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Official Title: Walk With Me (WWM) for Perinatal Grief

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STUDY PROTOCOL

Participant Recruitment, Enrollment, and Overall Design

Recruitment for the 52 parents for the evaluation testing was coordinated in collaboration with PeaceHealth staff members who provided potentially eligible parents with a brief description of the project and obtained consent to share their information with Influent Innovations staff for our research to contact them to provide further information about the study two weeks following their loss to mirror the in-app referral process that will occur in phase II. Parents that did not give permission for PeaceHealth staff were not contacted by Influent Innovations, though they could contact Influent Innovations directly using the contact information in a brochure that they received from PeaceHealth. Once PeaceHealth staff received permission from a parent for Influent Innovations to contact them, project staff called to further explain the details of the project, confirm eligibility requirements and discuss confidentiality. If the parent expressed interest in participating, we sent them an electronic informed consent and survey to complete intake. We were available by phone or email to answer any questions.

After consent, parents completed the baseline survey (T1) via the Qualtrics online assessment form and then be provided download access to the Walk With Me (WWM) prototype. After 6 weeks, parents were administered the post-treatment surveys (T2 and T3). This design allowed us to evaluate baseline to follow-up change in the proposed study outcomes and acceptability of the prototype WWM program.

We evaluated feasibility and initial efficacy of WWM in a within-subjects pre-post design study (pretest, 4- and 8-week posttests [T1-T3]). We provided the mobile-based provider component for use by Health Care Providers (HCPs) who worked in our partner hospital.

Walk with Me (WWM) Prototype Intervention Program

We developed professional training and modules for health care professionals (HCPs) and grief processing and healing activities for bereaved parents, via an iterative formative development process with stakeholder input. We embedded the core intervention components in administrative, provider, and client interfaces which will comprise the prototype Walk with Me (WWM) intervention.

Measures

T1, T2, and T3 surveys measured parents' parenting traumatic stress (Impact of Events Scale-revised with 22 items), grief intensity (Perinatal Grief Intensity Scale with 12 items), grief management self-efficacy (3 items that rate bereaved parents confidence in their ability to cope with grief, use knowledge of mindfulness skills to cope, and engage in positive behaviors to help coping), care experiences (6 items of experiences of care at the time of loss and follow-up appointments after loss), and difficulties with emotional regulation (11 items from the Emotional Regulation Scale). The T3 survey also contained measures of parent satisfaction, acceptability, and usability of the WWM intervention program. Demographics were collected at T1, and usage data measured parents' usage of WWM.

STATISTICAL ANALYSIS PLAN

Preliminary analyses included a descriptive summary of the sample, summary of participation and missing data, and attrition analysis.

For change in study outcomes, we used mixed effects growth models estimated with full information maximum likelihood using PROC MIXED from SAS (Version 9.4). The model included a fixed effect of time that was coded in weeks and the pretest assessment was defined as a random intercept. The time term is a test of the efficacy of the intervention to produce favorable change in the study outcomes.

A critical element of evaluation is the acceptability of the program for the targeted population. To address this factor, we provide a descriptive summary parent satisfaction with the program, and program use metrics.