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Effects of Caring, Measurement, and Time on Miscarriage Impact and Women's Well-Being

[Articles]

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Abstract

Background: Responses to miscarriage range from relief to devastation, yet there have been no randomized controlled studies that demonstrate significant effects of counseling with women who miscarry.

Objective: To test the effects of caring-based counseling, measurement, and time on the integration of loss (miscarriage impact) and women's emotional well-being (moods and self-esteem) in the first year after miscarrying.

Method: ANCOVA was used in this randomized, longitudinal Solomon four-group experimental investigation. Enrolled were 242; 185 completed. Outcomes included: self-esteem, overall emotional disturbance, anger, depression, anxiety, confusion, overall miscarriage impact, personal significance, devastating event, lost baby, and isolated.

Results: During the first year after loss (a) caring was effective in reducing overall emotional disturbance, anger, and depression; and (b) time passing led to increased self-esteem and decreased anxiety, depression, anger, confusion, and personal significance of loss.

Conclusion: Caring, measurement, and time had some positive and significant effects on the integration of loss and enhancement of well-being in the first year subsequent to miscarrying.

Approximately 15-20% of pregnancies end in miscarriage, the unexpected ending of pregnancy prior to the point of expected fetal viability (Hall, Beresford, & Quinones, 1987). Case studies

and comprehensive research reviews suggest that responses range from relief to devastation with resolution taking from days to years (Lee & Slade, 1996; Moulder, 1994; Slade, 1994). While a variety of supportive care strategies for parents experiencing perinatal loss have been described (Lasker & Toedter, 1994; Lee, Slade & Lygo, 1996; Leppert & Pahlka, 1984; Moohan, Ashe, & Cecil, 1994; Rajan & Oakley, 1993; Stirtzinger & Robinson, 1989; Turner et al., 1991) no controlled studies were found that demonstrated the significant effects of counseling with women who miscarry.

Studies of miscarriage suggest a profound event that is best understood in the context of women's personal expectations and life experiences. Common themes identified are: (a) uncertainty and dread in realizing impending loss; (b) multiple meanings attributed to loss; (c) feelings of emptiness, guilt, grief, and lack of control; (d) needs for information, recognition, and support; (e) failure of others, especially healthcare providers, to recognize and validate women's experiences; and (f) fear and vulnerability in future childbearing (Hutti, 1986; Reed, 1990; Swanson, 1983, 1985; Reinharz, 1987; Wall-Haas, 1985).

Given the pain, bleeding, cramping, uncertainty, and potential trauma, many women are quite anxious at miscarriage (Beutel, Deckardt, von Rad, & Weiner, 1995; Cecil & Leslie, 1993; Thapar & Thapar, 1992). For some this tension is ongoing as evidenced by increased levels of anxiety at 3 (Cecil & Leslie, 1993), 6 (Thapar & Thapar, 1992; Prettyman, Cordle, & Cook, 1993), and 12 weeks after miscarrying (Cecil & Leslie, 1993; Cordle & Prettyman, 1994). In a survey of 50 women 2 years after loss, Cordle and Prettyman (1994) found no significant difference in the prevalence of anxiety "caseness" (defined as cause for clinical concern) from the rate measured at 12 weeks post loss. Malmquist, Kaij, and Nilsson (1969) demonstrated that for women with a history of miscarriage anxiety may carry over into subsequent pregnancies. Theut, Pederson, Zaslow, and Rabinovich (1988) confirmed the focus of anxiety was specifically pregnancy and its outcome. Statham and Green (1994) documented highest anxiety in subsequent pregnancies for childless women with a history of elective abortion.

Elevated depressive symptoms have been documented at the time of miscarriage (Beutel et al., 1995; Beutel, Willner, Deckardt, von Rad, & Weiner, 1996; Hamilton, 1989; Prettyman et al., 1993; Thapar & Thapar, 1992) and the sense of loss may be ongoing. Increased depression has been documented at 2 (Goldbach, Dunn, Toedter, & Lasker, 1991; Neugebauer et al., 1992b), 4 (Friedman & Gath, 1989), 6 (Hamilton, 1989; Thapar & Thapar, 1992; Neugebauer et al., 1992a), 12 (Garel, Blondel, Lelong, & Kaminski, 1993; Robinson, Strirtzinger, Stewart, & Ralevski, 1994), and 18 weeks (Tunaley, Slade, & Duncan, 1993), as well as 6 months (Robinson et al., 1994; Neugebauer et al., 1992a, 1997), 8 months (Garel, Blondel, Lelong, Bonenfant, & Kaminski, 1994), and 1 year postmiscarriage (Robinson et al., 1994; Beutel et al., 1996).

Regardless of gestational age at loss, it has been consistently documented that women grieve longer and more actively and openly than men (Beutel et al., 1995; Goldbach et al., 1991; Theut et al., 1989; Theut, Zaslow, Rabinovich, Bartko, & Morihisa, 1990). When comparing grief following stillbirth or neonatal death versus miscarriage the duration is generally longer with later loss (Goldbach et al., 1991; Lasker & Toedter, 1991; Theut et al, 1989; Toedter, Lasker, & Alhadeff, 1988). However, when gestational age at loss is only measured in women who miscarry, length of gestation usually does not make a difference in intensity or duration of grief, anxiety, or depression (Jackman, McGee, & Turner, 1991; Neugebauer et al., 1992a, 1992b, 1997; Prettyman et al., 1993; Thapar & Thapar, 1992; Tunaley et al., 1993). One exception to this claim is the study of Beutel et al. (1996) that clarified that miscarriage at

a later gestational age was correlated with extended grieving but not with prolonged depression.

