Strength for U in Relationship Empowerment (SURE)

Study Protocol and Statistical Analysis Plan

NCT04218864

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STUDY TITLE: Computerized Intervention for Reducing Intimate Partner Violence for Perinatal Women seeking Mental Health Treatment

PI NAME: Caron Zlotnick, PhD

1. OBJECTIVES, SPECIFIC AIMS, BACKGROUND, AND SIGNIFICANCE

Background

Intimate partner violence (IPV) is a major public health concern for perinatal women. The American College of Obstetricians and Gynecologists (ACOG) has defined IPV as violence by an intimate partner that may involve physical altercation (e.g., such as hitting, slapping or kicking), emotional or physical threats, and/or forced sexual relations.[1] Prevalence rates of IPV prior to pregnancy (within the past year) range from 3% to 9%[2] and for the postpartum period rates of physical IPV ranging from 3.2% to 7.4%;[3,4] a rate that is in sharp contrast to the U.S. national average of 1.5% past-year prevalence for IPV among women.[5] When emotional abuse is included, studies have found from 21% to 33% of perinatal women report IPV.[6,7] Furthermore, perinatal women report commission as well as receipt of IPV,[8] consistent with the larger literature that finds that the majority of IPV victims have comparable rates of perpetration behaviors. [9,10] Bidirectional IPV can place women at high-risk for injury and revictimization.[11-13]

Negative effects of IPV during the perinatal period: Although IPV at any time during a woman's life is devastating, a woman who experiences IPV during the perinatal period is at risk not only for her own health (e.g., anemia, maternal death, and poor mental health,[14-16]) but also for the health of her developing fetus (e.g., preterm delivery, low birthweight[17] (see reviews,[18-20]) and the health of her infant (e.g., poor infant general health, difficult temperament,[21] deficits in emotional regulation,[22] eating and sleep disturbances[23], disturbed attachment relations).[24,25] Based on this literature, researchers have suggested that exposure to IPV in infancy may be a key mechanism underlying the intergenerational transmission of IPV.[26]

High mental illness burden among perinatal women with IPV: There is mounting evidence from epidemiological studies that IPV markedly increases the risk of several psychiatric disorders.[27,28] In general, IPV is associated with mental health burdens among women, that includes depression, posttraumatic stress disorder (PTSD), low-self-esteem, suicidal thinking, and suicide attempts.[27,29-36] Specific to postpartum women, research has found a strong association between IPV and postpartum depression.[37-39] Although no studies, to date, have focused exclusively on rates of psychiatric disorders found among pregnant women with IPV, research on perinatal women has found IPV-positive women to have a significantly higher rate of a current mood or anxiety diagnosis.[6] In general, research has found prevalence rates of lifetime physical IPV among women with mental health disorders that range from 50% and above[35,40-42] up to an astounding 75%.[42] Furthermore, women who report bidirectional IPV report more mental health problems than IPV victims alone.[11,12]

Screening and intervention of perinatal women at mental health clinics is important because: 1) A robust relationship exists between IPV and psychiatric disorders;[35,40-42] 2) The presence of IPV reduces the utilization of mental health care;[43,44] 3) In our study in which we conducted a retrospective chart review of 299 perinatal women attending mental health treatment, perinatal women with current victimization were more than twice as likely to leave treatment than those without current violence in their lives;[45] 4) IPV and untreated mental illness pose a dual threat of adverse health outcomes to a perinatal woman and her developing fetus/infant; 5) Untreated psychiatric disorders are associated with partner revictimization[46-49] and can interfere with IPV victims' ability to effectively use important shelter and community resources necessary for establishing safety for themselves and their children;[6,50] 6) At least 20% of perinatal women seeking mental health treatment report ongoing interpersonal violence at

intake[45]; 7) Given the high rates of IPV among women who seek mental health treatment,[31,38-40] mental health treatment settings compared to other medical settings (e.g. primary care) are more effective sites for focused case finding and interventions.[51,52]

