Evidence-based Intervention with Women Pregnant after Perinatal Loss

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Abstract:

Purpose: To test the feasibility and acceptability of a caring-based nurse home visit intervention for women pregnant after perinatal loss (PAL), the goal of which was to provide a safe, supportive environment, normalize the pregnancy after loss, reduce anxiety and depression through stress reduction skills, and facilitate prenatal attachment.

Study Design and Methods: This mixed methods study was conducted in two phases: Phase I, to determine the components of the intervention, and Phase II, a randomized trial that used the revised intervention components. Pregnant women with a history of at least one perinatal loss (9 in Phase I and 24 in Phase II) were recruited from obstetrical practices. Phase II sample size was adequate to detect group differences. Background measures of demographics, obstetrical history, and meaning of past losses were collected at baseline. Measured at three points across pregnancy were threat appraisal of pregnancy; and emotional states: anxiety (pregnancy, state, trait), depression, self mastery, prenatal attachment, and satisfaction with social support. The caring-based nurse home visit intervention included activities aimed to reduce anxiety and promote prenatal attachment. The control group were sent pregnancy information booklets that coincided with their gestational age. Qualitative and quantitative evaluations were obtained.

Results: In Phase I, 8 women received the intervention; in Phase II, 13 received the intervention and 11 were in the control group. No baseline between-group differences were found. The intervention group had significantly higher satisfaction with social support over time. Women's evaluations were very positive; home visits were rated most liked and helpful. They appreciated a knowledgeable nurse who knew their story, listened, normalized the PAL experience, and was there with nonjudgmental support.

Clinical Implications: The intervention is both feasible and acceptable. Most women felt that they could reduce their own anxiety using the tools and skills they were provided. Healthcare providers should consider past history's impact on current pregnancy experiences and incorporate process and content of the intervention into their practice.

Keywords: Anxiety | Empathy | Intervention studies | Pregnancy complications/psychology | Perinatal loss

Article:

[Picture Omitted]

Many believe that becoming pregnant again after a perinatal loss from miscarriage, stillbirth, or neonatal death will ease a parent's grief, wipe away the sad memories of loss, and make a woman smile again. However, pregnancy after perinatal loss (PAL) is increasingly recognized as a psychologically stressful period of time (Gaudet, Sejourne, Camborieux, Rogers, & Chabrol, 2010; Hutti, Armstrong, & Myers, 2011). Specifically, in subsequent pregnancies, women with a history of loss report high levels of fear of losing another baby (Côté-Arsenault, Bidlack, & Humm, 2001), greater anxiety specific to pregnancy concerns (Armstrong, 2002; Bergner, Beyer, Klapp, & Rauchfuss, 2008; Côté-Arsenault, 2003), an increased sense of vulnerability, hypervigilance to their pregnancy symptoms (Côté-Arsenault, Donato, & Earl, 2006), and doubt about their biological and psychological ability to successfully have and parent a baby. These pregnancies are appraised as a threat that remains moderately high across the pregnancy (Côté-Arsenault, 2007). In general, the gestational age of past losses does not predict the degree of threat appraisal, pregnancy anxiety, or meaning of the loss, although women with late losses report higher anxiety as they approach the time in pregnancy when their loss occurred (Côté-Arsenault, 2007; Côté-Arsenault & Donato, 2007).

Anxiety-laden pregnancies such as these are common, given that 3/4 million U.S. women a year experience perinatal loss, and the majority of these will become pregnant again. Pregnancy is no longer equated with having a baby (Côté-Arsenault et al., 2006; Côté-Arsenault & Marshall, 2000) but rather is viewed as a state in and of itself, with the idea of having a baby pushed to the back of the mother's mind for protection. Fear of further loss and grief, as well as disloyalty to babies who have died, often delay preparation for and attachment to the unborn baby (Côté-Arsenault & Donato, 2007, 2010); cautious optimism is common. It is somewhat logical then that women PAL have greater healthcare utilization, and thus higher costs, due to concerns about the baby than women without a perinatal loss history (Hutti et al., 2011).

High-stress levels in pregnancy are associated with a host of negative outcomes for mother and child, including premature birth, low birthweight (Grote et al., 2010), and irritable infant temperament (Van den Bergh, Mulder, Mennes, & Glover, 2005; Wurmser et al., 2006). Studies have also linked stress in pregnancy with impaired cognitive, behavioral, urological, and

neuroendocrine development in the child up to 6 years of age (Glover, O'Connor, Heron, Golding, & ALSPAC Study team, 2004; Huizink, Mulder, & Buitlaar, 2004; Huizink, Robles de Medina, Mulder, Visser, & Buitelaar, 2003; O'Connor, Heron, Golding, Glover, & ALSPAC Study Team, 2003). Additionally, altered parenting and attachment disorders have been reported with children born subsequent to perinatal loss (Gaudet et al., 2010; Hughes, Turton, Hopper, McGauley, & Fonagy, 2001; O'Leary & Thorwick, 2008). Despite the known risks of PAL, current prenatal care standards and guidelines do not address the unique needs of pregnant women with prior pregnancy loss (Akkerman et al., 2012). Thus, interventions to treat moderate high levels of pregnancy stress in women at high risk are clearly needed.

