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A Randomized Trial of a Bereavement Intervention for Pregnancy Loss

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ABSTRACT

Objective: To examine the effects of a secondary bereavement intervention on grieving in women who experienced a miscarriage (pregnancy loss) at 12–20 weeks gestation.

Design: Experimental, posttest only, control group design.

Setting: Obstetric emergency center of a county hospital in a large city.

Participants: Forty women who experienced complete spontaneous miscarriages in the first or second trimester (8–20 weeks gestation).

Methods: Participants were randomly assigned to the grief intervention treatment group or usual standard care control group. The Medical Professional Guidelines for Health Care Professionals were used to construct the perinatal grief intervention. The Perinatal Grief Scale (PGS) was completed during a routine follow-up visit 2 weeks postloss.

Results: A one-way multiple ANOVA (MANOVA) was used to examine the difference in grieving between the control and experimental groups. Three dependent variables were used: despair, difficulty coping, and active grieving. Analysis revealed a significant difference on the combined dependent variables, F(3, 36) = 22.40, p < .000. When considering the three dependent variables separately, the treatment group displayed significantly lower levels of despair, F(1, 38) = 42.27, p < .001. Active grieving was high in both groups with the treatment group mean higher than the control group. Group means were similar for coping difficulty.

Conclusion: A bereavement intervention administered immediately after the miscarriage promotes women's ability to cope with early pregnancy loss.

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regnancy loss is unique among losses and often leaves the woman who experiences it grieving and feeling helpless and hopeless. Of all pregnancies in the United States, 15% to 25% end in fetal loss or spontaneous miscarriage, which has been recognized as the most common complication of pregnancy (Blackmore et al., 2011; Kersting & Wagner 2012; Murphy & Philpin, 2010). Miscarriage is thought to end as many as one in four pregnancies, or even more, inasmuch as many losses during early gestation are unrecognized or unreported (Kersting & Wagner, 2012; Ventura, Curtin, Abma, & Henshaw, 2012). Grief associated with such a loss is complex, distinctive, and involves a sense of loss related to biological failure, loss of self, lack of memoires, loss of parental future hopes, and the minimization of the loss by others (Hutti, 2005; Weiss, Frischer, & Richman, 1989).

There have been remarkable improvements in care for women who experience loss of a fe-

tus after the stage of viability (20 weeks), which may include referrals to community social support groups and intervention from bereavement teams of chaplains and patient advocates (Bennett, Litz, Maguen, & Ehrenreich, 2008). Physical mementos are provided as tangible evidence of the loss (Capitulo, 2005). However, women who miscarry before 20 weeks gestation find that the health care is usually directed primarily to physical needs, including blood loss, infection prevention, and hemodynamic support. The woman's emotional and psychosocial needs get minimal or no attention. Care often occurs in an emergency or treatment room, and women are discharged as soon as they are physiologically stable.

Literature Review

Researchers have documented that grief, anxiety, and depression occur in women who suffer miscarriage (Adolfsson & Larsson, 2010; Brier, 2004; Peppers & Knapp, 1980; Robinson, Stirtzinger, &

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Stewart, 1994; Swanson, Conors, Jolly, Pettinato, & Wang, 2007). And though there have been improved psychological interventions for women suffering the loss of potentially viable fetuses, less attention has been paid to miscarriage prior to viability and to interventions that would ameliorate the resulting emotional effects. A search of the published literature yielded only a handful of studies in which investigators employed interventions to ameliorate the emotional effects in women who experienced early miscarriages. In the earliest of these experimental studies in 1996, Lee, Slade and Lygo used a trauma framework to examine the effects of a six-step debriefing process. Thirtynine middle-class women in their late twentiess or early thirties who suffered miscarriages (6 to 19 weeks) were randomly assigned to control and experimental groups. The debriefing intervention occurred 2 weeks postmiscarriage in the context of a 1-hour home counseling session. At 4 months no significant differences were detected in emotional effect, anxiety, or depression.