Participating in data-gathering interviews with an empathetic researcher may abate responses to miscarriage. At 2 weeks, and 3 and 6 months postmiscarriage, Neugebauer et al. (1992a, 1997) conducted in-depth interviews with women. The prevalence of depressive disorder among women interviewed for the first time at 3 or 6 months was higher than women being reinterviewed. The researchers introduced evidence that data gathering may unwittingly produce a therapeutic effect and emphasized the need for empirically testing therapeutics to enhance well-being subsequent to miscarrying.

The Miscarriage Caring Project addresses several issues raised by others. Most notably, the selected design facilitates examination of both the main and interaction effects of treatment (caring-based counseling), measurement (immediate versus delayed), and the passage of time on women's healing in the first year after miscarrying.

The purpose of this study was to test the effects of caring-based counseling, measurement (early versus delayed), and the passage of time on the integration of loss (miscarriage impact) and women's emotional well-being (self-esteem and moods) in the first year subsequent to miscarrying.

Three hypotheses were tested:

Hypothesis 1: Compared to controls, counseled women will experience less miscarriage impact, higher self-esteem, and less disturbed moods.

Hypothesis 2: The passage of time will result in women experiencing less miscarriage impact, higher self-esteem, and less disturbed moods.

Hypothesis 3: There will be no difference in miscarriage impact, disturbed moods, or self-esteem at 4 months and 1 year after loss between women completing early versus delayed outcome measures.

Hypotheses 1 and 2 were tested twice: on the subset of women for whom data was available at all four measurement points (early measures) and on data gathered from all participants (both early and delayed measures) at the final two measurement points. Because it was not known if completing immediate versus delayed outcome measures would make any difference Hypothesis 3 was stated nondirectionally.

Relevant Literature

The theoretic framework is Swanson's (1991) phenomenologically derived middle-range caring theory. Caring is defined as "a nurturing way of relating to a valued other toward whom one has a personal sense of commitment and responsibility" (p. 162). Caring involves five therapeutic processes: *knowing* (striving to understand the other's experience); *being with* (emotionally

present); *doing for* (as the other would do for the self if at all possible); *enabling* (facilitating resolution by validating and informing); and *maintaining belief* (in the other's potential to get through an event or transition and face a meaningful future). An assumption of Swanson's (1993) theory is that the recipient's capacity to make meaning (integrate a life event) and experience well-being should be enhanced by receipt of caring from a provider who is informed about common human responses to a designated health problem. Specifically, if women participate in focused discussions about their loss with a caring provider and if women feel understood, accepted, provided for, validated, informed, and believed-in, they will experience enhanced well-being and a stronger integration of miscarriage into their lives.

The intervention content (focus of discussions) was derived from a phenomenologic study of 20 women who had recently miscarried a desired pregnancy. (Swanson, 1986a, 1986b; Swanson-Kauffman, 1983, 1985). Their common experiences were summarized into the Miscarriage Model. *Coming to know* is the confusing, painful process of balancing mounting evidence of impending loss against hopes for a healthy pregnancy outcome. *Losing and gaining* involves struggling to identify for the self just what was lost (e.g., "my baby") and potentially gained (e.g., the growth realized through experiencing her own inner strength or in discovering the capacity of her relationships to handle adversity). *Sharing the loss* refers to who was available to the woman to share her feelings, most importantly partners and other women who miscarried. *Going public* means receiving helpful and hurtful comments of others and being overcome with "waves of emotions" when encountering reminders of loss (e.g., seeing infants or pregnant women). Getting through it means healing to the extent that "good times in the day begin to outweigh the bad". The final challenge, *trying again,* is deciding if and when to attempt conception while living with ongoing fears of future loss.

Method

Hour-long counseling sessions were conducted by the principal investigator (PI) or a research associate at 1, 5, and 11 weeks after study entry. When partners accompanied women to counseling, sessions began with a reminder that the purpose was to focus on the woman's experience. In Session I women detailed coming to know and considered what was lost and possibly gained. Session II explored women's experiences of going public and sharing the loss. In Session III women chronicled their own experience of getting through it and openly discussed trying again. Although the protocol outlined intended content, the intervention process (personalized caring) oftentimes meant that topics were addressed out of order according to each participant's unfolding individual needs. To assure integrity in application of the caring theory and adequate coverage of the Miscarriage Model, counselors reviewed and critiqued occasional transcripts of each other's sessions.

A Solomon four-group randomized experimental design with delayed measurement for some (see Figure 1) was chosen because the potential existed that participating in a longitudinal control group with early focused attention on loss might, in itself, serve as a form of recognition, support, and validation. Hence, the design was selected to address the possibility that early survey completion (measurement) could, in itself, serve as a form of treatment. Treatment levels included intervention and control (no intervention). Measurement occurred immediately after

enrolling (t_1); and at 6 weeks (t_2); 4 months (t_3); and 1 year after enrolling (t_4) or it was delayed until 4 months (t_3) and 1 year after enrolling (t_4).

