STUDY PROTOCOL: MOMSonLINE2

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Background

Stillbirth (death in the second half of pregnancy) and early infant death (in the first month of life) are devastating events for families. Bereaved mothers have significantly higher rates of depression, post-traumatic stress disorder, and generalized anxiety disorder. To date, there are very few bereavement interventions (only 2 identified in a recent systematic review) for parents after perinatal death.

Internet message boards and social media sites are common sources of support for women with pregnancy and infant loss. Research by the study team and others shows that users subjectively describe tremendous support from these sites and say they feel less alone in their grief. The boards allow users to post free of charge at any time of day or night and quickly get support from others. However, despite the proliferation of such groups for all sorts of health and social issues, there are very few evaluations of whether such existing groups can improve mental health outcomes, sense of belonging and support, and reduce grief. Virtually all studies of internet support involve the development of a brand new intervention and/or brand new on-line group, despite the fact that millions of users are already connected with existing groups.

We recently completed a 6-week pilot study (MOMSonLINE) which randomized 30 women with remote history of perinatal loss (6-7 years previously) to one of three study arms: a closed Facebook group for perinatal loss, an anonymous BabyCenter group for perinatal loss, or a control arm without an interactive support component. We collected data from monitoring site usage, online and text surveys, and semi-structured interviews. Mothers reported clear preference for the BabyCenter site and the study allowed us to test various aspects of the study including text messaging, on-line enrollment and consent, and implementation. We also identified important challenges with recruitment and retention, including low enrollment of women of color and difficulty with trying to hand-track usage of the sites.

BabyCenter LLC is a member of the Johnson & Johnson family of companies and provides global digital parenting content. The company estimates that 7 in 10 expectant moms in the United States use BabyCenter.com. Company products include websites, mobile apps, online communities, email series, social programs, and public health initiatives. We propose to use one of the online communities in this study: “Miscarriage, Stillbirth, & Infant Loss Support.” https://community.babycenter.com/groups/a15155.

Proposed Study and Aims

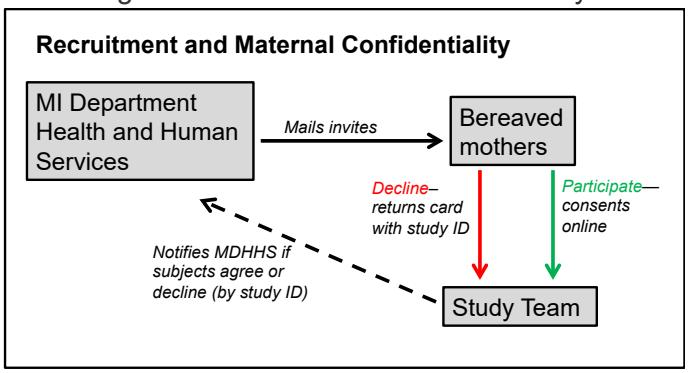
We now are proposing a new pilot study (MOMSonLINE2) to evaluate recruitment specifically for women of color who are closer to the time of perinatal loss. This is a feasibility study. We will track data about group usage through a new collaboration with BabyCenter.com. Once this pilot is completed, we will have adequate data and knowledge to develop a much larger randomized control study of on-line support outcomes after perinatal loss.

Aim #1: Demonstrate the ability to recruit and retain recently-bereaved women of color to the pilot through a partnership with the Michigan Department of Health and Human Services.
Aim #2: Test a collaboration with BabyCenter which would provide proprietary data about the support group usage of our study participants and allow much more accurate tracking of use.
Aim #3: To test whether incentives based on group usage (compared with incentives based on survey completion) lead to increased engagement with the online group.
Aim #4: To test preliminary mental health outcomes (symptoms of depression, anxiety, post-traumatic stress, and grief) with a pilot group using standardized measures.

Research Methods

Recruitment: From 2011-2013 we conducted the Michigan Mothers Study, a collaboration with the Michigan Department of Health and Human Services (MDHHS) for a population-based statewide survey of mental and physical health outcomes of mothers with stillbirth, early infant death, or live birth. At the time, birth and death certificates in Michigan were submitted in writing by hospital staff and it took 6-8 months after delivery for the state to identify bereaved and live-birth parents. In the intervening years, MDHHS has transitioned to on-line reporting of vital records so birth and death information is now available to the state within days, rather than months. Our prior work has shown that women want information about online support within the first month after loss so this change in reporting will allow us to reach out much earlier.