Despite the need, recent research suggests that there are low screening and intervention rates of female mental health patients with IPV by mental health providers[35] psychiatrists hold less supportive attitudes towards IPV victims than other physicians,[53] IPV training and knowledge of resources is limited among psychiatric residents,[54] and mental health professionals find enquiry about domestic violence difficult because of their lack of knowledge and expertise in this area and/or because they do not think it is part of their role.[55] As researchers have noted, there are much needed but inadequate systems in place for mental health clinics or providers to respond to women with IPV.[51,52] Virtually no empirically-based interventions exist that address IPV among mental health treatment-seeking perinatal women. Women in the perinatal period were selected for two primary reasons: (a) interventions at this juncture may take advantage of a particularly salient point in a woman's life, in which she may be more open to considering behavior change; and (b) any positive change made has the possibility of a dual impact, on the woman's life as well as that of her infant. The proposed project will test an innovative, high-reach, easily implementable, low-cost computer-delivered intervention, Reach Out for a Safe Environment (ROSE), which is theoretically driven and addresses known barriers in early intervention with at-risk women throughout the perinatal period. Preliminary data from our pilot study provide reassurance that ROSE will successfully reduce IPV in our target population. A fully powered RCT trial of ROSE is necessary to determine efficacy. A cost estimate in a real-life clinical setting will provide information to facilitate implementation and dissemination.

The intervention (ROSE) will represent the first IPV risk reduction intervention for women, which is tailored to the specific needs of perinatal women with IPV within a mental health treatment setting. If the proposed intervention is found to be efficacious in our vulnerable target population, we anticipate that it could have significant implications for IPV prevention efforts for other childbearing victimized women seeking mental health treatment and victimized women, in general.

Objectives

In our R21 preliminary work, we demonstrated the feasibility and acceptability of ROSE, a computerized intervention for perinatal women with recent IPV who seek mental health treatment. In our pilot work, there were high ratings of satisfaction for ROSE. 100% completed the computerized intervention; 93% participated in the booster and 92% in the 4-month follow up assessment. Further, participants in the ROSE condition demonstrated a significantly larger change in frequency of IPV from baseline to follow-up (4 months after intake) than participants in the control condition ($p < 0.007$).

The goal of this proposed study is to build upon these promising preliminary findings by testing whether ROSE reduces the frequency of IPV in a larger sample of perinatal women seeking mental health treatment, compare the effects of ROSE to an attention, time, and information matched control condition in two real-life clinical settings, examine the effects of the intervention for a more extended period of time, and include a cost estimate of ROSE. To achieve this, we propose a two-group, randomized controlled trial in which 186 perinatal women seeking mental health treatment are assigned to either (a) a computer-delivered, single-session brief intervention plus one interventionist-led phone booster; (ROSE); or (b) a computer-delivered control + one interventionist-led phone booster condition. Computer-delivered follow-up assessments will occur at 6-weeks, 3 months, 6 months, and 12 months after the baseline assessment. More specifically, we propose the following Specific Aims:

Aim 1 (Primary Outcome)

To test the hypothesis that ROSE, compared to an attention, time and information matched control condition, will be associated with a lower frequency of IPV among perinatal women seeking mental health treatment at 6-weeks, 3 months, 6 months, and 12 months follow up.

Aim 2 (Secondary Outcomes)

(a) ROSE, as compared to control, will result in greater positive affect and well-being at 6-weeks, 3, 6- and 12-months follow up;
(b) ROSE, as compared to control, will result in greater perceived emotional support at 6-weeks, 3, 6- and 12-months follow up;
(c) For future implementation and dissemination, we will estimate the resources needed and costs to deliver ROSE. Additionally, we will estimate the incremental cost effectiveness of ROSE compared with treatment as usual.

Aim 3 (Mediation)
To examine the role of theorized mediators of empowerment and self-efficacy on the effect of SURE.

2. STUDY DESIGN, METHODS, AND PROCEDURES

Study Design

Women (18 to 45 years old) presenting for an intake appointment at The Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH) and at The Perinatal Psychiatry Clinic (PPC) at the University of Michigan Health System (UMHS) will be screened for IPV victimization. Women who are pregnant or within 12 months postpartum – and report past 12-month history of IPV will be invited to participate in the study. At each site, those providing informed consent will be randomized either to an attention, time and information matched control condition or ROSE arm. Participants in both conditions will receive a phone booster within 4-weeks of their baseline assessment. Follow up assessments consisting of validated questionnaires will occur at 6-weeks after baseline assessment, and 3-, 6-, and 12 months, which will capture both immediate and sustained change and allow us to capture trajectories of IPV change. The booster session will be audio recorded so that adherence and competence ratings of the booster sessions can be conducted. These digital recordings which will be labeled with the study identification number and the booster session date and will be transferred to Women and Infants Hospital secure computer server via a secure server access. Access to the audio recordings will be limited to research staff. See "Sources of Materials" section for the assessments to be collected at each time point. If participants do not want to be audio recorded, they can still participate in the study.