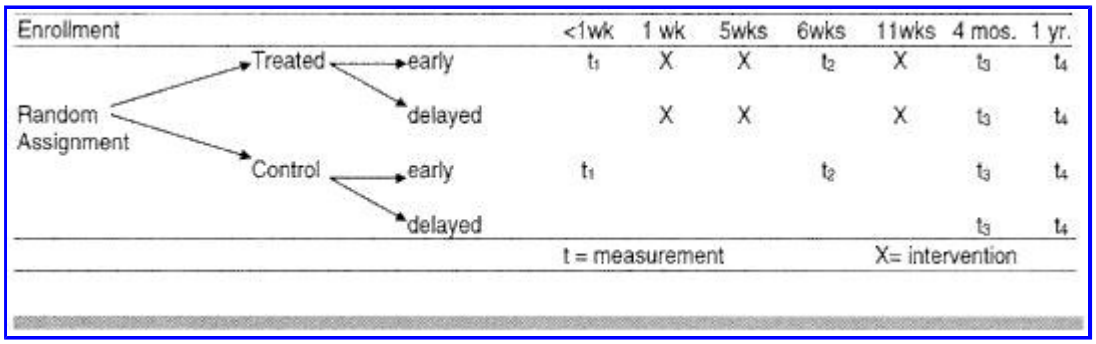

Figure 1. Solomon four-group randomized experimental design with repeated measures.

Ideally, times of measurement would have been chosen empirically; however, when the Miscarriage Caring Project was developed, there were no published prospective longitudinal descriptions of psychosocial responses to miscarriage. Hence, measurement times were chosen based on the following rationale: t_1 was scheduled as close to the loss as possible and prior to intervention; by t_2 most women would have returned to menses, thus returning to their prepregnant physical state; by t_3 many women would be past the "crisis" and trying to conceive again (Swanson-Kauffman, 1983); at t_4, a year of healing time would have passed and women would be very close to the anniversary date of their loss.

Sample: Participation criteria were: at least 18 years of age, miscarried at 20 weeks or less, within 5 weeks of loss, and could speak and write English. Care providers throughout the area shared recruitment pamphlets at the time of loss or during follow-up appointments. When women called the study site, they were reminded that there was a 50% chance of receiving counseling. While still on the phone women were randomly assigned. Approval for protection of human subjects was received from the study site and all referral sites.

Based on a power analysis (Cohen, 1977), it was estimated that if sample size diminished to 40 per group, there would remain a 60% chance of detecting a treatment effect of 1/2 standard deviation and a 90% likelihood of detecting a treatment effect of 3/4 standard deviation (two tailed, alpha = 0.05). Allowing for a 25% attrition rate, target sample size was set at 60 subjects per group.

Of the 249 women who called, seven were ineligible. The remaining 242 women were randomly assigned to groups: 56 to treated, early measures; 60 to treated, delayed measures; 64 to control, early measures; and 62 to control, delayed measures.

All surveys were returned by 185 participants (46 treated, early measures; 44 treated, delayed measures; 43 control, early measures; and 53 control, delayed measures). Overall attrition (defined as at least one survey missing) was 24% (n = 57) of those randomized. When comparing those who completed all surveys to those who did not, there were no significant

differences in maternal age, gestational age at loss, or length of time (days) between miscarrying and study enrollment. Chi-square analysis of group attrition rates revealed a near significant difference between groups ([chi]^2 = 7.63; *df* = 3; *p* = 0.054) with the largest gap being between the two control groups. The rate of attrition for control, delayed measures was 14.5% and for control, early measures it was 32.8%. Of those returning all surveys, there were missing data for several individuals on some measures, hence group sizes for reported findings are not consistent.

Data Collection: Women completing four measures (early measures, treated and control) were immediately mailed written consents and t_1 surveys. Those completing only two outcome measures (delayed measures, treated and control) were mailed consents immediately; their first surveys were sent at 4 months after enrolling. Self-reported obstetrical history and demographics were gathered at t_1 (early measures) or t_3 (delayed measures). The same outcome data were gathered at each measurement point. In addition to the measures discussed here, there were several other closed as well as open-ended questionnaires.

Measures: *Self-esteem* was measured via the 10-item Rosenberg (1965) scale, a widely used standardized measure (four-point, Likert-type) initially developed to measure attitudes toward the self in adolescent males. Woods and Lentz (1986) used the Rosenberg in a study of perimenstrual symptoms in 659 women 18-45 years of age. They demonstrated convergent validity with indices of vitality and general well being and divergent validity with measures of depression, anxiety, and high life-stress. Cronbach's alpha for Woods' sample was 0.85 and for the current sample at t_4 (N = 194), it was 0.89.

Mood states were measured via the Profile of Mood States (POMS), a 65-item, widely used standardized five-point Likert-type measure of self-reported affect (McNair, Lorr, & Droppleman, 1981). It has a total mood disturbance scale and six subscales: anxiety-tension, depression-dejection, anger-hostility, vigor, fatigue, and confusion-bewilderment. The developers report subscale internal consistencies of 0.90 or better and claim convergent validity with other measures of distress and divergence with social desirability.

For this study, the vigor and fatigue subscales were dropped as outcome measures because they were confounded by alterations in women's physical health status due to the pregnancy-related changes experienced by many women in the first year after loss. For this study at t_4 (N = 175), the Cronbach's alpha for overall *emotional* disturbance (does not include vigor and fatigue) was 0.96, with subscale alphas ranging from 0.79 (confusion) to 0.94 (depression).

