lost pregnancy or child and still re-engage in meaningful activities and social contacts.

Women who experience perinatal loss may also be undergoing repeated role transitions, or life changes. For many women, perinatal loss constitutes an unanticipated event representing the death of a future child and disruption of reproductive plans. As a result, it may affect decisions about family, work, and housing plans. Women may be faced with a number of unexpected practical issues such as when and how to return to work, and what to do with the baby's room or other baby gifts that have already been received. Re-engaging in work and social roles can be challenging for women after a perinatal loss, because women often repeatedly have to explain what happened to the pregnancy or to the infant. Perinatal loss may also affect women's role identification because it may engender doubts about procreative competence (Neugebauer et al., 1997). Medical complications resulting from the loss may also interfere with a woman's role functioning and require her partner or those around her to temporarily assume other roles (such as care for other children). In IPT generally, role transition issues are addressed by helping patients express guilt, anger, and loss at the change in roles; and then helping them acquire the skills, attachments, and supports needed to function in the new circumstances. Our adapted role transitions focus addressed women's concerns that they did not adequately perform their role as mothers and to help them make the unexpected transitions to their new roles.

Finally, women who experience perinatal loss may also be experiencing differing expectations in important relationships, or interpersonal conflicts. A stressful event such as a perinatal loss can lead to differences between a woman and her partner or other family members about how to cope with the event, or may exacerbate existing tensions. She may also feel estranged from her female peers who have had live births. IPT typically works to ameliorate these difficulties by helping women to identify and express their interpersonal expectations and to negotiate differing expectations effectively with others. In this study, IPT was adapted to help women identify and request the support they need from others following a perinatal loss in the absence of social norms about how to do so. Women were invited to bring their partner or another support person to 3 of the 12 group intervention sessions. These sessions helped couples clarify their needs and expectations of each other (including permission to grieve differently) and reduce conflicts over how to grieve (including discussing different reactions to the loss, different rates of grieving, what they each believe is appropriate public and private grief, and the meaning or intentions of each other's behavior).

Structure. Group sessions were semi-structured. Each woman had the opportunity to participate in groups covering the four topics (the emotions of grief, understanding what happened, grieving with others, and holding the memory and moving forward; see Table 1) three times: once to begin work on each issue, once to assess progress and problem-solve any difficulties that arise, and then a final time to address any remaining issues and solidify gains. We have found that entering new women into the groups every four weeks allows remaining women to see their own progress and encourages new women by illustrating how the grief process and healing develop over time. For example, the emotions and perspective associated with telling one's loss story and feeling the associated feelings (see Table 1)

changed over women's time in the group (they tended to be less raw and overwhelming and to involve greater perspective over time).

CWD.—The Coping with Depression (CWD) course is a highly structured, manualized (Lewinsohn et al., 1984) psycho-educational group treatment for MDD. We chose CWD as a comparison condition over other standard depression treatments because it is the group treatment with the most empirical support for treating MDD (Cuijpers, 1998; Johnson, 2009) and because it is distinct from IPT. Theoretically, the CWD course is based on social learning theory which posits that depression is associated with a decrease in pleasant and an increase in unpleasant person-environment interactions. The course content is cognitive-behavioral in nature and is designed to train skills that can be used in the alleviation of depression. CWD sessions covered: an introduction to social learning rationale of depression; learning to relax; relaxation in everyday situations; pleasant activities and depression; formulating a pleasant activities plan; two approaches to constructive thinking; formulating a plan for constructive thinking; and maintaining gains. To avoid overlap with IPT, we removed the two CWD sessions on social skills and expanded the other content to fill these sessions. CWD focused on skills for reducing depression in general and did not have perinatal-loss specific components. We also instructed CWD therapists to steer conversations away from the perinatal loss, and to focus on pleasant activities planning primarily on solitary, rather than interpersonal, activities. Therefore, our CWD control did not offer the primary theorized mechanisms of the adapted IPT: work on interpersonal relationships, grief, and social support, loss-related interpersonal challenges, loss-related social support, couple adaption to the loss, and grief-specific coping. As a result, we chose secondary outcomes (social support and social functioning, couple distress, and grief) that assessed hypothesized differences between treatments.

Therapists.—IPT therapists included a psychiatric nurse practitioner with expertise in grief and IPT (ABP), and two clinical psychology postdoctoral fellows. CWD therapists included two clinical psychology postdoctoral fellows with CWD expertise and a psychiatry resident. Sessions were audiotaped. Supervision of IPT was provided by JJ and supervision of CWD was provided by CZ. Weekly supervision consisted of audiotape review and case discussion.

Treatment integrity measures were adapted from existing measures for IPT and CWD, with additional items designed to assess theorized differences between treatment conditions (e.g., addressing loss-related interpersonal challenges, loss-related social support, couple adaption to the loss, and grief-specific coping). A trained postdoctoral clinical psychology fellow conducted adherence and competence ratings on 14% of the sessions. The rater also assessed the percent of time spent discussing the perinatal loss and discussing loss-related communication strategies (intended differences between conditions) in rated group sessions.