Intervention Conditions

1. **<u>Reach Out for a Safe Environment (ROSE)</u>**
   ROSE participants will receive a 40-minute online/computer-based intervention immediately after their baseline assessment and an in-person 30-minute booster session conducted by interventionists within a month after the intervention. The online intervention will be sent by email as a link (URL) to the intervention. The link will not contain any wording that could reveal the nature of the intervention/study. The link will become inactive once the intervention is completed. If online, research staff will call ROSE participants after the intervention in case they have questions after the completion of the online session. If on site, research staff will be available after the intervention in case ROSE participants have questions after the completion of the session. The ROSE Program is specifically tailored, innovative and relevant to diverse, racial and ethnic perinatal women in a number of ways including the images and content used in the intervention. It will also be tailored on the current IPV risk assessment, pregnancy or postpartum status of each participant, will be designed to reach participants across levels of motivation for change, and will follow guidelines for brief interventions as recommended by the ACOG. The content of ROSE is theory-driven, consistent with the MI model of behavior, and consistent with the literature on effective interventions that address IPV.

Possible distress due to sensitive items will be noted clearly in the informed consent information sheet (for screening) and in the written informed consent form (for participants). All participants will be told that they can skip any question or quit at any time if they become uncomfortable. To further address possible distress due to sensitive items, participants will be asked by the research assistant if anything during the assessment or intervention has made them feel upset. At a minimum, all participants indicating some distress will be given a list of referral options. If in treatment women will be encouraged to contact their mental health provider. Suicidality will not be assessed during the course of this research study.

2. Control Condition

The control condition will be the same, well-validated, attention, time and information-matched online/computerized control intervention condition used successfully in our previous studies with perinatal women, in which ratings of acceptability were equally high among intervention and control group participants. The online intervention will be sent by email as a link (URL) to the intervention. The link will not contain any wording that could reveal the nature of the intervention/study. The link will become inactive once the intervention is completed. This condition consists of a series of questions regarding television show preferences and viewing a brief series of videos of popular entertainers/shows, with subsequent requests for ratings of subjective preference. This content will serve to control time and help to limit inadvertent therapeutic effects that plague control groups in brief intervention research. The telephone booster session will be comparable in time to ROSE's telephone booster session (10-15 minutes). The booster session will consist of an interventionist reviewing with the participant her ratings of the various of popular entertainers/shows that she watched in the intervention, discussing with the participant more in-depth her preferences, and discussing any other forms of entertainment/shows that participant has watched, heard of, or would like to see.

Interventionists

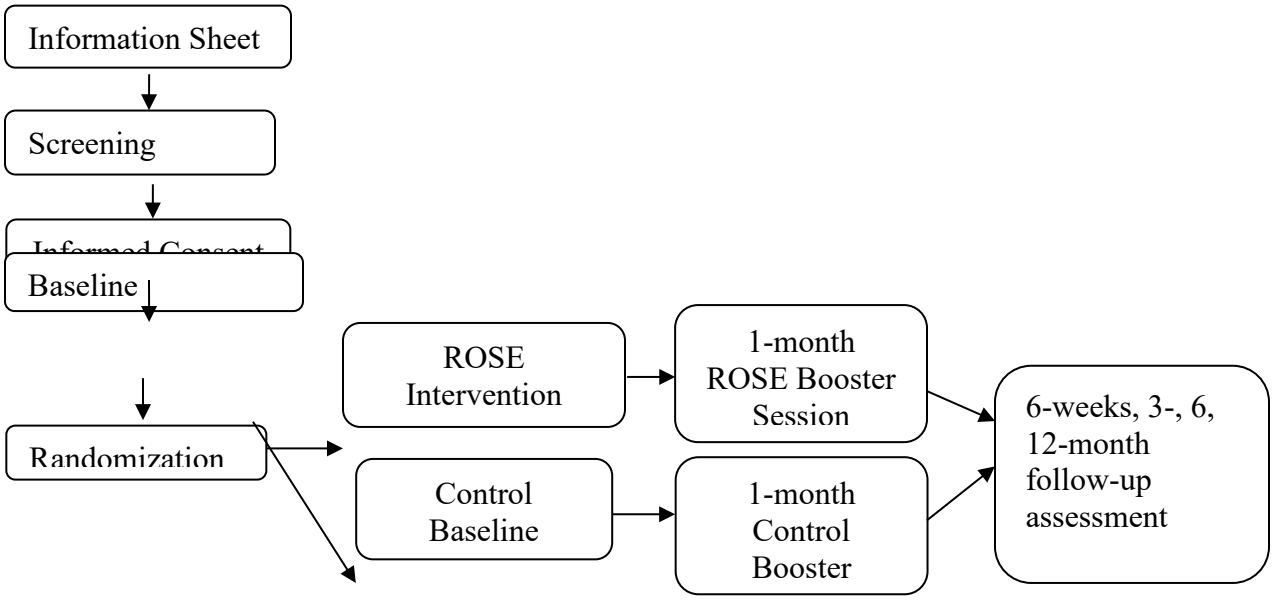
Interventionists for the ROSE and control booster sessions will be trained for both conditions. Dr. Zlotnick has previously successfully trained interventionists with Bachelor of Arts Degree to administer the highly scripted MI-based intervention booster session. In our pilot study, interventionists with only a bachelor's degree were successfully trained for the MI-based booster (independent ratings for adherence and competence were very high). There will be a 2-hour training that consists of a review of MI and empowerment principles, how to conduct the booster session, and role-plays of standard, challenging, and emergency situations. Training for the booster control condition will be 45-minutes and involve instruction on how to conduct the booster session and role-plays of challenging and emergency situations.