The *impact of miscarriage* on each woman's life was examined using the "Impact of Miscarriage Scale" (IMS). It consists of 24 items (listed in Table 1). Thirteen items have a four-point Likert-type scale (definitely-true-for-me to definitely-not-true-for-me) and 11 items have a four-point Harter (1980) forced choice format (respondent chooses which of two opposite statements are most like her, then indicates if it is "sort of" or "really" like her). The IMS was developed by the investigator in three phases.

Item No.	H/L*	Factor Loading Score	Item	Scale Scores n	Mean	SD	Cronbach's α
Impact of miscarriage: overall				188	59.8	15.4	0.93
Lost baby				196	17	4.87	0.86
21	H	0.87	Some women who miscarry feel they have lost a person, *but* some women who miscarry do not feel they have lost a person.				
19	H	0.85	Some women who miscarry feel there will always be a place in their heart for that baby, *but* some women who miscarry do not feel there will always be a place in their heart for that baby.				
18	H	0.70	Some women who miscarry do not feel they have lost a part of themselves, *but* some women who miscarry do feel they have lost a part of themselves.				
27	H	0.68	Some women would describe their miscarriages as just a loss of pregnancy *but* some women would not describe their miscarriage as just a loss of pregnancy.				
17	L	0.61	Miscarriage equals a loss of a part of my partner and me.				
24	H	0.59	Some women who have miscarried are irritated when their baby is called a fetus, *but* some women who have miscarried do not feel irritated when their baby is called a fetus.				
Personal significance				195	15.7	5.13	0.83
7	L	0.76	I have gotten through with dealing with my miscarriage.				
15	L	0.64	My miscarriage represents a major setback for me.				
8	L	0.63	I feel my body has betrayed me.				
6	L	0.59	My miscarriage destroyed my zest for life.				
13	L	0.58	When I think of my miscarriage, I still feel emotional pain.				
20	H	0.57	For some women miscarriage equals a lost chance to be a mother, *but* for some women miscarriage does not equal a lost chance to be a mother.				
3	L	0.52	After my miscarriage I was feeling down for several days, but then I got over it.				
Devasting event				193	13.5	4.5	0.86
11	L	0.80	Miscarriage is like a nightmare.				
9	L	0.77	Miscarriage is like going from one extreme of happiness to the other, total unhappiness.				
1	L	0.73	My miscarriage was a horrendous devastating event.				
12	L	0.63	Miscarriage equals a loss of hope.				
4	L	0.51	Miscarriage equals one big loss of control.				
Isolated				192	13.2	4.3	0.79
30	H	0.74	Some women who miscarry feel very isolated by their experience, *but* some women who miscarry are amazed at the number of people who shared in their loss.				
2	L	0.70	I felt very much alone in my loss.				
28	H	0.61	Some women feel guilt about their miscarriage, *but* some women do not feel guilt about their miscarriage.				
22	H	0.56	Some women who miscarry experience a loss of pride in themselves, *but* some women who miscarry do not experience a loss of pride in themselves.				
25	H	0.52	Some women dwell on the fact that their child will only exist in their memory, *but* some women do not dwell on the fact that their child will only exist in their memory.				
26	H	0.51	Some women who miscarry wonder "why did it happen to me," *but* some women who miscarry do not wonder "why did it happen to me."				

*H = Harter Forced Choice [really like me (1); sort of like me (2), *but* sort of like me (3); really like me (4)]. Likert [definitely true for me (1) to definitely *not* true for me (4)].

TABLE 1. Psychometric Properties of the Impact of Miscarriage Scale Using Data Gathered at 1 Year

In Phase I, *item derivation,* 105 emic statements were taken from interviews with 20 women who described what miscarriage meant to them (Swanson, 1983). In Phase II, *scale development,* those 105 statements were converted into Likert-type or Harter (1980) forced-choice format items

that would allow survey participants to indicate the relevance of each statement to her experience of miscarrying. The 105-item IMS with demographic and obstetrical history questions were mailed to a conveniently recruited sample of 446 North American women who were within 10 years of having miscarried. After soliciting expert critique and user comments, and carefully reviewing item level variances, item-to-item, and item-to-total correlations, the IMS was reduced to 30 items with a Cronbach's alpha of 0.93. To discern the capacity of the reduced IMS to discriminate between groups of women for whom miscarriage should theoretically hold different meanings (i.e., construct validity), several hypotheses were posed and tested on the 446 participant data set. Significant differences ($p < .05$) were detected between women: with and without a history of infertility; with and without children; and with less than three versus three or more miscarriages (so-called "recurrent aborters") (Swanson, Kieckhefer, Powers, & Carr, 1990).

In Phase III, subscale derivation, (using t_4 data from this study, N = 188) six additional items were dropped due to low variance or poor item-to-item or item-to-total correlations. Principal components factor analysis with varimax rotation of the remaining 24 items yielded four subscales with five to seven items each (see Table 1). Retained subscales/factors had an Eigen value greater than 1.0. Items had factor loading scores of 0.5 or better. *Devastating event* refers to miscarriage as a hopeless, no-control, catastrophic occurrence. *Losing a baby* measures how strongly a woman feels she lost her baby. *Personal significance* measures the degree to which miscarriage is experienced as a personal setback. *Isolated* examines how alone and guilty a woman feels in dealing with her miscarriage. The four subscales combined account for 59.3% of the IMS' total variance; suggesting that the overall impact of miscarrying is more than the mere sum of the four subscales. Hence, the Total IMS (Cronbach's alpha = 0.93) is used as an overall estimate of miscarriage impact. Subscale alphas were devastating event (0.86), lost baby (0.86), personal significance (0.83), and isolated (0.79).