The only existing intervention, support groups for couples pregnant again after prior loss, are difficult to find and not acceptable to all due, in part, to the group setting and inflexible schedule. However, a mini-ethnographic study of existing support groups found that groups were beneficial, and provide a place where women felt safe, normal, and understood (Côté-Arsenault & Freije, 2004); their feelings were accepted as legitimate, and they were able to honor both their babies who have died and their "in utero" baby. Delivery of similar care, within a caring-based home visitation model, is the foundation of the intervention tested here. Nurse home visitation of new mothers is a well-established, effective birth mechanism well suited to meet the needs of this understudied, underserved population (Kitzman et al., 2000; Olds et al., 2004).

Theoretical Framework: Swanson's Theory of Caring

The key theory guiding this intervention is Swanson's descriptive, Theory of Caring (Swanson, 1991). Caring is defined as a "nurturing way of relating to a valued other toward whom one feels a personal sense of commitment and responsibility" (p. 165) with the goal of client well-being. Caring comprises five processes:

- 1. Knowing is "striving to understand an event" and its meaning for the other (p. 163);
- 2. Being with is "being emotionally present to the other" (p. 163), available, but without burdening the other;
- 3. Doing for "entails doing for others what they would do for themselves" if they could (p. 164);
- 4. Enabling involves "facilitating the other's passage through life transitions and unfamiliar events" (p. 164) by supporting and explaining current events; and
- 5. Maintaining belief is a hopeful attitude based on one's "faith in the other's capacity to make it through events or transitions" (p. 165), and helping to find meaning in life's events.

Caring is an appropriate process through which to convey knowledge, understanding, support, and new skills (Swanson, 1991).

Provision of caring-based support requires knowledge of the needs of pregnant women who have had prior loss. The first author's descriptive and correlational studies, as well as the work of others provide detailed descriptions of women's experience of PAL (Côté-Arsenault, 2003; Côté-Arsenault et al., 2006; Côté-Arsenault & Freije, 2004; Côté-Arsenault & Marshall, 2000; O'Leary, 2004). For example, because of their fear of another loss, women are very worried about miscarriage in the first trimester of pregnancy (up to 13 weeks), but some comfort is gained once they feel fetal movement (15–20 weeks). Therefore, it is important to acknowledge women's high anxiety and its source (past experience) and introduce ways to reduce it (e.g., relaxation, positive self-messages, noting fetal movement, journaling). The goal of the theoretically and evidence-based intervention studied here is to provide a safe, supportive environment, normalize the pregnancy after loss experience, reduce anxiety and depression through stress reduction skills, and facilitate prenatal attachment to the baby within.

The purpose of this study was to test the feasibility and acceptability of this caring-based nurse home visit intervention to women pregnant after perinatal loss. The research questions were as follows:

- 1. What is the acceptability of the home visit nursing intervention?
- 2. What components of the intervention are most helpful to the women?
- 3. What is the effect of the intervention on threat appraisal, pregnancy anxiety, anxiety, depression, prenatal attachment, and satisfaction with social support among PAL women?
- 4. What is the retention rate of women in the control group?

Study Design and Methods

Recruitment

Women were recruited from central and western New York through obstetrical healthcare provider sites, including two regional perinatal centers, perinatal loss support group leaders, and community perinatal networks. Inclusion criteria for Phase I were healthy, adult pregnant women, able to speak, read, and write English, receiving prenatal care, 21 years of age or over, with a history of at least one spontaneous perinatal loss (miscarriage, stillbirth, or neonatal death), and currently in their first or second trimesters. We excluded women with medical conditions or fetal diagnoses that precluded any chance of a healthy baby, multiple gestation beyond twins, or uncontrolled medical or mental illness. Prior elective abortion was not an exclusion criterion. Phase II inclusion criteria were the same as above except but the aim was to recruit women prior to feeling consistent fetal movements, generally prior to 18 weeks gestation.

This study was approved by the IRB at the University of Rochester. Informed consent was received from each participant prior to the collection of baseline data (Time 1). Random

assignment to group, intervention or control, was then made with equal probability.