In our Michigan Mothers Study, we were able to protect the confidentiality of non-participants by having MDHHS keep the identity of parents. MDHHS mailed out our first surveys, and parents who wanted to participate completed and returned the survey with their identifying data. Those who did not want to be included could ignore the mailing or return a card with random study ID declining to participate. In this way, only MDHHS knew personal information about non-participants. For this study, MDHHS will send our first mailing (a bereavement card expressing consolation for the loss and mentioning the study and that we will contact them in a few weeks). The bereavement card will go out no earlier than 3 weeks after the loss of their baby. Subsequent mailings will have information describing the study and how to enroll.

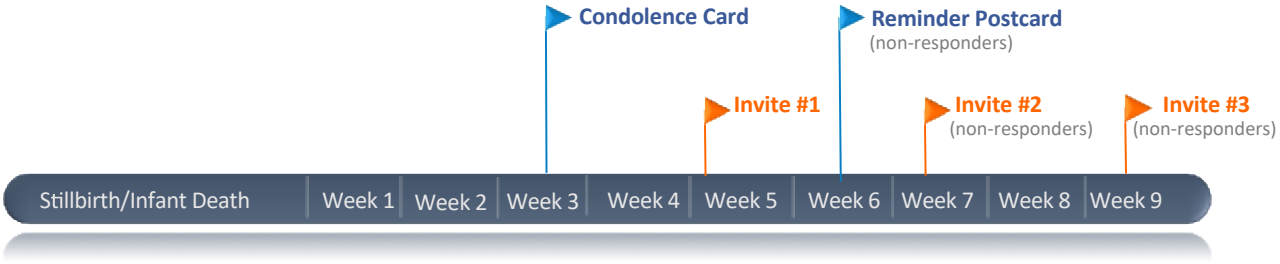


Subjects and Sample Size

This study will only enroll non-Caucasian women. African-American women face twice the risk of perinatal death compared to white women. They have similar rates of depression and post-traumatic stress disorder after a loss but are far less likely to seek mental health care. In previous research, bereaved African-American mothers expressed strong interest in on-line support but most were unaware this existed at the time their baby died. For this pilot MDHHS will send mailings to 200 recently bereaved non-Caucasian mothers. Assuming a 20% response rate, this will enroll 40 women in the study. We are requesting approval for up to 75 mothers in case more women respond than we anticipate. (We had a 22% participation rate among this group in the Michigan Mothers Study). MDHHS will send the initial condolence card no earlier than 3-weeks or later than 8-months post-loss.

Inclusion criteria: Michigan residence and delivery; age 18 or older at delivery; non-Caucasian race and/or Hispanic ethnicity; read/speak English; gave birth to a stillborn baby or had an infant death in the first 28 days of life; did not give the baby up for adoption pre-loss; and internet access.

Mailings: MDHHS will send the initial condolence card followed by up to three survey invitations and a reminder post-card per Dillman protocol. The mailings will include a cover letter from MDHHS. The three invitations will also include a pre-stamped card which subjects may send back to the study team if they do not want to participate. The card contains only a random study ID. The study team will report this ID to MDHHS who will then remove the subject from their subsequent mailing lists.



Consent: Study invitations will describe the study and provide mothers with an online link to learn more about the study, email (or call) the study team with questions, answer eligibility screening questions, and to complete the full written consent on-line. This is a single-arm study to test recruitment and engagement.

Subjects will sign up for a BabyCenter account (unless they already have one), will agree to follow all the rules of the BabyCenter site and the community group, and agree to share their username with both the study team and with BabyCenter (so that BabyCenter can send us information about usage). As BabyCenter is a commercial web site, they have their own privacy rules and disclosure about what information they collect and/or share for users, described here: https://www.babycenter.com/help-privacy. BabyCenter automatically sends out a "daily digest" email with links to any new posts in the group which encourages members of a community support group to visit the group, and subjects in our study will get this same digest.

Participation: During the study, subjects will be asked to

a. Sign on to the BabyCenter community group for people with pregnancy or infant loss at least 3x weekly for 6 weeks. Participants may choose to post or comment on the site but are not required to do so.
b. Complete two on-line surveys (at the beginning and end of the study) which ask about demographics, use of social media, other types of support after the loss of their infant, satisfaction and experience with the on-line group. Both surveys will include 4 standardized instruments to measure depression (PHQ-8), anxiety (GAD-7), post-traumatic stress (PTSD-Checklist, civilian version), and grief (Perinatal Grief Scale).
c. Receive 3 weekly text-messages from the study team (to remind them to go online to the group). BabyCenter staff can track usage patterns of participants who visit the group and are logged in. If a subject has not signed on for 4 days, information will be provided to alert the study team. We will then reach out to her by personalized text message or phone call to encourage participation and assess for barriers.
d. Get two phone calls from the study team. The first will be made after they consent to ensure they understand the study and/or answer any questions. The second will be made in the middle of the study to assess for any problems signing on.
e. Participate in a 10-20 minute semi-structured phone interview at the end of the 6-week study.