A Solomon four-group design was employed by Swanson (1999) to study the effect of nurse counseling predicated on Swanson's caring theory. A sample of 185 mostly White, married, and well educated women who were 1- to 5 weeks postmiscarriage were randomly assigned to one of four groups. The counseled women demonstrated significantly less depression, anxiety, and disturbed mood within the first year after the miscarriage.

Using Swanson's caring theory as a guide, Adolfsson, Bertero, and Larson (2006) conducted a two-group randomized experiment to examine whether a structured follow-up visit by a midwife 3 to 4 weeks postmiscarriage would reduce grieving in a sample of 88 Swedish women who had suffered miscarriage. Measurement with the PGS 4 months postintervention revealed a nonsignificant reduction in grief scores in the intervention group.

Nikcevic, Kuczmiercyzk, and Nicolaides (2007) recruited a sample of 66 women who were predominantly White, well educated, married, and suffered a missed miscarriage at 10- to 14 weeks postgestation. They were randomly assigned to a group (MCP) that received medical counseling plus cognitive therapy or a group (MC) that received only the medical counseling and no therapy. These 66 women were also compared to a control group of 61 women who received no counseling or therapy. The counseling and/or therapy was conducted 5 weeks after the miscarriage diagnosis. At 4 months, the women

Women who miscarry before 20 weeks gestation find that the health care is usually directed primarily toward blood loss, infection prevention, and hemodynamic support.

completed the Texas Grief Inventory (Nikcevic, Kupek, Snijders, & Nicolaides, 1999) and the Hospital Anxiety and Depression scale (Zigmond & Snaith, 1983). The MCP group had significantly less levels of grief and worry, and the MPC and MC groups had significantly less levels of anxiety than the control group.

Neugebauer et al. (2006) conducted a small pilot study in which interpersonal counseling (IPC) was administered via telephone and used to determine whether depression could be lessened in women who had suffered miscarriage. The mean within-subject decline in depression scores was significantly greater in the IPC group than in the treatment as usual group (Neugebauer et al., 2006). In a second study with a sample of 17 low-income, inner-city dwelling, White, Hispanic and Black women, each woman suffered a miscarriage fewer than 18 weeks earlier and tested as mildly depressed (Neugebauer et al., 2007). They all received from one to six weekly counseling phone calls. Nine women completed the study and were tested for depression using the Center for Epidemiology Studies Depression Scale (CES-D) (Radloff, 1977). Their posttest scores were compared to the CES-D pretest scores of the eight noncompleters. There was a small, nonsignificant difference in depression between the two groups. The nine women who completed the treatment showed a significant decrease in depression when comparing their pre to posttest scores.

Swanson, Chen, Graham, Wojnar, and Petras (2009) conducted a randomized controlled trial to examine the effectiveness of three couplesfocused interventions on depression and grief levels following miscarriage. Three hundred fortyone predominantly White, well educated, and affluent couples were recruited and randomly assigned to one of four groups. The four groups included a nurse caring group that received three counseling sessions, a self-caring group that received three self-paced modules, a combined caring group that received counseling and self-paced modules, and a control group. All the women were approximately 1-month postdischarge after a miscarriage at 19 weeks or fewer gestation. A Bayesian odds analysis revealed that nurse counseling had the largest

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Despair scores were significantly lower after 2 weeks among the women who received the bereavement intervention compared to those in the control group.

effect on resolving grief and depression for the couples.

In summary, all the interventions reported took place from 1 to 18 weeks after miscarriage. Outcome variables included anxiety, depression, and grief using a variety of measures. Measurements took place from 4 months to 1 year postintervention. Participants were predominantly White, well educated, and affluent except for the participants in the Neugebauer et al. studies (2006, 2007), who were lower class, White, Black, or Hispanic women from the inner city. All studies included women with early pregnancy loss at fewer than 20 weeks gestation). Swanson et al. (2009) also recruited the male partners of the women for intervention and study.