Measures

Background measures obtained at baseline included demographics, obstetrical and medical history, and fetal personhood assigned to each loss. Repeated measures included self-report of threat appraisal of pregnancy, emotional states—pregnancy anxiety, state and trait anxiety, depression, and self mastery; prenatal attachment, and satisfaction with social support. See Table 1for description, source, and psychometric properties of each measure.

Table 1. Measures Description, Source, and Psychometrics

| Construct/Measures | Source | No of Items; (range of scores) | Reliability Cronbach's alpha | Established Validity |
|-------------------------------------|----------------|--------------------------------------|------------------------------------|-------------------------|
| Background | l | , | * | 1 |
| Demographics— | | 8 | | |
| race/ethnicity, | | | | |
| marital status, | | | | |
| education, income, | | | | |
| religion/religiosity, | | | | |
| occupation | | | | |
| Obstetrical | | 12 | | |
| History —past | | | | |
| pregnancies, length, | | | | |
| outcomes, numbers | | | | |
| of losses, elective | | | | |
| abortions, infertility | | | | |
| history, number of | | | | |
| living children, current medical | | | | |
| problems | | | | |
| Loss—Assignment | Côté-Arsenault | 2 (0–5) | | Construct |
| of Fetal Personhood | and Dombeck, | 2 (0-3) | | Construct |
| (AFP)—Response to | (2001) | | | |
| questions: "What is it | (=001) | | | |
| that you feel that you | | | | |
| lost?" responses | | | | |
| choices: a pregnancy, | | | | |
| a baby, a baby with a | | | | |
| name, a baby who | | | | |
| would now be | | | | |
| years old (scored 0– | | | | |
| 3, respectively) and | | | | |
| "Did you have a | | | | |
| memorial or funeral | | | | |

| 1 · · · · · · · · · · · · · · | 1 | | | |
|--|-----------------------|-----------|-------|-----------------------------|
| service?" (no = 0 ; | | | | |
| yes = 1). Scores | | | | |
| range from 0 to 5; | | | | |
| higher scores | | | | |
| indicate more | | | | |
| assigned fetal | | | | |
| personhood | | | | |
| Threat— | Moneyham et | 15 (5–75) | 0.876 | Content; |
| Appraisal- | al. (1998); | | | construct |
| Moneyham Threat | Hatmaker and | | | |
| Index (MTI); | Kemp (1998) | | | |
| perceived threat of | | | | |
| this pregnancy; (a) | | | | |
| what is at stake, (b) | | | | |
| the expected | | | | |
| outcome, and (c) | | | | |
| degree of perceived | | | | |
| control; 15 item, 5- | | | | |
| point Likert scale | | | | |
| from strongly | | | | |
| disagree (1) to | | | | |
| strongly agree (5) | | | | |
| Emotional State | | | | |
| | | | | |
| Pregnancy | Côté-Arsenault | 9 (0–100) | 0.872 | Content; |
| | Côté-Arsenault (1995) | 9 (0–100) | 0.872 | Content; discriminant; |
| Pregnancy | | 9 (0–100) | 0.872 | · · |
| Pregnancy Anxiety— | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) | | | | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— | | 9 (0–100) | 0.872 | discriminant; |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait | (1995) | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory | (1995) Spielberger | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory (STAI); measures | (1995) Spielberger | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory | (1995) Spielberger | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory (STAI); measures | (1995) Spielberger | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory (STAI); measures anxiety-proneness | (1995) Spielberger | | | discriminant; predictive |
| Pregnancy Anxiety— Pregnancy Anxiety Scale (PAS); nine questions about apprehension and concern for this pregnancy measured on a visual analog scale (anchors: "definitely no" at zero mark; "definitely yes" at 100-mm mark) Trait Anxiety— State & Trait Anxiety Inventory (STAI); measures anxiety-proneness (trait anxiety) and | (1995) Spielberger | | | discriminant; predictive |