Participants

We recruited women ($n = 50$) between 18 and 50 years old who: (1) had experienced a perinatal loss (including early and late fetal death, the death of a liveborn neonate within the first 28 days, and termination due to medical indications) in the last 2 weeks to 18 months;

and (2) currently met all criteria but criterion E (bereavement exclusion criterion) for DSM-IV major depressive disorder as assessed by the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First et al., 1996). To enroll those whose current depressive episode occurred during or subsequent to a perinatal loss, we excluded women whose (1) onset of *current* major depressive episode prior to news of difficulties with the pregnancy or health risk to the infant (women with prior depressive episodes were included). Other exclusion criteria were: (2) SCID-I criteria for lifetime schizophrenia, schizoaffective, or bipolar I disorder (or, if bipolar II, had hypomania episodes in the last year), (3) current SCID-I drug or alcohol dependence, (4) current SCID-I anorexia/bulimia; (5) severe SCID-II borderline personality disorder; (6) any IPT or cognitive-behavioral treatment in the previous 12 weeks. For women with suicidal ideation ($n = 14$; often a desire to die as a way to join their deceased babies), a licensed clinician evaluated them to ensure that they were stable enough for outpatient care. Women with moderate to severe thyroid difficulties or anemia (determined by appropriate lab tests) were referred for care for these problems before being enrolled in the study. If a possible participant had recently begun psychotherapy or antidepressant medications, the study waited until they had been stable on the dose of the other treatment for at least 8 weeks and then verified that they still met criteria for current MDD before enrolling them.

Because the time following a perinatal loss is sensitive, the study did not approach any women in person for recruitment. Instead, we advertised through pamphlets in clinics and hospitals, a study website, and advertisements on local buses and on the internet. We also recruited through providers including those in the women's hospital emergency rooms, social work, psychiatry, as well as infertility clinics, primary care, OBGYN clinics, and loss support groups. After women volunteered for the study, informed consent procedures were conducted before the baseline assessment. Participants were compensated with a \$30 gift card for each assessment (6 assessments total). The study followed ethical guidelines under approval from the institutional review board of both Brown University and Women and Infants Hospital. It was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under Protocol #NCT01867749.

Randomization occurred in a 1:1 ratio and was stratified by type of loss (miscarriage, stillbirth, early neonatal death) and whether or not a participant was receiving other mental health (pharmacotherapy or psychotherapy) treatment. Dose of mental health treatment (pharmacotherapy or psychotherapy) was required to have been stable for at least 8 weeks. The random sequence was generated by an individual not affiliated with the study, with group assignment placed in sequentially numbered opaque envelopes that were sealed until the principal investigator verified that each individual was eligible for the study.

Assessments

Study assessments were conducted by trained research assistants (RAs), one of whom was blinded and one of whom was not, and took place between June 2011 and June 2014. Assessments took place at baseline, treatment week 4, treatment week 8, immediately following treatment, and 3 and 6 months after the end of treatment. Participants had up to 20 weeks after randomization to complete the 12 group and 2 individual sessions. Therefore, the "treatment week 4" assessment actually took place after approximately four group

sessions should have taken place, which was an average of 7 (range 5 – 11) calendar weeks after baseline, the “treatment week 8” assessment actually took place an average of 11 (range 9 – 16) calendar weeks after baseline, the post-group assessment took place an average of 18 (range 11 – 25) calendar weeks after baseline, and follow-ups an average of 31 (range 25 – 37) and 45 (range 38 – 53) weeks after baseline, with no differences between conditions and no relation to depression outcomes. Assessments included structured interviews and self-report measures, and took place at our research offices or at women’s homes. The Social Adjustment Scale, Inventory of Complicated Grief, and the Dyadic Adjustment Scale were only given at baseline, immediately following treatment, and at the two follow-up assessments. Other measures were given at all time points. Data were double entered with discrepancy resolution.

Feasibility and Acceptability.—We assessed the feasibility and acceptability of IPT for MDD after perinatal loss and CWD as a control condition by examining rates of treatment attendance, rates of partner or significant other attendance (for designated IPT sessions), and rates of treatment drop-out (defined as attended 4 or fewer of the 14 possible intervention sessions). We also examined reasons for termination for consistent patterns. Overall treatment satisfaction was measured with the Client Satisfaction Questionnaire-Revised (CSQ-8-R et al., Larsen, 1979). We gathered information on the perceived helpfulness of each treatment component using versions of the End of Treatment Questionnaire (Najavits et al., 1998). We also collected qualitative data on the acceptability of both the adapted IPT-G and the standard CWD using structured individual exit interviews, which asked about the most and least helpful parts of the treatments, the most and least helpful things done by therapists, critical events, responses to the structure of the treatment (i.e., group, allowing new women every four weeks), and helpfulness of treatment components.