Analysis: Measures of central tendency and dispersion were examined for all variables. Cronbach's alpha was estimated for each scale. To confirm group equivalence at t_1 and account for potentially confounding t_4 historical data, ANOVA or $[chi]^2$ analysis were performed on selected obstetric, demographic, and descriptive variables (alpha set at 0.05). Upon completion of data collection, to control for Type I errors when performing multiple tests of the effects of treatment and time over the first year, a repeated measures MANCOVA was performed on data from subjects who completed all four measures. Likewise, a repeated measures MANOVA was performed on data gathered from all participants at t_3 and t_4 to control for Type I errors when examining the effects of treatment, measurement, and time between 4 months and 1 year.

The alpha level was set at $p = 0.05$ when testing the three research hypotheses. The test of treatment (H_1) and time (H_2) effects over 1 year involved repeated measures ANCOVA of data from the early measures groups. Time and treatment were factors and t_1 scores were used as covariates. The tests of treatment (H_1), time (H_2), and measurement (H_3) effects between 4 months and 1 year involved repeated measures ANOVA of data gathered at t_3 and t_4 from all subjects.

Results

Confirmation of Group Equivalence: *Group equivalence at study entry.* There were no significant differences between groups on any of the recruitment criteria. Maternal age ranged from 19-45 years (*M* = 32.5; *SD* = 5.5). Mean gestational age at loss was 10.41 weeks (*SD* = 3.3) with 79% less than 12 weeks. They enrolled from 0-35 days post miscarriage (*M* = 7.86; *SD* = 7.5; *mdn* = 5). Fearing that length of time since loss might be associated with t_1 variables, the relationships (Pearson's r) between enrollment (days post loss) and t_1 outcome measures were examined. No significant associations were identified.

There were also no significant differences between groups on any of the demographic variables. The majority were married/partnered (88.8%), employed (76.4%), somewhat to very religious (81%), well educated (*M* = 15.65 yrs., *SD* = 2.3), and financially secure (average annual family income was approximately $50,000). The sample had limited ethnic diversity, 93.8% (198) were Caucasian. Others were Asian/Pacific Islander (5), Hispanic (4), African American (3), Native American (1), or undisclosed (13).

There were no significant differences between groups in obstetrical background. Whereas 71% said their pregnancies were planned, only five (2.4%) said pregnancies were not wanted. Participants had miscarried from one to six times (*M* = 1.44; *SD* = 0.79; *mdn* and mode = 1). Seventy-two percent had prior pregnancies and 54.2% currently had children. Previous losses included infertility (22.5%), elective abortions (30.6%), late gestation losses (4.5%), and previous miscarriages (30.3%).

There were no significant differences in care received at the time of miscarrying. Groups were equivalent on how many received care from a physician (82.9%), nurse (67.1%), and/or midwife (33.8%). Groups were also equivalent in obstetrical management of their loss with 82.2% having had an ultrasound and 59.9% having undergone dilatation and curettage.

Group equivalence at 1 year. During the year after loss there was no difference between the groups in the proportion of women who had conceived (62.4%), miscarried again (19%), or given birth (17%). Nor were there any differences in attending support groups (9.6%), having sought personal counseling (33%), or experiencing positive (*M* = 17.46, *SD* = 10.9) or negative life events (*M* = 8.58, *SD* = 8.3) as measured by Norbeck's (1984) Life Event Questionnaire. Finally, at t_4 there were no differences in proportion of women who were currently pregnant (31.4%), trying to become pregnant (26.7%), or avoiding pregnancy (34.4%).

Effects of Treatment and Time Over I Year: *Control for Type I errors.* Repeated measures MANCOVA using data from those early measured subjects who had complete data for all measures at all four time points (*n* = 75) was near-significant for both treatment (Omnibus F = 2.47; *df* = 3, 68; *p* = 0.069) and time (Omnibus F = 2.00; *df* = 6, 68; *p*=.078). Data analysis proceeded forward with an understanding that the possibility of Type I errors when claiming significance for the effects of treatment or time on any of the individual outcome measures was slightly greater than the preferred 5% rate.

Main effects. Focusing only on women completing four measures (early measures, treated and control) there were significant effects for treatment on overall emotional disturbance, anger,

and depression with treated women having lower scores on each measure (see Table 2). Significant effects for time were demonstrated by declines and overall emotional disturbance, anxiety, depression, anger, confusion, and personal significance of miscarrying and an enhancement of self-esteem. For women completing all four outcome measures there were no significant two-way interaction effects between time and treatment.