| point Likert | | | | |
|--|-----------------|-------------|-------|------------|
| responses; scores | | | | |
| range from 20 to 40 | | | | |
| State Anxiety—see | Spielberger | 20 (20–80) | 0.937 | Construct |
| above | (1983) | _ (_ 3 | | |
| Depression—The | Radloff (1977) | 20 (0-80) | 0.827 | Construct |
| Center for | , , | | | |
| Epidemiologic | | | | |
| Studies Depression | | | | |
| Scale (CES-D); | | | | |
| measures duration | | | | |
| and frequency of | | | | |
| depressive symptoms | | | | |
| during the past week | | | | |
| on a 4-point scale | | | | |
| from 0 (rarely, or | | | | |
| none of the time) to 3 (most or all of the | | | | |
| time); scores >15 | | | | |
| indicative of higher | | | | |
| depressive symptoms | | | | |
| Self Mastery— | Pearlin and | 7 (7–28) | 0.877 | Construct |
| Measures the extent | Schooler (1978) | 7 (7 20) | 0.077 | Construct |
| to which a person | Schooler (1970) | | | |
| regards their life | | | | |
| chances as being | | | | |
| under their own | | | | |
| control in contrast to | | | | |
| being fatalistically | | | | |
| ruled; uses 4-point | | | | |
| Likert scale for seven | | | | |
| items; higher scores | | | | |
| indicate higher self- | | | | |
| mastery | | | | |
| Mother-Baby Relatio | | 10 (10, 05) | 0.056 | |
| Prenatal | Condon (1993) | 19 (19–95) | 0.856 | Construct |
| Attachment—The Maternal Antenatal | | | | |
| Attachment Scale | | | | |
| (MAAS) 19-item | | | | |
| scale that measures | | | | |
| emotional bond | | | | |
| mother feels toward | | | | |
| her unborn baby | | | | |
| Social Network | 1 | ı | L | l |
| Satisfaction with | Sarason, | 6 | 0.887 | Concurrent |
| | | | | <u>.</u> |

| Social Support— | Shearin, and | | |
|-----------------------|---------------|--|--|
| Social Support | Pierce (1987) | | |
| Questionnaire | | | |
| (SSQ-6); measuring | | | |
| satisfaction with six | | | |
| dimensions of | | | |
| support from | | | |
| individuals self- | | | |
| identified as | | | |
| supportive of the | | | |
| pregnant woman | | | |

Research Design

We conducted this intervention study in two phases: Phase I was done with women of varying gestational ages to introduce the components of the intervention, develop and refine the intervention, and receive feedback and suggestions from the pregnant women. Phase II was a two-group randomized trial of the refined intervention. The control group in Phase II received pregnancy information booklets on the same schedule as the intervention group home visits (HV). (See Supplemental Digital Content 1 and 2 for a schematic of data collection and intervention time schedule, http://links.lww.com/MCN/A12 and http://links.lww.com/MCN/A13.)

Data were collected from all participants in Phase II at baseline, at 22 to 24 weeks gestation (Time 2) and 32 to 34 weeks gestation (Time 3). A research assistant blind to group assignment, picked up completed questionnaires from all women. Payment of \$20 was made at the time of pick-up; totaling \$60 across the study. In addition, a book to read to baby was given postbirth.

Intervention

The intervention goal was to provide a safe, supportive environment, reduce anxiety and depression through normalizing the PAL experience, promote prenatal attachment, and teach skills known to reduce stress and anxiety.

Process. We used the Caring process (Swanson, 1993) during all interactions with the women. This entailed getting to know each woman, her pregnancy and her loss story, focusing on being with her and where she was emotionally in her current pregnancy (including prenatal attachment to her baby), offering anxiety-reducing coping skills, encouraging use of her pregnancy diary, providing information on topics of interest or concern, and continually maintaining belief in her ability to focus on positive events, reduce anxiety, and make it through the pregnancy. For example, when a woman described her pregnancy fears and worries and reported that others tell her she worries too much, the caring, informed response is listening, knowing her story, and

reassuring her that worries are normal in PAL. (Supplemental Digital Content, http://links.lww.com/MCN/A12 and http://links.lww.com/MCN/A13 provide details of the integration of content and process of home visit I, as an example.)

Content. The intervention group received a comprehensive nurse caring intervention from the Principal Investigator (PI), an experienced maternity advanced practice nurse (APN) with expertise in providing care to women PAL. The intervention consisted of HV, pregnancy diary, and anxiety-reducing skills teaching.

Nurse Visits/Contacts. HV began as soon as possible after enrollment; four were planned in Phase I but were expanded to six in Phase II due to feedback from the participants in Phase I. The content of the HV, based on evidence of women PAL, included commonly experienced emotions, physical milestones, and social aspects of pregnancy as they change across pregnancy. Conversation included all of the women's children living, deceased, and the unborn. Contact with the APN between HV was encouraged.

Guided Pregnancy Diary. Written emotional expression about stressful or traumatic events has been found to improve physical health, psychological well-being, physiological functioning, and general functioning in numerous studies (Smyth, 1998). Therefore, each woman was provided a Guided Pregnancy Diary, developed by the PI for this study, to record pregnancy events and personal entries, as well as to reinforce the content from HV and skill practice.