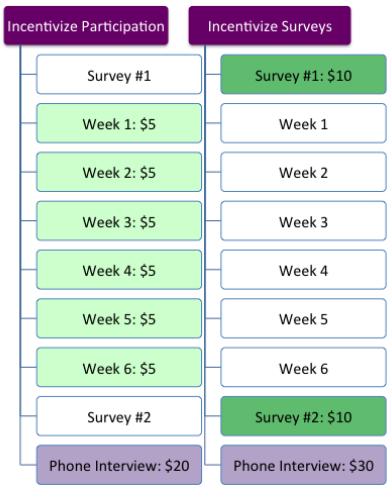
Tracking Usage: BabyCenter.com has agreed to share data about use of the pregnancy/infant support group among our study subjects. We will ask subjects to stay logged in when using the BabyCenter application , or bookmark the site in their browser, and mark the box "keep me logged in." By marking this box, they will only be logged out if they purposefully log out, change browser, or clear their cookies. BabyCenter will provide the following information for each of our participants: the day and number of visits, page views, URLs visited in the group, and data on posts, comments, and "hugs" (similar to a "like" on Facebook). At the end of the study, BabyCenter will give us aggregate, de-identified data about activity of the full group, e.g. total number of weekly users, number of weekly posts, comments, and hugs.

Risks and benefits: The study is no more than minimal risk. We are asking bereaved mothers to go to an anonymous, public online support site. They are not required to post. Several experienced group members serve as volunteer group moderators. Extensive research by our team has shown that women typically find forums for loss to be supportive and help reduce the isolation which is very common in the months after a loss. There are no direct benefits to participants, but we are hopeful that by participating, some mothers may receive support and find satisfaction from supporting others.

Incentives

One study aim is to test how incentivizing different activities impacts participation. We will randomize participants either to a group which

a) incentivizes support group participation ($5 per week that they go to the BabyCenter.com group at least three times and $20 for completion of the phone interview); or
b) incentivizes survey completion ($10 per survey and $30 for completion of the phone interview).



Participants in either group can earn up to $50—they are simply compensated for different parts of the study. Subjects may withdraw at any time and will be paid for all elements they have completed at the time of withdrawal. The incentives will help to cover if participants are charged by their internet provider for text messaging.

Online Safety:

BabyCenter has a site-wide process which allows any user to report on a post or comment they are concerned about, documented here: https://www.babycenter.com/community-help-howto
At the top of the loss group, there is a post which includes lists of other related support groups for loss as well as support sites outside of BabyCenter.com. Every posting and comment has the option to click a link to "Report this comment" where users can send a report to staff, to the group owners, or both. Users can also email the URL and text to community@babycenter.com.
BabyCenter maintains a list of resources which include links to two national suicide hotlines:
https://www.babycenter.com/community-help-resources#articlesection16
BabyCenter also has a section of resources at
https://www.babycenter.com/community-help-resources#articlesection1
which includes this statement:

> *Emergency*
> *If you believe another person is a threat to himself, herself, or someone else, please call 911, your local police department, or any other appropriate government agency. Law enforcement officials can get help and get involved where BabyCenter cannot. However, we will cooperate with officials who contact us about any situation. They can reach us by emailing community@babycenter.com.*

In our surveys, we are using the PHQ-8 so will not be asking about suicidal thoughts. Nevertheless, we will include information about a toll-free 24-hour suicide hotline as a resource; the number will be place in the survey, after the PHQ-8.

Analysis:

This single-arm feasibility study will primarily be descriptive and provide summary-type information. While we will assess mental health and grief outcomes, we recognize it is not powered for significance.It is meant to demonstrate ability to recruit, retain, and engage users and will also give preliminary data on our primary outcomes, including willingness of participants

to complete the measures. For the qualitative data, we will explore participant attitudes about online privacy and data monitoring, the experience online, and identify potential problems that may occur during recruitment in a larger trial. Qualitative interviews will be transcribed verbatim. Two researchers will review the transcripts to develop a preliminary codebook, code a subset of the interviews, and use an iterative process to revise the codebook. Transcripts will be re-coded and we will test inter-coder agreement using the final codebook. Transcripts will then be analyzed to identify themes emerging from the transcripts with particular focus on information to help us edit, adjust, or improve the intervention for the RCT.