Time to MDD recovery.—The Longitudinal Interval Follow-up Examination (LIFE; Keller et al., 1987) interview was used to assess timing of MDD remission. The LIFE uses Psychiatric Status Ratings (PSRs) to provide weekly ratings of the severity of each DSM-IV MDD symptom on a scale of 1 (asymptomatic) to 6 (incapacitated); therefore, participants can be classified as in episode or out of episode each week. “Recovery” is defined as 8 consecutive weeks of a PSR 1–2 (Keller, 2003); time to recovery is defined as the number of weeks between baseline and the beginning of the 8+ week series of PSR 1–2. We also tracked posttraumatic stress disorder (PTSD) and non-study treatment received (medications or psychotherapy) using the same method.

Depressive symptoms were assessed using two measures, the 17-item interviewer administered Modified Hamilton Rating Scale for Depression (HRSD; Hamilton, 1980) and the self-report Beck Depression Inventory-II (BDI-II; Beck et al., 1996).

Social and interpersonal variables.—We used the 12-item Multidimensional Scale for Perceived Social Support (MSPSS; Dahlem et al., 1991) to assess overall perceived social support. The Social Adjustment Scale (SAS; Weissman and Paykel, 1974) was used to assess social role impairment; specifically, difficulties in the ability to do work, as well as functioning in social and friendship relationships, partner relationships, and parenting and other family relationships. We used the total score (sum of all individual items, excluding the

4 global rating items at the end); higher scores reflect worse functioning, so this scale is labeled “social role impairment” in Tables 2 and 3. We used the Dyadic Adjustment Scale (DAS; Antill and Cotton, 1982) to measure couple distress among the 48 (of 50) participants who considered themselves to have intimate partners.

Grief.—Grief symptoms were measured using the Perinatal Bereavement Grief Scale (PBGS; Ritsher and Neugebauer, 2002), which measures grief distinct from depressive symptoms (Klier et al., 2002). Complicated grief is distinct from both typical grief and depression, and is characterized by longstanding, chronic disbelief and anger/bitterness over the death, and intense yearning for and preoccupation with the deceased (Shear et al., 2005). Symptoms of complicated grief were measured using the Inventory of Complicated Grief (ICG; Prigerson et al., 1995). A few items on the ICG were slightly reworded to refer to perinatal loss.

Data Analysis

The main purpose of this pilot study was to adapt IPT to treat MDD following perinatal loss and to collect feasibility and acceptability data on this adapted intervention. Therefore, this was not a fully powered study. With data from 50 participants in intent to treat analyses and some boost in power provided by repeated measures analysis (Faes et al., 2009), we would only have statistical power adequate (.80) to detect moderate to large effects ($d > .50$) with alpha of .05. With an evidence-based, active control condition (CWD), smaller effect sizes ($d \sim .3-.4$) are more likely, reducing power to 39–61%. Per Kraemer (2006), between-condition comparisons in pilot studies like this should be considered exploratory and report 95% confidence intervals around observed effect sizes for all between-conditions comparisons. Therefore, rather than providing definitive tests of treatment effects, analyses examined the direction of effects and the range of effect sizes for differences between conditions. Analyses were intent-to-treat; strategies used (hierarchical linear modeling for repeated measures [HLM] and Cox regression) can accommodate missing data. There were no interim analyses or trial stopping rules.

Most feasibility and acceptability measures were evaluated descriptively. However, we examined preliminary evidence to support the hypothesis (Hypothesis 1) that the adapted IPT treatment was more acceptable than the CWD treatment using t-tests to compare CSQ treatment satisfaction scores, and by comparing number of sessions attended and drop-out (attending 4 or fewer of the 14 possible sessions) rates between conditions.

We calculated the effect size and confidence intervals for time to recovery from depressive episode (Hypothesis 2a). Exploratory tests for differences between conditions used Cox regression, with condition as the predictor and initial HRSD score as the covariate. We also explored time to PTSD recovery among participants meeting criteria for PTSD at the beginning of the study. We also calculated between-conditions effect sizes and confidence intervals for reduction in depressive symptoms using HRSD and BDI-II scores (Hypothesis 2b). Separate, exploratory tests for differences between conditions used HLM with baseline scores as covariates. We did not compare the slopes of change in this small study, but instead

specified the model to compare the mean difference between conditions across all post-intake time points.

Per Hypotheses 3a, 3b, and 3c, we also estimated the effect sizes and 95% confidence intervals for the adapted IPT treatment relative to CWD for social support and social role impairment (MSPSS and SAS total scores), couple distress (DAS scores), and grief (PBGS and ICG scores). Separate exploratory tests for differences between conditions used HLM with baseline scores as covariates. Differences in scores within conditions from baseline to 6-month follow-up used paired-sample t-tests.