Skill Building. Skill building was an important component of the intervention so that the women would be able to "do for" and be "enabled" to advocate and care for themselves and their baby. Four skills, expected to affect anxiety in pregnancy, were taught: relaxation, problem solving, daily fetal movement records, and "I" message training. Women were assessed for their current skill level and their need for skills. Anxiety-reducing skills were demonstrated by the APN, with immediate return demonstrated by the mother. Skill practice and utilization were noted in the pregnancy diary by the mother. Skills were reinforced in subsequent HV as needed.

Fidelity Checks. To confirm that the intervention was received as planned each woman was asked to complete the Caring Professional Scale (Swanson, 2009) and the empathy subscale of the Barret-Lennard Relationship Inventory (Wampler & Powell, 1982) confidentially after each HV. In addition, checklists of home visit topics were completed across the pregnancy by the PI, and initial skill practice was verified verbally and through pregnancy diary notations.

Study Evaluation. The study was evaluated via a self-report survey with Likert-type and open answer questions whether they liked the various aspects of the intervention and if the skills were helpful. Additionally the research assistants conducted a telephone survey with women in both groups to ascertain their experience with the APN and in the study.

Statistical Methods

An effect size (variance of group by time effects) of 0.275 could be detected using repeated measures ANOVA and assuming a moderate correlation of repeated measures of 0.50, a 0.05 significance level, and at least 80% power under a sample size of 24. For feasibility of the study intervention, numbers assessed for eligibility, randomized, and remaining in the study at each of the three time-points were tabulated. For reliability of measures, internal consistency was estimated using Cronbach's alpha. For assessing intervention effects, longitudinal regression using linear mixed-effects modeling of postbaseline outcomes explicitly adjusting for outcome scores at baseline and additional covariates on postbaseline data was performed (Fitzmaurice, Laird, & Ware, 2004). This modeling adjusted for outcome scores at baseline, gestational age at baseline, number of intervention HV, and the first principal component for obstetrical history, fetal personhood, and time of loss. This principal component accounted for 59.3% of variation in these measures. Obstetrical history measures included in this component were number of previous pregnancies, pregnancy losses, miscarriages, lost pregnancies, and gestation ages of losses. A two-sided *p*-value < 0.05 was considered statistically significant.

Results

Sample

Nine women of diverse racial/ethnic backgrounds were recruited in Phase I of the study and eight received the intervention. Participant ages ranged from 23 to 39 years, education at high-school level and beyond, of low economic status, and had first or second trimester losses in their history. Twenty-four women entered Phase II; these women were predominantly Caucasian, 22 to 41 years of age, diverse education of some high school through graduate school, middle to high incomes, diverse loss histories of first trimester through neonatal deaths. See CONSORT table (Figure 1) for recruitment and retention of the sample. In Phase II, 95.8% of enrolled women (n = 23) completed the study; 100% retention in the control and 92% in the intervention group.

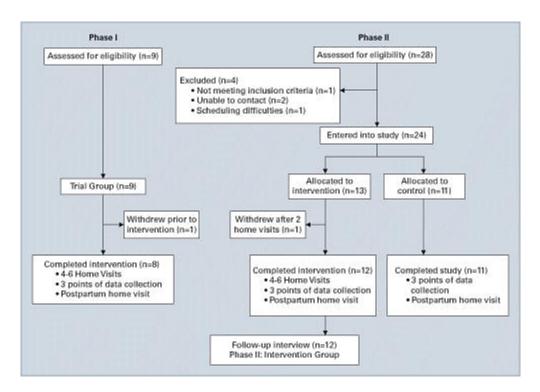


Figure 1. CONSORT Table of Study Sample

Detailed characteristics of the study participants at baseline are reported in Table 2. No significant differences in characteristics were found between the intervention and control groups. Estimated reliability via internal consistency of the study instruments at baseline is presented in Table 1, and all alpha coefficients were at least 0.75.

Table 2. Characteristics of the Study Participants by Group (n = 33)

| Demographics | Phase I | Phase II | | | |
|------------------|-----------------|-----------------|-----------------|----------------------|------------------------------|
| Characteristic | Pilot $(n = 9)$ | Overall ($n =$ | Intervention | Control (<i>n</i> = | <i>p</i> -Value ^a |
| mean \pm SD or | | 24) | (n = 13) | 11) | |
| n (%) | | | | | |
| Age (years) | 30.3 ± 6.24 | 31.5 ± 4.44 | 32.3 ± 4.94 | 30.6 ± 3.80 | 0.3701 |
| Highest grade | 14.2 ± 3.11 | 15.5 ± 2.84 | 15.6 ± 3.33 | 15.3 ± 2.28 | 0.7933 |
| completed | | | | | |
| Married, | 5 (56%) | 21 (88%) | 12 (92%) | 9 (82%) | 0.5761 |
| current | | | | | |
| pregnancy | | | | | |
| Race | | | | | 1.0000 |
| American | 1 (11%) | 0 | | | |
| Indian | | | | | |
| African- | 2 (22%) | 1 (4%) | 1 (7%) | 0 | |
| American | | | | | |
| Caucasian | 6 (67%) | 21 (88%) | 11 (85%) | 10 (91%) | |
| Hispanic | 0 | 1 (4%) | 1 (7%) | 0 | |