		Time Since Enrollment				Effects[a]			
	n	1 Week M (SD)	6 Weeks M (SD)	4 Months M (SD)	1 Year M (SD)	Treatment F	Treatment p	Time F	Time p
Overall emotional disturbance									
tx	43	74.9 (27)	39 (27.2)	36.7 (23.5)	30.2 (22.4)	4.94	0.029	4.62	0.011
con	40	68.9 (33.5)	46.7 (32.9)	43 (35.3)	35.2 (34.8)				
Anxiety									
tx	43	17.3 (6.7)	10 (5.4)	10.9 (6.8)	8.7 (5.6)	1.43	0.236	3.49	0.033
con	40	16.2 (8.1)	11.5 (7.3)	11 (7.3)	9.3 (7.3)				
Depression									
tx	43	27.1 (12.2)	12.1 (11.0)	9.8 (8.7)	8.4 (9.3)	6.14	0.015	3.41	0.035
con	40	24.1 (13.9)	14.8 (12.7)	12.6 (13.7)	11.4 (14.5)				
Anger									
tx	43	14.7 (8.3)	8.7 (8.3)	7.9 (7.1)	6.2 (6.4)	4.57	0.035	4.30	0.015
con	40	14.8 (9.8)	11.3 (9.6)	11.3 (11.3)	7.8 (9.9)				
Confusion									
tx	43	15.7 (5.1)	8.1 (5.4)	8.1 (5.0)	6.9 (4.6)	0.85	0.359	3.71	0.027
con	40	13.9 (6.4)	9 (6.3)	8.1 (6.7)	6.8 (5.5)				
Self-esteem									
tx	45	31 (5.8)	31.6 (5.2)	32.8 (5.2)	33.4 (4.4)	1.22	0.272	9.16	0.001
con	42	31.4 (5.6)	31 (5.5)	32.5 (4.4)	32.9 (5.1)				
Overall impact									
tx	42	65.7 (11.8)	63.3 (14.4)	63.2 (14.4)	62.6 (14.9)	0.22	0.640	0.20	0.816
con	36	64 (14.6)	62.2 (16.1)	62.4 (16.2)	62.2 (16.0)				
Lost baby									
tx	45	17.7 (3.1)	18 (4.3)	18.1 (3.8)	18.1 (4.4)	1.79	0.184	1.20	0.303
con	42	18.2 (3.9)	17.4 (4.9)	18 (4.5)	17.8 (5.1)				
Personal significance									
tx	42	19.6 (4.1)	17.7 (5.1)	17.7 (4.7)	16.7 (5.5)	0.90	0.345	4.43	0.013
con	36	18 (5.4)	17.4 (5.5)	16.4 (5.7)	16.2 (5.7)				
Devestating event									
tx	42	14.1 (3.9)	13.4 (4.2)	13.7 (4.3)	13.9 (4.2)	0.09	0.768	1.33	0.268
con	36	14.1 (4.4)	13.3 (4.7)	13.6 (4.9)	13.7 (4.5)				
Isolated									
tx	4	14.1 (3.9)	14.2 (4.3)	13.9 (4.2)	13.7 (4.3)	0.03	0.874	0.11	0.899
con	41	14 (4.1)	13.8 (4.2)	13.9 (4.8)	14 (5.0)				

tx = treated group; con = control group; M = mean; SD = standard deviation.
[a]There were no significant interaction effects.

TABLE 2. Effects of Treatment and Time on Moods, Miscarriage Impact, and Self-Esteem in the First Year After Loss (Early Measured Groups Only)

Effects of Measurement, Treatment, and Time Between 4 Months and I Year: *Control*

for Type I errors. Repeated measures MANOVA using data from both delayed and early measures subjects who had complete data at 4 months and 1 year (N = 176) was significant for both measurement (Omnibus F = 3.97; df = 3, 170; p = 0.009) and time (Omnibus F = 7.37; df = 3, 170; $p < 0.001$). However, it was not significant for treatment (Omnibus F = 0.891; df = 3, 170; p = 0.447). Data analysis proceeded forward with an understanding that the possibility of a Type I error when estimating the main effect of treatment on any of the individual outcome measures was far greater than the preferred 5% rate.

There was one significant effect for treatment. Treated women (both early and delayed measures) had lower anger scores than controls (F = 4.35; p = 0.038). There were two significant effects for measurement. Compared to those measured earlier, delayed measures women (both treated and control) had higher anger scores (F = 3.86; p = 0.051) and lower lost-baby scores (F = 5.84; p = 0.017). Between 4 months and 1 year, there was a main effect for time on several variables as indicated by a statistically significant increase in self-esteem (F = 6.00; p = 0.015) and decrease in overall emotional disturbance (F = 18.35; p = 0.001), anxiety (F = 8.51; p = 0.004), depression (F = 10.59; p = 0.001), anger (F = 21.48; p = 0.001), confusion (F = 11.87; p = 0.001), overall impact of miscarriage (F = 9.91; p = 0.002), and personal significance of miscarrying (F = 13.58; p = 0.001).

There were no significant three-way interaction effects. However, between t_3 and t_4 there were five significant two-way interactions.

There was one significant treatment × time interaction. This involved the personal significance of miscarrying. Compared to women in the control groups, treated women realized a greater decrease in personal significance over time (F = 4.44; p = 0.037). Mean scores for treated women (early and delayed measures combined) were 16.59 (SD = 5.3) at t_3 and 15.29 (SD = 5.4) at t_4. For the controls mean scores for personal significance was 16.61 (SD = 5.0) at t_3 and 16.23 (SD = 5.0) at t_4. When the mean scores are compared for treated women (in a measurement by time repeated measures ANOVA), time is highly significant (F = 14.74; p < 0.001). However, for those women in the control groups, the same analysis reveals a nonsignificant effect for time (F = 0.865; p = 0.535).