Dose-response analyses added the total number of study treatment sessions attended as an additional predictor of HRSD score (using HLM) and incidence of MDD recovery (using Cox regression) over post-intake assessment points. We also explored whether bringing a partner to at least one treatment session was an additional predictor of post-intake DAS scores (using HLM). Finally, we calculated how many participants engaged in new non-study treatment during the active treatment and follow-up phases, and whether engaging in new non-study treatment was a predictor of post-intake HRSD scores or MDD remission.

Results

Sample

About two-thirds of the sample was non-Hispanic White. Women were on average around 30 years old and living with a romantic partner. About half experienced miscarriage, and 40% experienced stillbirth (or late fetal death, 20–40 weeks gestation). Women enrolled in the study a mean of 10 weeks (range 2–49 weeks) after their loss. Nearly two thirds had previous depressive episodes, and participants were on average severely depressed at baseline (see Table 2 for more details). The most frequent comorbidity with MDD in our sample was symptoms meeting criteria for posttraumatic stress disorder (PTSD) except duration (a few women were assessed less than 1 month after their loss). A majority of women in our study ($n = 27$; 54%) had these high levels of PTSD symptoms (19 related to the recent perinatal loss, 3 from another trauma only, and 5 from both traumas). Other common comorbidities included generalized anxiety disorder ($n = 6$; 12%) and panic disorder (with or without agoraphobia; $n = 6$; 12%). Because complicated grief is diagnosed by having a score of at least 30 on the Inventory of Complicated Grief at least 12 (K. Shear, personal communication, January 10, 2012) months after a loss, and because time since loss at intake ranged from 1.4 to 49.1 weeks in our sample, no participants met criteria for complicated grief at intake.

The CONSORT table in Figure 1 shows the flow of participants through the study. Follow-up rates were 66% for Week 4, 76% for Week 8, 72% for the post-treatment assessment, 68% for the 3-month follow-up, and 78% for the 6-month follow-up, with 90% of participants providing at least some follow-up data. Overall, participants completed a mean of 3.6 f/u assessments (of 5) per person; mean number of follow-up assessments completed did not differ by treatment condition ($t = .48$, $df = 48$, $p = .63$). Data on attendance at study treatment are available for all 50 participants.

Feasibility and Acceptability

Attendance.—Of the 14 possible group and individual sessions, CWD participants ($n = 25$) attended a mean of 7.3 ($SD = 5.5$) sessions and IPT participants ($n = 25$) attended a mean of 9.3 ($SD = 5.2$) sessions ($d = 0.37$, 95% $CI = -0.19$ to 0.94 , $p = .19$). Nine of the 25 IPT participants (36%) had a partner who participated in at least one ($M = 1.9$) treatment session. Reasons given for partners not coming to treatment sessions included not having a partner, partner's work schedule, or partner being unwilling to come. Among those whose partners did attend at least one session, these sessions were perceived to be, on average, "very" helpful. Seven of 25 (28%) IPT participants and 11 of 25 (44%) of CWD participants were considered to have dropped out of study treatment (attended 4 or fewer of 14 study treatment sessions; $\chi^2 = 1.39$, $df = 1$, $p = 0.24$). Reasons for dropout given by IPT participants included "didn't want to be in a group with grieving women when she was 8 months pregnant," "lost contact," "scheduling conflict with group time," and "prefers medication." Reasons for dropout given for CWD participants included "didn't want to bring up the feelings again," "wanted to focus on her loss" ($n = 4$), "didn't think she was depressed," "lost contact" ($n = 5$).

Satisfaction with study treatments (Hypothesis 1).—Client Satisfaction

Questionnaire treatment satisfaction scores were higher in the IPT condition than in the CWD condition ($t = 3.54$, $df = 33$, $p = .001$, $d = 1.03$, 95% $CI[d] = 0.44$ to 1.63). On the End of Treatment Questionnaire scale items from "−3 = very harmful" to "3 = very helpful," IPT received significantly higher scores than did CWD for "intervention helped with your depression" ($p = .03$), "intervention helped you adjust to life after perinatal loss" ($p < .001$), and the "helpfulness of the intervention, overall" ($p = .01$). Mean helpfulness ratings of specific IPT treatment components (telling the story of the loss, discussion of what caused the loss, what the loss means, bringing a support person to group, information about how people grief differently, work on how to communicate with others about the loss, how to remember the baby, and how to re-engage in other life roles) was 2.34 ($SD = .43$). Mean helpfulness ratings of specific CWD treatment components (learning about what causes depression, learning to relax, applying relaxation in everyday situations, planning for pleasant activities, learning constructive thinking, making a plan for construct thinking, planning to hold onto what was learned, and treatment handouts and homework) was 1.98 ($SD = .96$).