| Other | 0 | 1 (4%) | 0 | 1 (9%) | |
|----------------------------|------------------|------------------|------------------|----------------------|------------------------------|
| Family | 40.0 ± 35.97 | 77.5 ± 40.05 | 78.5 ± 44.97 | 76.4 ± 35.50 | 0.4682 |
| income, | | | | | |
| thousands | | | | | |
| Religiosity | 2.4 ± 1.33 | 2.3 ± 0.61 | 2.2 ± 0.60 | 2.3 ± 0.65 | 0.8699 |
| (VAS ^b) | | | | | |
| Pregnancy | Pilot $(n = 9)$ | Overall ($n =$ | Intervention | Control (<i>n</i> = | <i>p</i> -Value ^a |
| History | | 24) | (n = 13) | 11) | |
| No. of times | 4.2 ± 2.68 | 3.8 ± 1.80 | 3.9 ± 2.15 | 3.6 ± 1.36 | 0.8596 |
| pregnant | | | | | |
| No. of elective | 0.4 ± 1.01 | 0.4 ± 0.77 | 0.5 ± 0.97 | 0.2 ± 0.40 | 0.4304 |
| abortions | | | | | |
| No. of step- | 1.1 ± 2.26 | 0.2 ± 0.59 | 0.2 ± 0.60 | 0.2 ± 0.60 | 0.7273 |
| children | | | | | |
| No. of | 0.8 ± 0.83 | 1.0 ± 1.02 | 1.0 ± 1.15 | 1.0 ± 0.89 | 0.8294 |
| biological | | | | | |
| children living | | | | | _ |
| Fetal | [0, 4], 1 | [1, 5], 4 | [1, 5], 4 | [1, 5], 4 | NS ^d |
| Personhood ^c | | | | | |
| No. of losses | 2.0 ± 1.00 | 2.8 ± 1.07 | 2.9 ± 1.28 | 2.6 ± 0.81 | 0.9743 |
| Gestational | [3, 22], 6 | [4, 39], 6 | [4, 39], 8 | [4, 28], 6 | NS ^d |
| age of losses ^c | | | | | |
| Gestational | 17.6 ± 6.77 | 14.2 ± 3.73 | 13.8 ± 3.34 | 14.8 ± 4.23 | 0.5087 |
| age at baseline | | | | | |

a *p*-Value from comparison of Phase II intervention versus control groups.

Table 3 gives the results from the longitudinal analysis of study outcomes. Ranks for depression scores, quality of prenatal attachment, and satisfaction (social support) were modeled as assumptions of normality were in question for these outcomes. All outcome means over the postbaseline time period were not significantly different between the intervention group and the control group, controlling for baseline outcome and covariates.

Table 3. Multivariable Longitudinal Modeling Results for Study Outcomes^a

| Outcome | I versus C Mean Difference ^a | 95% CI for Mean Difference | p -Value |
|--------------------|--|-------------------------------|----------|
| CES-D ^b | 8.33 | (-35.74, 52.40) | 0.6940 |
| Mastery | -0.79 | (-2.46, 0.88) | 0.3287 |
| State anxiety | 12.11 | (-44.54, 68.77) | 0.6574 |
| Trait anxiety | 21.62 | (-10.18, 53.42) | 0.1686 |
| Quality of | 4.73 | (-29.89, 39.36) | 0.7754 |

b Visual analog scale (0–4) where 0 = not at all religious, 2 = somewhat, 4 = extremely religious.

c [Min, Max], mode reported.

d Compared for each loss; NS = not significant with all p > 0.10.

| attachment ^b | | | |
|-----------------------------|---------------------|-----------------|-----------------|
| Intensity of | -0.27 | (-2.25, 1.72) | 0.7797 |
| attachment | | | |
| Global attachment | -0.04 (-1.17, 1.08) | 0.9366 | |
| Threat | 2.09 | (-24.15, 28.33) | 0.7218 |
| Pregnancy anxiety | -13.02 | (-84.16, 58.11) | 0.7039 |
| Number of support | -2.43 | (-7.59, 2.73) | 0.3345 |
| people | | | |
| Satisfaction ^{a,b} | Depends on time | Depends on time | Depends on time |