We focused on implementing an immediate intervention structured to ameliorate the potential negative consequences of grieving. The intervention was delivered in the emergency center at the time the miscarriage occurred. Grief levels were measured 2 weeks after miscarriage to examine the immediate effect of the intervention. We addressed the following research question: "Do women who experience early miscarriage and receive a structured bereavement intervention in the emergency center at the time of the miscarriage demonstrate different levels of grief at two-week follow up than members of a control group?"

Methods

Design

We used an experimental posttest only design. Women who suffered miscarriage in pregnancies between 8 weeks and 20 weeks gestation were randomly assigned to the bereavement group (treatment) or a usual standard of care group (control). After a woman consented to participate, a sealed envelope was randomly selected from a lot of 40 envelopes that contained the word *control* or the word *treatment*. Appropriate protocol measures were instituted immediately after assignment.

Setting and Sample

The obstetric emergency center (OBEC) and obstetrics-gynecology clinic of a 350-bed, county-

funded facility in a large city in the south central United States was the setting for this study. Care for pregnant women with complaints of bleeding is provided more than 1500 times per month in the OBEC. Institutional Review Board approval was provided by Texas Woman's University, and written approval and permission were obtained from the hospital facility. A detailed informed consent was obtained from all participants.

Forty women were enrolled and completed the study. Seven women declined to participate. Women enrolled in the study were selected using the following inclusion criteria: (a) fetal loss of pregnancy of no more than 19 weeks 6-days gestation but no fewer than 12 weeks gestation, (b) ability to read and write English or Spanish, and (c) ability to complete all study forms with minimal assistance. A loss involving a fetus weighing 500 grams or more was an exclusion criterion.

Data Collection

Measures. Data were collected by the investigator and a trained Spanish speaking research assistant using a demographic questionnaire and the Perinatal Grief Scale (PGS) (Lasker, Toedter, & Janseen, 2001). The demographic questionnaire was developed by the researchers and collected personal information such as age, race, marital status, education, and income as well as pregnancy information such as gravidity, parity, prenatal visit frequency, and pregnancy loss. The PGS short version English and Spanish language was used to measure grief 2 weeks postmiscarriage. The PGS short version is a 33-item tool divided into three subscales that were derived using a factor analysis. The subscales of active grief, difficulty coping, and despair each contain 11 items and represent increasingly severe responses to grief (Lasker, Toedter, & Lori, 2000; Potvin, Lasker, & Toedter, 1989). This instrument has been translated into 22 languages and used in multiple studies in multiple countries. Toedter, Lasker, and Janssen (2001) reported overall Cronbach's alpha coefficients of 0.5 or greater across studies with subscale coefficients ranging from 0.70 to 0.96. The Spanish language version of the PGS has also shown excellent internal reliability with reported coefficients ranging 0.92 to 0.96 (Toedter et al., 2001). The Cronbach alpha coefficients for this study were 0.92 for the total PGS scale and 0.93, 0.73, and 0.96 for the active grief, difficulty coping, and despair subscales, respectively.

Procedures. Initial participant contact occurred in the emergency department (ED) where consent was obtained and participants were enrolled in the study. A follow-up telephone call occurred 1 week before a scheduled return clinic visit, and final contact occurred at the return visit.