When asked what they would do if designing their own intervention for women experiencing depression after perinatal loss, participants in both conditions said that they would provide the same or a very similar treatment to the one they received. When asked open-ended questions in exit interviews about helpful aspects of the treatments, several participants in both conditions mentioned the opportunity to hear about other women's experiences with depression and feeling supported and not judged. In addition, IPT participants valued the opportunity to express and normalize feelings; CWD participants valued learning relaxation and pleasant activities skills.

Reactions to discussing/not discussing the loss.: In the exit interviews, many women in the IPT condition described telling the story of their loss as difficult but helpful ("it helped me

process it better”), and all rated it as helpful on the End of Treatment Questionnaire ($M = 2.52$, $SD = .60$). Although initially concerned about hearing other women’s loss stories, most IPT participants also described this as helpful in the exit interviews; however, one woman who had a miscarriage said that she did not like hearing about stillbirths because she “didn’t want to know that could happen.” In exit interviews with CWD participants, at least two said they would have liked to directly discuss the loss. However, another three described wanting to talk about the loss at first, but ultimately deciding it was better not to in the end. Therefore, despite overall differences in treatment satisfaction between conditions, participants seemed to try to find ways to make the best of whatever treatment they received.

Treatments and treatment integrity.—Across rated IPT and CWD tapes, therapists spent 95% of session time on-model (89% for IPT and 99% for CWD), 3% time on opposite-model topics/activities (5% for IPT and 2% for CWD), and 3% of the time on topics/activities from neither model (6% for IPT and 0% for CWD; numbers do not add to 100% due to rounding). In terms of specific expected differences between conditions, 30% of time in rated IPT sessions was spent talking about the perinatal loss (vs. 1% in CWD, $p < .001$); 14% of time in rated IPT sessions was spent facilitating mourning including guilt, anger, and sadness (vs. 0% in CWD, $p < .001$), and 51% of time in rated IPT sessions was spent discussing loss-related communication (vs. 0% in CWD, $p < .001$). Every rated IPT session involved discussion of how the couple was dealing with the loss, whereas only one rated CWD session did. IPT participants spent more time in sessions feeling (45% vs 6%, $p < .001$), less time thinking/learning intellectually (28% vs. 56%, $p < .001$), and about the same amount of time doing (including practicing/planning; 27% vs. 38%, NS) as CWD participants. All items reflecting work on relationships, communication, social support, interpersonal conflicts, the loss itself, effects of the loss, grief, and exploration of emotions differed significantly ($p < .01$) between conditions.

On a scale from “1 = poor” to “7 = ideal,” the independent rater rated IPT sessions between “4 = moderate” and “7 = ideal” quality in terms of helping group members take concrete steps toward solving interpersonal problems or increasing social support ($M = 4.7$), helping them experience emotions ($M = 3.9$), helping group members disclose and feel safe/comfortable ($M = 6.6$), and overall quality of the session from an IPT perspective ($M = 4.9$). CWD sessions were rated in the same range for helping group members take concrete steps toward changing thoughts/activities ($M = 5.2$), delivering assigned lecture materials ($M = 5.6$), assigning and reviewing homework ($M = 6.1$), and the overall quality of the session from a CWD perspective ($M = 5.5$).

Other Outcomes

Time to MDD recovery (Hypothesis 2a).—Controlling for intake HRSD score, non-significant Cox regression results favored the IPT condition ($B = .30$, $SE[B] = .41$, $Wald = .52$, $p = .47$). The hazard ratio was 1.35 (95% CI = 0.60 – 3.02), indicating that participants in the IPT condition had a 35% higher incidence of MDD recovery at any given time during the study (95% CI = 40% lower to 3 times as high) than did those in the CWD condition (see Figure 2). Among those who recovered, median time to recovery was 15 weeks from baseline for IPT participants and 22 weeks from baseline for CWD participants.

Time to PTSD recovery.: Among the subset of women who met criteria (with the possible exception of time since trauma) for PTSD at baseline, significant Cox regression results favored IPT ($B = 1.73$, $SE[B] = .67$, $Wald = 6.78$, $p = .009$). The hazard ratio was 5.65 (95% CI = 1.54 – 20.82), indicating that participants in the IPT condition had more than 5 times the incidence of PTSD recovery at any given time during the study (95% CI = 54% higher to 20.8 times as high) as did those in the CWD condition (see Figure 2). Among those who recovered, median time to recovery was 11 weeks from baseline for IPT participants and 24 weeks from baseline for CWD participants.

Reduction in depressive symptoms (Hypothesis 2b).—Depressive symptom (HRSD) scores improved significantly from baseline to 6-month follow-up in both conditions (from 26 to 8 in IPT, and from 24 to 7 in CWD; both $p < .001$). Differences between conditions on HRSD and BDI depression scores *averaged over the entire period* (including follow-up) were extremely small to non-existent (see Table 3). However, post-hoc analyses of HRSD scores across during-treatment (4 week, 8 week, and post-group) assessments only (excluding the 6 month follow-up period) estimated a between-conditions effect size of $d = 0.36$ (95% CI = -0.04 to 0.75) favoring IPT (see Table 3). This finding is consistent with the (non-significant) survival analyses for recovery from MDD, which suggested the possibility for faster MDD recovery in the IPT condition.