^a Estimated difference in means for I versus C across times 2 and 3 (assuming no time by group interaction) after explicitly controlling for time 1 outcome values as a covariate, gestational age at time 1, number of HV, the first principal component for obstetrical history, fetal personhood, time of loss, and correlations induced by repeated measures on patients. Only satisfaction did not satisfy the assumption of no time by group interaction (p = 0.0057), specifically for the intervention group for time 2 versus time 3. There, patients in the intervention group tended to be higher on satisfaction with increasing weeks of gestational age (p = 0.0019). However, tests for group differences at time 2 (p = 0.2723; at median gestational age of 23.5 weeks) and time 3 (p = 0.6028; at median gestational age of 33.25 weeks) were not significant.

These results assumed no postbaseline interaction of time and treatment group, which was first explicitly tested (e.g., test if there exist time 2 specific differences for Intervention vs. Control) and none were significant except for satisfaction scores. For this outcome, there was a significant interaction of postbaseline time and group (p = 0.0057), but there were no differences between intervention and control at median gestation age at time 2 (p = 0.2723) or at median gestational age at time 3 (p = 0.6028). However, for the intervention group only, increasing weeks of gestational age was significantly associated with higher predicted mean satisfaction (p = 0.0019). Thus, the source of this interaction was within the intervention group, rather than between the two groups at postbaseline time periods.

The modal number of HV across the study was 5 (mean \pm SD = 4.8 \pm 1.4). HV ranged in length from 40 to 100 minutes (mean \pm SD = 67 \pm 18.9). Fidelity checks of caring and empathy were completed after 86 HV. Caring Professional scores ranged from 54 to 75 (mean \pm SD =72.8 \pm 4.2); empathy ranged from 35 to 60 (mean \pm SD =53.6 \pm 6.0). When specifically asked if the nurse was caring, 100% responded positively; a majority of comments were similar to this one: she "made eye contact, looked directly at me, never seemed rushed."

Evaluations of the Study. Women in both groups found participation fairly easy. Payment was generally viewed as adequate. All participants found the research assistants friendly and flexible. Women in the control group were disappointed that they did not receive an intervention but grateful that research was being done to help women in PAL.

Intervention components were scored on a scale of 0 to 4; scores ranked HV as most liked and

^b Ranks used in modeling (both outcome and its baseline value at time 1).

helpful (mean = 3.8), followed by relaxation (3.57), pregnancy diary (3.0), problem-solving (3.0), I messages (2.5), and daily fetal movements (2.43). Women found the intervention therapeutic: "Being in the study was good for me because it made me feel more confident and not alone." Another stated that it provided "great added support to relieve the stress and tension I was feeling during the pregnancy." The skills and pregnancy diary were rated as variably useful, but each woman found one or more helpful.

Evaluations of the nurse HV can be summed up by one woman's responses: "It was great to know that I had someone else to talk to, someone knowledgeable, about my feelings, about the pregnancy and anxiety I had. It was helpful to have someone who isn't that close to my situation to talk about things with and turn to if I needed it." The women found the nurse nonjudgmental, knowledgeable, supportive, and an outsider that they could talk to.

Follow-up Interviews

After group comparison analyses indicated that emotional state had not been affected as anticipated, the PI interviewed all Phase II intervention group women 6 to 19 months after birth to obtain more detailed information about the usefulness of the learned skills and to gather their thoughts about the study findings. Interviews were recorded, transcribed, and content analyzed by the research team. A summary of topics and impressions from the interviews were then mailed to the 12 women as a member check; 10 were returned with comments that they could see their experience in our summary. These retrospective reflections were generally consistent with the postpartal evaluations. The follow-up interviews provided longer-term insights into the most helpful aspects of the intervention and that women appreciated its client-centeredness.

Home Visits by Expert Nurses

All participants shared that the *home visits* by the *expert nurse* were valuable, and that the discussions with the nurse increased their self-confidence and helped to reduce their anxiety. Many reported that the visits boosted their positive feelings about the pregnancy and helped to normalize the anxiety that they did feel. Typical comments were: "I think the best thing was that I was glad to have someone who would listen, like a professional listener, and I know you weren't judging at all, so whatever I said was okay;" and "You actually helped to keep me like [sic] grounded and somewhat focused". Although participants had phone and e-mail access to the Phase I during the study, only two women contacted the PI using these resources; however, all felt that having the phone access was comforting, even if they never needed to use it. One participant commented that just knowing she could contact the APN was "a lifesaver."