Intervention

While in the ED, the treatment group received a 1-hour bereavement intervention based on Guidelines for Medical Professionals Providing Care to the Family Experiencing Perinatal Loss, Neonatal Death, SIDS or other Infant Death (Bereavement Support Work Team of the National SIDS and Infant Death Program Center, 2002). A specific protocol was developed from these guidelines and reinforced during the follow-up telephone call. The protocol provided (a) early identification and labeling of the participant's room and chart for acknowledgement of the loss: (b) offer of chaplain services or notification of the woman's personal spiritual leader; (c) honor of any special request such as baptism, special ceremony, or prayer; (d) a packet of flower seeds of remembrance to be planted at home; (e) a soft plush care bear; (f) other physical mementos, if applicable; (g) participation in a naming ceremony; and (h) completion of a self-addressed sympathy card. Routine discharge orders with instructions to return to the ED with complaints of fever, pain, and/or excessive bleeding and a return appointment time were then provided. A 15-minute telephone call 1 week later was used to reinforce the information from the bereavement intervention, validated the loss, and encouraged women to seek support.

Control

The control group received routine care in the ED that focused on physical stability and pain management. This group was given routine discharge instructions with no elements of the bereavement intervention. During the follow-up phone call, they were reminded of the upcoming clinic visit. At the clinic visit all women completed the PGS and a social demographic survey, received \$10.00 for participating, and received a list of perinatal support group websites.

Data Analysis

The sample size for this study was based on a Cohen's *d* effect size of 0.57 using a power of 0.80 and an alpha of 0.05. The effect size was estimated from two metaanalyses of educational interventions for improvement of patient care (Dreil & Keijsers, 1997; Theis & Johnson, 1995). Results of

these analyses indicated effect sizes that ranged from 0.46 to 0.57 for primary prevention and patient education.

Data from the demographic questionnaire were analyzed using descriptive statistics to compare the control and treatment groups. Chi-square and *t* tests were used to check for differences between the two groups on the collected demographic variables. MANOVA was used to examine the differences between the two groups on the three PGS subscales. A Bonferroni adjustment factor was applied to the alpha value when examining between-subjects effects. The adjusted alpha was 0.017. Assumptions for normality, linearity, multicollinearity, homogeneity of variance—covariance matrices, and outliers were checked with no evidence of violation.

Results

Sample Characteristics

Forty women were enrolled and completed the study without loss to follow-up. Participants ranged in age from 18 to 42 years with an average age of 27. The majority were Hispanic, spoke English as a primary language, and possessed at least some high school education. Marital status was mixed. Average annual income was less than \$21000, and most had no health insurance. There were no significant demographic differences between the control and experimental groups on the demographic variables (Table 1). The number of pregnancies ranged from one to eight with the majority of the participants reporting from one to three pregnancies. Most had one to three living children. The majority (62.5%) suffered a miscarriage between 14-19 weeks gestation. One half of the women had one or more prenatal care visits. There were no significant differences between the two groups on any of the pregnancy variables (Table 2).

Treatment Effects

Total PGS scores ranged from 47 to 138 (potential range, 33–165). The women in both groups displayed moderate levels of overall grief (M=11.7, SD=22.9). MANOVA results (Table 3) revealed a statistically significant difference between the intervention and control groups in the overall model, F(3,36)=22.40, p<.000, Wilks's lambda =.349, partial eta squared =.651, with the reported mean score in the control group 12 points greater than that of the experimental group. The effect size indicated that 65% of the variance

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Table 1: Demographic Characteristics (N = 40)