Improvements in social support and social functioning, couple distress, and grief (Hypotheses 3a, 3b, and 3c).

Within-subjects comparisons.: SAS social role impairment scores decreased significantly ($p = .001$) and MSPSS social support scores improved trend-significantly ($p = .06$) from baseline to 6-month follow-up in IPT; neither of these improved in CWD. Grief (PBGS) and complicated grief (ICG) scores improved significantly over time in both IPT and CWD conditions (all $ps < .001$), though this appeared to occur (non-significantly) sooner in the IPT condition. Dyadic adjustment (DAS scores) did not change significantly over time in either condition.

Comparisons between IPT and CWD conditions.: Analyses of likely effect size ranges for the comparisons between conditions for MSPSS social support and SAS social role impairment scores across all post-intake assessments favored IPT for better outcomes, with $d \sim .27$ for each (see Table 3 for ranges). Analyses of likely effect size ranges for PBGS grief symptoms also favored IPT ($d = .33$; see Table 3). There was no compelling evidence for a difference between conditions in ICG complicated grief symptoms, and no evidence at all for a difference between conditions on DAS dyadic adjustment scores across the post-intake assessments (see Table 3). Of 38 women who provided 6-month follow-up data, only one had symptoms that would meet criteria for complicated grief (ICG score of at least 30); this participant was in the CWD condition.

Dose-response.—Accounting for treatment condition and intake HRSD score, total number of study treatment sessions attended was a significant predictor of MDD recovery ($p = .001$). The hazard ratio was 1.20 (95% CI = 1.07 – 1.34), indicating that for each additional treatment session attended, the incidence of MDD recovery at any given time rose

by 20%. Accounting for treatment condition and intake HRSD score, more study treatment sessions attended also significant predicted lower depressive symptoms across all post-intake assessments ($B = -0.59$, $SE[B] = 0.12$, $t = -4.96$, $p < .001$). There were no interactions between number of sessions attended and intervention condition in predicting either MDD recovery or reduced depressive symptoms, meaning that more sessions attended meant better outcomes in both intervention conditions. Accounting for intake DAS score, IPT participants who had a partner attend at least one treatment session ($n = 9$) had trend-significantly better improvements in dyadic adjustment across all post-intake assessments ($F = 3.51$, $df = 1$, $p = .06$; $d = .34$, 95% $CI[d] = -.02$ to 2.06) than did participants (IPT and CWD) who did not have at least one session with a partner.

Other treatment.—Of the 45 participants on whom follow-up data were available, 22 began new treatment (including another psychotherapy, seeing a provider about psychiatric medications, or starting any psychiatric medication; 9 in the IPT condition and 13 in the CWD condition), despite our asking them not to, during the active treatment phase ($p \sim .2$ for difference between conditions). An additional 8 did so during the 6-month study follow-up period (6 in the IPT group and 2 in the CWD group). Accounting for intake HRSD score, initiating new non-study treatment after intake was not associated with incidence of MDD remission ($p = .64$) or with post-intake HRSD scores ($p = .11$; if anything those who initiated new treatment had slightly worse HRSD scores). There were no study-related serious adverse events (SAEs).

Discussion

MDD that occurs in the context of perinatal loss is a critical public health problem because of its prevalence and because women who experience MDD in the context of perinatal loss suffer both MDD- and loss-related impairment. Unique social issues faced in the context of perinatal loss warrant a *specific, adapted* treatment, yet treatments for any disorder in this vulnerable population have not been adequately investigated. In addition, very few treatment studies to date have included women having experienced stillbirth or neonatal death. This randomized controlled pilot study is a first step toward addressing an important research and treatment need by providing and evaluating a treatment addressing the interpersonal and social factors that place women who experience perinatal loss at risk of continued MDD, morbidity and impairment.

This pilot study explored whether an IPT adapted specifically for perinatal loss was more acceptable to patients and better alleviated MDD (and associated social and interpersonal challenges) relative to a generic depression treatment (CWD) with different purported mechanisms of change. Our adapted IPT was feasible and acceptable. As expected, IPT (which directly addressed the perinatal loss, grief, and associated interpersonal challenges in an emotion-focused way) yielded significantly higher CSQ treatment satisfaction scores than did CWD (a cognitive-behavioral intervention that addressed depression, but not the loss; Hypothesis 1). IPT was also rated as significantly more helpful with depression and with life after perinatal loss than was CWD. Non-significant differences in treatment attendance also favored IPT. Although women varied to some extent at randomization about their desires to tell the story of their loss and hear about others' losses in a group setting, IPT participants

said in exit interviews that doing so was “difficult but helpful.” Most CWD participants reconciled themselves to not discussing their losses in group. Therefore, although participants seemed to try to find ways to make the best of whatever treatment they received, IPT was more acceptable overall.