There were two significant measurement × treatment interactions. These involved the personal significance of miscarrying and the devastating event scores. Treatment appears to operate differently in the early and delayed measures groups with the t_3 and t_4 personal significance of miscarrying (F = 7.01; p = 0.009) and devastating event scores (F = 4.15; p = 0.043) being lowest for women in the treated, delayed measures group. For both of these subscales when repeated measures ANOVA (treatment × time) are run separately for the delayed versus early measures groups, there were significant effects for treatment (with those treated having lower scores) for the *delayed measures women only.* For the delayed measures women significant treatment effects were found for personal significance of miscarrying (F = 6.47; p = 0.013) and devastating event (F = 4.35; p = 0.040). For the early measures women treatment effects were not significant for personal significance of miscarrying (F = 1.64; p = 0.204) or devastating event (F = 0.706; p = 0.403).

There were two significant measurement × time interactions. These involved the overall impact of miscarriage and devastating event scores. Time appears to have a different effect in the early versus delayed measures groups with the decline over time in overall impact ($F = 4.77$; $p = 0.030$) and devastating event ($F = 4.81$; $p = 0.030$) scores being greatest in the delayed measures groups. For overall impact, early measures women ($n = 87$) experience a miniscule mean decrease of 0.48 points between 4 months ($M = 62.40$; $SD = 15.1$) and 1 year ($M = 60.95$; $SD = 16.3$) whereas delayed measures women ($n = 91$) experience an average decrease of 2.44 points between 4 months ($M = 59.85$; $SD = 14.4$) and 1 year ($M = 57.40$; $SD = 15.1$). When assessing miscarriage as a devastating event early measured women ($n = 87$) experience a slight mean rise of 0.17 points between 4 months ($M = 13.53$; $SD = 4.5$) and 1 year ($M = 13.70$; $SD = 4.4$) whereas delayed measures women ($n = 92$) experience an average decrease of 0.64 points between 4 months ($M = 13.87$; $SD = 4.0$) and 1 year ($M = 13.23$; $SD = 4.5$). In sum, the healing effects of time as indicated by less overall impact of miscarriage and a diminished perception of miscarriage as a devastating event were most evident between t_3 and t_4 for those women (both treated and control) who went unmeasured until 4 months after enrollment. TABLE

		Time Since Enrollment				Time Since Enrollment	
	n	*4 Months M (SD)*	*1 Year M (SD)*	*n*	*4 Months M (SD)*	*1 Year M (SD)*	
Emotional disturbance				Impact of miscarriage			
e-t	47	63.5 (32.1)	57.3 (28.9)	e-t	46	63.4 (14.2)	62.8 (14.9)
e-c	42	68.8 (44.6)	60.7 (40.9)	e-c	41	61.2 (16.3)	60.9 (16.3)
d-t	43	75.2 (36.5)	61.5 (31.9)	d-t	39	57.2 (15.3)	53.7 (15.1)
d-c	53	79.2 (38.0)	66.1 (34.4)	d-c	52	61.8 (13.6)	60.1 (14.7)
Anxiety				Lost baby			
e-t	47	10.4 (6.7)	8.8 (5.6)	e-t	47	18 (3.9)	17.9 (4.4)
e-c	42	10.9 (7.1)	9 (7.3)	e-c	43	18.1 (4.5)	17.9 (5.1)
d-t	43	12.3 (6.9)	9.9 (6.6)	d-t	41	16.8 (4.9)	16.2 (5.1)
d-c	53	11.6 (6.6)	11 (7.5)	d-c	52	16.3 (4.7)	16 (5.1)
Depression				Personal significance			
e-t	47	9.2 (8.5)	8 (9.1)	e-t	46	17.8 (4.7)	16.8 (5.4)
e-c	42	12.4 (13.4)	11.1 (14.3)	e-c	41	16 (5.5)	15.8 (5.6)
d-t	43	12.8 (11.7)	8.7 (7.6)	d-t	40	15.2 (5.5)	13.5 (4.9)
d-c	53	14.3 (12.3)	10.2 (9.6)	d-c	52	17.1 (4.0)	16.6 (4.4)
Anger				Devastating event			
e-t	47	7.7 (6.9)	6.2 (6.3)	e-t	46	13.8 (4.2)	14.1 (4.2)
e-c	42	11 (11.1)	7.6 (9.7)	e-c	41	13.2 (4.8)	13.2 (4.6)
d-t	43	10.6 (8.3)	7.8 (7.5)	d-t	40	13 (3.9)	12.1 (4.2)
d-c	53	13.4 (9.0)	9 (7.9)	d-c	52	14.5 (4.1)	14.1 (4.5)
Confusion				Isolated			
e-t	47	7.8 (4.9)	6.9 (4.5)	e-t	48	13.9 (4.2)	13.6 (4.3)
e-c	42	7.9 (6.6)	6.7 (5.4)	e-c	43	14 (4.8)	14 (4.9)
d-t	43	8.6 (5.4)	6.9 (4.8)	d-t	41	12.2 (3.8)	12 (3.5)
d-c	53	8.8 (5.5)	7.3 (5.0)	d-c	53	13.8 (3.7)	13.4 (4.2)
Self-esteem							
e-t	48	33.1 (5.2)	33.6 (4.4)				
e-c	43	32.5 (4.4)	33 (5.1)				
d-t	41	31.9 (5.6)	32.5 (5.3)				
d-c	53	32.3 (5.7)	33.2 (5.3)				

M = mean; SD = standard deviation; e-t = early, treated group; e-c = early, control group; d-t = delayed, treated group; d-c = delayed, control group.