	Treatment		Control		Total			
Characteristics	n	%	n	%	n	%	Statistic	
Race or ethnicity								
Hispanic/Latino	10	50.0	11	55.0	21	52.5	$\chi^2(3) = 0.635; p = .888$	
African American	5	25.0	4	20.0	9	22.5		
White	4	20.0	3	15.0	7	17.5		
Other	1	5.0	2	10.0	3	7.5		
Total	20	100	20	100	40	100		
Language spoken								
English	14	70.0	11	55.0	25	62.5	$\chi^2(1) = 0.960; p = .327$	
Spanish	6	30.0	9	45.0	15	37.5		
Total	20	100	20	100	20	100		
Education completed								
Elementary through 8th grade	9	45.0	7	35.0	16	40.0	$\chi^2(2) = 1.750; p = .417$	
High school	6	30.0	10	50.0	16	40.0		
College	5	25.0	3	15.5	8	20.0		
Total	20	100	20	100	40	100		
Marital status								
Single	7	35.0	8	40.0	15	37.5	$\chi^2(3) = 2.50; p = .645$	
Living together	5	25.0	6	30.0	11	27.5		
Married	3	15.0	4	20.0	7	17.5		
Separated/divorced	5	25.0	2	10.0	7	12.5		
Total	20	100	20	100	40	100		
Mean income (US \$)	\$23,1	11	\$20	,916		\$20,240	t(38) = .619; p = .540	
Health coverage								
None	13	65.0	15	75.0	28	70.0	$\chi^2(3) = 1.676; p = .642$	
Private pay	3	15.0	2	10.0	5	12.5		
Gold card ^a	3	15.0	1	5.0	4	10.0		
Medicaid	1	5.0	2	10.0	3	7.5		
Total	20	100	20	100	40	100		
Age-Mean (SD) in years	28.8 (7.3)		25.2 (6.2)	27.0	(7.0)	t(38) = 1.672; p = .103	

Note. a County-issued card authorizing state-subsidized medical care for income-qualifying individuals without health insurance.

in overall grief was explained by group membership. When considering the three dependent variables separately, the treatment group displayed significantly lower levels of despair, F(1,33) = 42.27, p < .001. The differences between the groups on active grieving and difficulty in coping were not significant. Active grieving was reported in both groups with the treatment group mean six points greater than the control group mean. Group

means were similar and moderate for coping difficulty.

Discussion

The findings from this study indicated that women who received the bereavement protocol reported lesser levels of overall grieving. These women were less likely to display despair than the

Table 2:	Pregnancy	Variables	(N=40)
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	Treatment		Co	Control		otal		
Variables	n	%	n	%	n	%	Statistic	
Weeks pregnant at loss								
Less than 14 weeks	8	40.0	7	35.0	15	37.5		
14-19 weeks	12	60.0	13	65.0	25	62.5		
Mean# weeks at loss	14.3 (2.8)		14.8	14.8 (2.3)		5 (2.5)	t(38) = .617; p = .541	
Prenatal care visits								
Yes	8	40.0	12	60.0	20	50.0	$\chi^2(1) = 1.600; p = .206$	
No	12	60.0	8	40.0	20	50.0		
Number of children								
0	5	25.0	1	5.0	6	15.0		
1–3	9	45.0	18	90.0	27	67.5		
4–6	5	25.0	1	5.0	6	15.0		
7-10	1	5.0	0	0.0	1	5.0		
Mean # children (SD)	2.6	2.6 (2.6)		1.8 (0.95)		(2.0)	t(38) = 1.273; p = .211	
Number of pregnancies								
1–3	10	50.0	14	70.0	24	60.0		
4–8	10	50.0	6	30.0	16	40.0		
Mean # pregnancies (SD)	3.8	(2.2)	3.2	(1.3)	3.5	(1.9)	t(38) = 1.112; p = .273	

women who received the standard treatment protocol. Women in both groups reported high levels of active grieving. These findings are congruent with those of other investigators who reported that high levels of active grief are normal and expected in the period immediately following loss (Adolfsson & Larsson, 2006; Lasker et al., 2000; Lasker et al., 2001). Women in both groups displayed similar coping levels and had begun to cope with the loss. This is an indicator that although they were still actively grieving, the return to activities of daily liv-

ing had begun. As further evidence, women in both groups were able to keep their follow-up clinic appointments, and some reported that they had returned to work and resumed household activities.