Therapist training procedures and treatment manuals which resulted from this development project were also feasible and acceptable, yielding excellent adherence and good competence. The interventions differed in theorized ways: our data demonstrated that IPT sessions had significantly more time spent talking about the perinatal loss, facilitating mourning, and discussing loss-related communication than did CWD sessions. Relative to CWD sessions, IPT sessions spent more time eliciting feelings and expressing of emotion related to the loss, and less time thinking/learning intellectually. Thus, the study was successful in creating two theoretically and practically distinct treatments for comparison.

Effect size ranges favored the IPT condition for faster time to MDD recovery, faster time to PTSD recovery, and for larger decreases in depressive symptoms during treatment. However, depressive symptoms of participants in both conditions improved significantly over the study period, with no differences in depressive symptoms between conditions by the end of the follow-up period 6 months after treatment ended. Study treatment attendance was related to more improvement in depressive symptoms in both conditions.

Effect size ranges also favored the IPT condition for improvements in social support (MSPSS scores), social role impairment (SAS scores), and grief symptoms (PBGS scores; see Table 3), but not for complicated grief (ICG scores) or for couples functioning (DAS scores). It may be that IPT had no effect on complicated grief on couples functioning relative to CWD. For example, one CWD participant spontaneously mentioned that her husband liked CWD, because it made her “less grumpy” as her depression improved. However, two other explanations are possible. The first is that, examining change curves over time (not shown), IPT resulted in faster changes, meaning that the largest differences between conditions were found during the active treatment phase rather than the follow-up period. Unfortunately, complicated grief and dyadic adjustment were not assessed during treatment, but only at baseline and during the follow-up phase. Therefore, we would have missed any differences between conditions in these outcomes during the active treatment phase. The second explanation is that only 9 of the 25 IPT participants had a partner attend at least one treatment session. These participants had trend-significantly ($p = .06$) larger improvements in dyadic adjustment across all post-intake assessments than did participants (IPT and CWD) who did not have at least one session with a partner. Given the importance of couple issues to adjustment after perinatal loss, couples functioning should be continue to be targeted in future research in this area.

This study examining the feasibility and acceptability of an adapted IPT treatment and exploring its preliminary efficacy relative to CWD for theoretically salient outcomes had several strengths. Strengths include the randomized controlled trial (RCT) study design; an active, well-established, well-specified control condition; use of treatment manuals; good therapist adherence resulting in clear differences between conditions; a well-characterized sample; thorough assessment of feasibility/acceptability and preliminary efficacy; and a

focus on an at-risk, understudied population (i.e., a perinatal loss sample meeting full criteria for MDD, which included women who had experienced stillbirth and neonatal death, not just miscarriage). The primary limitation is the limitation of all pilot randomized trials, which is that a lack of power precludes strong efficacy conclusions. Another potential limitation is that, despite us asking them not to do so, many participants, especially CWD participants, began other MDD treatments (medications or psychotherapies) during the active treatment phase. If anything, this may have provided a potential advantage to the CWD condition.

In sum, this randomized controlled pilot RCT demonstrated the feasibility and acceptability of our adapted IPT for MDD after perinatal loss, its superior acceptability relative to CWD, and some evidence of preliminary efficacy in terms of faster recovery from disorder, reduced in-treatment depressive symptoms, and more improvement in social support, social functioning, and grief symptoms. A full-scale RCT is warranted. From a longer term perspective, this program of research will result in the adaptation of a specialized, efficacious treatment for a vulnerable and understudied population whose distress has historically been minimized, and will therefore have important clinical and public health significance.

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Figure 1:
Consort Diagram

Survival plot of time to recovery from MDE

Survival plot of time to recovery from PTSD

Figure 2.

Survival plots for time to recovery* from Major Depressive Episode (MDE) and PTSD by condition

* recovery is defined as 8 consecutive weeks of being asymptomatic or having 1–2 symptoms to a very mild degree. Week shown is the first week of the recovery period.