TABLE 3. Effects of Treatment, Measurement, and Time at 4 Months and 1 Year

Discussion

Hypothesis 1 was partially supported. For those in the early measurement groups, significant treatment effects were found for overall emotional disturbance, depression, and anger. Between 4 months and 1 year only one main effect was found for treatment. Treated women (regardless of measurement status) had significantly lower anger scores than controls. Hypothesis 3 could not be totally accepted because women in the delayed measures groups (both treated and control) were more angry and less likely to view their loss as a baby than their early measures counterparts. Also there were five significant interactions identified between 4 months and 1 year after enrollment, four of these involved measurement. Specifically, women in the delayed measures groups responded differently to treatment (as indicated by treatment effects on personal significance and devastating event occurring only for those in the delayed groups). Delayed measures women also responded differently to the passage of time between 4 months and 1 year (as indicated by time effects for overall impact of miscarrying and personal significance occurring for only those in the delayed measures groups).

Hypothesis 2 received substantial support as time had a significant healing effect in many instances. Over the year women completing early measures (both treated and control) realized enhanced self-esteem and diminished personal significance attributed to miscarrying, they were also less anxious, depressed, angry, and confused. Time continued to contribute to well-being as late as 4 months and 1 year postloss as evidenced by all groups experiencing an increase in self-esteem, and decrease in overall miscarriage impact, overall emotional disturbance, anxiety, depression, anger, and confusion. Finally, between t_3 and t_4, when women in the treated groups (early and delayed measures) were examined separately from those in the control groups, time had a significant healing effect on the personal significance attributed to miscarrying for only those women who had received the caring-based counseling.

The effects (both main and interactive) due to measurement offer insight into the mechanisms through which survey completion may, in itself, be a "self-caring" therapeutic. With the exception of anger, the only main or interaction effects for measurement were observed with the IMS scale, which has very specific probes about miscarriage. It is possible that the IMS is useful in both prompting meaning-making and detecting made-meaning. The discovery that between 4 months and 1 year postloss the women in the delayed measurement groups (both treated and control) experienced a decrease in perceived amount of devastation and overall impact of miscarriage (t_3 to t_4 time effect) suggests that for them measurement may have had the therapeutic effect of "initiating" time's capacity to heal. Also, compared to their controls, treated women from the delayed measures group only, realized treatment effects between 4 months and 1 year as evidenced by significant declines in their personal significance and devastating event scores. In this case, it seems that completing measures for the first time at 4 months may have worked synergistically with treatment to prompt additional integration of their loss.

There were several limitations in this study. The sample had minimal ethnic diversity and was quite highly educated, thus limiting generalizability. One of the key outcome measures was investigator developed and tested through this investigation. While psychometric properties for

the IMS were quite strong, it needs to be revised with uniformly constructed items and examined for applicability beyond the current sample. More than two-thirds of the interventions were conducted by the PI who was also responsible for developing the counseling protocol and the caring theory tested via the investigation. Therefore, it is hard to separate the intervention from the PI. Future inquiry is needed to determine if others would achieve similar results.

There were two noteworthy drawbacks to using the Solomon four-group design. The greatest delta in scores between any two data collection points occurred between t_1 and t_2, yet, this window of healing remained unobserved for half of the participants. The costs of four cells to fill automatically meant that group sizes were diminished, power compromised, analysis doubled, and with the exception of findings pertaining to t_3 and t_4, conclusions could only be drawn on 50% of the recruited subjects.

The chances of making a Type I error were enhanced by the multiple comparisons made through this investigation. Ideally, analysis would have proceeded with the insurance provided by achieving a significance level of 0.05 on all main effects for the Omnibus F tests. However, this was not the case. It must be noted that this was a study of a never-before-tested treatment program and hypothesized effects were quite speculative. Outcome variables and measurement times were chosen on an exploratory basis (that is, based on clinical observations versus empirical descriptions of the miscarriage healing trajectory). Hence, it is not surprising that some measures were not responsive to treatment, time, or measurement. The presence of such nonresponsive outcome variables could account for those Omnibus F tests that did not achieve a desirable level of significance.

The Miscarriage Caring Project was an attempt to translate caring into a potentially replicable therapeutic intervention. In a recent review of approximately 130 data-based nursing publications on caring (Swanson, 1999) it was noted that there were no prospective controlled intervention studies in which caring was the independent variable. The Miscarriage Caring Project is somewhat unique; with origins in phenomenology, it was derived from a research program in which caring and the human response to miscarriage were originally interpreted from the stories of women who miscarried. Fidelity to intervention protocol for this research meant that consistency in adherence to the process (caring) took precedence over predictability in delivery of the content.

Historically, investigators have examined miscarriage from psychoanalytic (Gannon, 1994), bereavement and/or depression (Beutel et al., 1995), and fetal attachment/loss paradigms (Moulder, 1994); however, none have focused on women's anger as an outcome. This study indicated that anger was the most sensitive outcome as documented by significance found for treatment and measurement for every subgroup studied. As a stage of grief, anger is an essential healthy step toward resolution (Brown, 1993). The findings of higher anger and lower likelihood to recognize miscarriage as loss of a baby for those completing delayed measures suggests the need to further examine the link between making meaning of just what was lost and the experience of anger.

Findings suggest that there may be different routes to healing for different women. Survey-completion could in itself be a "self-caring" module that assists women to identify what they lost and to let go of anger. Three hours of one-on-one caring-based nurse counseling were effective in

diminishing overall emotional disturbance, anger, and depression in the first year after miscarrying.

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