Pregnancy Diary

Although two women reported not using the *pregnancy diary* due to time constraints and not enjoying writing, the other 10 women found the diary useful, especially since it provided an

opportunity to write their feelings down instead of talking about them. Many commented they used the diary to reflect on how their feelings and emotions changed over their pregnancies.

Relaxation Exercises

All women used some of the anxiety-reducing skills. The *relaxation* exercises were used and found helpful by all but one woman, who had a previously diagnosed anxiety disorder. The visualization exercises, which encouraged focus on the fetus, were not used by four of the women who all felt it was difficult to separate visualizing the growing fetus from the infant they had previously lost.

Problem-Solving Process

The *problem-solving* process was seen as valuable. One woman commented that "it was a difficult time, it was helpful in sorting out some of those issues that I was having with relationships..."

Fetal Movement Records

Interestingly responses to the *fetal movement records* were mixed. Although in retrospect, 10 women found counting the fetal movements reassuring *that "everything was alright,"* the majority admitted that feeling for fetal movements had made them anxious until they felt their baby move, and may have contributed to their stress. All participants used the assertiveness technique, "I" *messages*, in stating their feelings in interactions with others. One woman who experienced an infection that her "regular doctor missed" responded that she felt "out of control" when talking with her doctor; however, since learning the technique, she stated: "So now I'm even much more assertive ... I just tell doctors this is exactly how I'm feeling."

Clinical Nursing Implications

This caring-based nurse home visitation intervention was found to be both feasible and acceptable to PAL women as evidenced by the request for more HV, the high retention rate, and women's evaluations of the intervention. Satisfaction with social support increased over time for intervention-receiving women. Reduction in anxiety and depression were not detected in the intervention group which is likely due to the on-going nature of PAL (i.e., they did not yet have a healthy baby in arms), encouragement of women to talk about and process their worries and concerns rather than suppressing them with emotional cushioning (Côté-Arsenault & Donato, 2011). However, most women felt that they could reduce their own anxiety, as needed, using the tools and skills they were provided. Anxiety-reducing skills and the caring process could be taught and used by all healthcare providers. Continuity of care with consistent healthcare providers would facilitate knowing each woman's story and being able to support her during pregnancy and postpartum. Acknowledgment of pregnancy anxiety in PAL would help

normalize the experience for healthcare providers and mothers alike.

Although there was no statistically significant difference in prenatal attachment between the groups, half of the women reported that the intervention interfered with their tendency to suppress thoughts of their prior perinatal losses and to avoid attaching to their unborn child, but most felt that that was a positive outcome. HV, the most-valued aspect of the intervention, provided an opportunity for one-on-one time for talking, receiving support and information, and to learn new skills for dealing with their anxieties. Pregnancy after loss was normalized for the women through hearing of others with similar feelings, and women reported that this reduced their anxiety. Groups were found to be comparable when taking obstetrical history into account; it therefore follows that healthcare providers need to consider women's past history's impact on the current pregnancy experience.

Strengths of this study include use of a theory and evidence-based intervention, the multi-phased testing and mixed method evaluation of the intervention, randomization of groups, and repeated measures design. This study was limited by the fact that the PI was the nurse interventionist, due to her availability and expertise. Future studies should train intervention nurses to deliver the care to a larger and perhaps a more homogeneous sample. Although HV were acceptable and convenient, it should also be noted that they are very time consuming. Also, there were few non-Caucasian women enrolled in the study, which limits generalizability toward these women.

Returning to the evidence provides insights for future research. Descriptive work on early PAL, as well as comments by women who received the intervention, reveals not only worry over the first 2 trimesters of pregnancy but also a growing sense of confidence in pregnancy (Côté-Arsenault et al., 2006) that was not measured in this study. It then follows that the inclusion of measures of positive emotions such as confidence in pregnancy and hope be used to better capture benefits of future interventions. Perhaps consideration of the notion that it may be unrealistic to significantly reduce anxiety and depression when the threat of potential loss remains; episodic moderation of stress may be more realistic.

This intervention serves as an initial model to address women's unique pregnancy needs after perinatal loss so they can be emotionally able to care for themselves and their children.

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Box 1. Clinical Implications

Learn each mother's obstetrical history and details of their loss experiences.

Acknowledgment of pregnancy anxiety in PAL would help normalize the experience for healthcare providers and mothers alike.

Some women pregnant after loss may find doing daily fetal movement records anxiety producing.

HV were the most-valued component of the intervention but many other aspects could be used by healthcare providers in other settings.

Ask about pregnancy worries and concerns since the last visit you interacted with each woman pregnant after loss.

Suggest that women find activities that help them with their anxiety such as relaxation exercises, journaling, and using problem-solving techniques.

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