Table 1:

IPT for major depression following perinatal loss

Session Name	Activities of Session
Session #1 The Emotions of Grief	<p>Each woman tells her perinatal loss story with focus on:</p> <ul style="list-style-type: none"> -expressing her feelings at the time of her loss -feeling and expressing her current feelings about her loss -eliciting support from the other women in the group -helping the women to tolerate each other's emotional differences <p>Each woman is guided to:</p> <ul style="list-style-type: none"> -identify current supportive people -select one person to ask for grief support -role-play how to ask for this help
Session #2 Understanding What Happened	<p>Each woman:</p> <ul style="list-style-type: none"> -explores her understanding of what happened to the pregnancy/baby ---explores her thoughts/feelings about fault or blame -explores what the loss means to her and for her -begins to explore who she has talked to about the loss and how she talks to them about her needs -identifies whom she will invite to Session #3 -role-plays how she will communicate this invitation <p>The therapist:</p> <ul style="list-style-type: none"> -helps each woman unpack and examine whether there was anything she could have done to change the outcome, with help from the group -provides information about what does and does not contribute to perinatal loss -helps women identify additional questions they may have for their ob-gyn providers -helps each woman explore how she makes sense of her loss
Session #3 Grieving with Others	<p>The therapist actively leads the group with psychoeducation</p> <ul style="list-style-type: none"> -to understand depression causes and symptoms -to understand grieving processes and styles -to discuss ways to manage grieving differences -to understand how the grief groups help the women recover -how partner and family support help the women recover <p>Then, the therapist guides each partner pair to:</p> <ul style="list-style-type: none"> -complete a written communication exercise about both partners' loss-related emotional needs -discuss their written answers in a private room for 20 minutes -discuss as a group what they learned from each other about support -discuss how each pair will manage communication with others in their social network -develop communication homework to improve each pair's support of each other regarding the loss
Session #4 Holding the Memory and Moving Forward	<p>Each woman discusses how she:</p> <ul style="list-style-type: none"> -holds the memory/meaning of her loss experience -can re-engage in life roles -seeks support and communication with key people -reflects on her grief process and her recovery from depression <p>The therapist guides the group by:</p> <ul style="list-style-type: none"> -Reminding that new members are added next week and discussing ways to welcome them -Eliciting and role-modeling how to offer well-wishes for women completing their group treatment in this session

Table 2.**Participant Characteristics**

	IPT (n = 25)	CWD (n = 25)	Overall (n = 50)
Ethnicity			
Hispanic	16%	20%	18%
Race			
African-American	12%	12%	12%
Native Hawaiian/ Pacific Islander	4%	4%	4%
White	68%	60%	64%
Other	16%	20%	18%
Mean age (SD)	31.8 (7.3)	28.8 (5.6)	30.3 (6.6)
Household Income Below \$20,000/year	44%	32%	38%
Living with Partner	80%	88%	84%
Current Loss			
Miscarriage (4–19 weeks gestation)	52%	48%	50%
Stillbirth (20–40 weeks gestation)	40%	40%	40%
Early neonatal death	8%	4%	6%
Medically-necessary termination	0%	8%	4%
Mean weeks from loss to MDE onset (SD)	1.9 (13.1)	0 (0.3)	1.0 (9.2)
Mean weeks between loss and intake (SD)	11.4 (13.2)	8.4 (10.7)	9.9 (11.9)
Diagnoses and Other Treatment			
Had previous MDEs	56%	72%	64%
Median number of past MDEs	1	1	1
MDE with psychotic features	4%	0%	2%
Likely PTSD	60%	48%	54%
Panic disorder	12%	12%	12%
Generalized anxiety disorder	16%	8%	12%
Stable on psychiatric medication	32%	48%	40%
Stable on non-study psychotherapy	32%	52%	42%
Baseline Values of Dependent Variables			
HRSD depression ^a : Mean (SD)	26 (10)	24 (9)	25 (9)
BDI depression ^a : Mean (SD)	29 (13)	27 (9)	28 (11)
PBGS grief ^a : Mean (SD)	11 (3.0)	12 (4.0)	12 (3.6)
ICG complicated grief ^a : Mean (SD)	41 (12)	39 (14)	40 (13)
SAS social role impairment ^a : Mean (SD)	73 (13)	65 (10)	69 (12)
MSPSS social support ^b : Mean (SD)	60 (14)	69 (13)	64 (14)
DAS dyadic adjustment ^b : Mean (SD)	91 (11)	96 (17)	94 (14)

^aParticipants with lower scores are better off

^bParticipants with higher scores are better off

Table 3:

Likely effect size ranges for differences between conditions

	df	F	d	95% CI for d
HRSD depression	1, 166	0.69	0.12	[−0.17, 0.41]
During tx only	1, 101	3.18 ⁺	0.36	[−0.04, 0.75]
BDI depression	1, 139	0.08	−0.04	[−0.32, 0.24]
MSPSS social support	1, 117	3.63 ⁺	0.27	[−0.01, 0.56]
SAS social role impairment	1, 93	1.56	0.26	[−0.15, 0.68]
DAS dyadic adjustment	1, 141	0.00	0.00	[−0.30, 0.30]
PBGS grief	1, 168	4.80 [*]	0.33	[0.03, 0.62]
ICG complicated grief	1, 106	0.44	0.12	[−0.25, 0.50]

Positive effect sizes indicate a better outcome (fewer symptoms or better functioning) for the IPT condition

^{*}
 $p < .05$ ⁺
 $p < .08$