Despair levels were 50% less for women who received the bereavement protocol. This category represents a more complex form of grieving that is often delayed (Adolfsson & Larsson, 2006; Lasker et al., 2000). When coping strategies fail to ameliorate the grief reaction, despair sets in. Study

Table 3: MANOVA Results and Perinatal Grief Scale (PGS) Mean Scores (N = 40)

	Treatment ($n = 20$)	Control ($n = 20$)		Statistics			
Measures	Mean (SD)	Mean (SD)	F(1, 38)	р	Partial Eta ²		
Active grief	46.00 (11.42)	39.40 (10.67)	3.57	0.067	.086		
Difficulty coping	29.95 (6.52)	30.40 (6.61)	.047	0.830	.001		
Despair	29.60 (8.65)	48.10 (9.34)	42.27	0.000	.527		
Total PGS	105.55	117.90	22.43 ^a	0.000	.651		

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A structured bereavement intervention that is implemented immediately following miscarriage can help women work through the grieving process.

findings indicated that the intervention was instrumental in altering levels of despair. This may mean that the intervention provided tangible proof that helped the women to validate that pregnancy had existed and to recognize and acknowledge the loss (Adolfsson & Larsson, 2006; Lasker et al., 2000). Women receiving the intervention indicated that they felt supported and cared for and were glad to have an opportunity to talk about what had happened to them.

Our results add to the findings of previous intervention studies involving women who experienced early miscarriage (Adolfsson et al., 2006: Lee et al., 1996; Neugebauer et al., 2006; Neugebauer et al., 2007; Nikcevic et al., 2007; Swanson, 1991; Swanson et al., 2009). These previous authors indicated that counseling interventions implemented from 1 to 18 weeks after miscarriage were effective in lowering grief, anxiety, and depression from 2 months to a year following intervention. Participants in these studies were predominantly White, well educated, and financially well off. This study's participants included low-income Hispanic, White, and Black women with little education. Our results indicated that the bereavement intervention implemented at the time of the miscarriage was effective in lowering overall levels of grief within 2 weeks of the loss of the pregnancy. Levels of despair were more than 50% less in women receiving the intervention. The effect of the intervention to lessen the despair of the women in the intervention group validates the usefulness of developing a structured bereavement protocol for women experiencing early pregnancy loss.

Strengths and Limitations

Strengths of this study included (a) a diverse racial and low-income sample, (b) a structured bereavement protocol using standardized guidelines for providing care for women with perinatal loss, (c) random assignment to study group, (d) delivery of the intervention immediately after miscarriage, and (e) measurement of grieving soon after the intervention. Limitations of the study included (a) a small sample drawn from one setting that limits generalizability of the findings and (b) lack of further follow-up after the loss that limits the

ability to determine the effects of the intervention over time

Clinical and Research Implications

Early miscarriage needs to be recognized as a potentially significant event in a woman's life. Emotional support must be provided and the woman actively included in decision making about the loss. Recommendations for improving practice in an ED include implementing a bereavement protocol as routine practice for all women experiencing pregnancy loss, regardless of gestational age or type of loss. To ensure appropriate delivery of such a protocol, bereavement education should be instituted for all health care professionals who provide care for women experiencing miscarriage.

This study revealed the need for further investigation. Replication using a larger, more diverse sample of women randomly drawn from multiple settings would extend the generalizability of our findings. Longitudinal studies to measure grief at multiple points after the pregnancy loss could allow for an exploration of the grief process over time. Further examination of the relationships between the concepts of active grief, coping and despair could provide a fuller understanding of the interrelated workings of the grief process. Establishment and maintenance of a national registry to track fetal losses from pregnancies of fewer than 20 weeks gestation could be valuable in determining the true extent of early pregnancy loss.

Conclusions

Our results indicated that the grief experienced by women after an early miscarriage is similar to the grief experienced at later periods of gestation. Researchers that have implemented treatment protocols have demonstrated that it is possible to help women deal with their losses after early miscarriages. This study adds further evidence that a structured bereavement intervention implemented immediately following the miscarriage can aid women in working through the grieving process and may play a large role in preventing despair. This immediate intervention coupled with the judicious use of follow-up counseling may form the best approach to aid in the emotional healing of women after early pregnancy loss.

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