Economic Considerations

Participants will receive check or gift cards (total equivalent up to $215) for their participation. Participants will receive a $5 gift card for completing screening, $30 for completing the baseline session, $20 for the booster session, $30 for 6-weeks, and for 3 month follow-up assessment, $40 for the 6-month follow-up, and $60 for the 12-month follow-up. For women who choose to do follow up assessments over the phone we would ask them for their Social Security Number if they preferred a check for their monetary compensation to be mailed to them or an gift card. Cab transportation through a voucher system arranged with a local cab company will be provided for participants who may not own or have access to a car and need to have transportation in order to attend study procedures. Child-care expenses or data usage expenses will be reimbursed to the study participants at a rate of $10 per hour for up to a 2 hour time

period when applicable. Women who do not live alone and do not have headphones will be sent a set of headphones to view the online intervention.

Overview of study phases



Inclusion and Exclusion Criteria/ Study Population

The inclusion criteria of this study are being a woman 18 to 45 years old who presents for an intake appointment at The Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH). Women who are pregnant or within 12 months postpartum – and report past 12-month history of IPV will be invited to participate in the study. Other inclusion criteria are the ability to understand study procedures in English, and willingness to complete follow-up session.

Exclusion criteria include: 1) No access to a computer (PC, tablet, iPad, Mac) or Smartphone (a device with internet) and unwilling to come to the hospital to be consented and to view the intervention; 2) Reports discomfort with using the internet and unwilling to come to the hospital to be consented and to view the intervention; 3) Living with an abusive partner,at risk for severe injury or homicide as determined by the 5-item Danger Assessment, unwilling to create a private email and unwilling to come to the hospital, 4) Has a past or current abuser who is making the woman feel unsafe or she has no private email and unwilling to set up a temporary email or come to the hospital to be consented and to view the intervention, 5) Reports no privacy to view the consent form online and view a 40-minute online intervention on domestic violence and unwilling to come to the hospital to be consented and view the intervention. 6) Responds yes to any of the questions to determine if Spyware or Stalkerware is likely operating on her device and is unwilling to come to the hospital to be consented and view the intervention. Others include inability to provide informed consent (e.g., due to psychosis, intoxication, or other clear cognitive impairment) or inability to understand English (understand the consent form when read aloud and assessments that are narrated by computer). Perinatal transgender men will be excluded because transgender persons confront many IPV issues that are unique to them as a group.

Plan to Include a Diverse Population

We will be including pregnant women in our study. Intimate partner violence (IPV) is common among perinatal women, especially those with mental health issues. IPV is associated with negative consequences for the mother, fetus, and infant. The presence of mental health difficulties in addition to IPV compounds adverse health risks. Very few IPV-focused interventions have reduced IPV among perinatal women, and there are currently no brief IPV interventions and none for perinatal women seeking mental health treatment. This study will test an innovative, high-reach, easily implementable, low-cost, theoretically driven online/computer-delivered intervention. This study holds out the prospect of a direct benefit both to the pregnant woman and the fetus and is no greater than minimal risk. Furthermore, the knowledge we hope to gain from this study that will also help future pregnant women cannot be gained without including the patients we enroll into the study. The risk is the least possible for achieving the objectives of this research, and we will be minimizing anticipated risk in various ways.

Perinatal transgender men will be excluded because transgender persons confront many IPV issues that are unique to them as a group.

Number of Subjects

93 subjects will be recruited at the Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH). Another 93 subjects will be recruited at the Perinatal Psychiatry Clinic (PPC) within the University of Michigan Health System (UMHS).

Setting

The research study sites will be patients from the Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH), and patients at the Perinatal Psychiatry Clinic (PPC) within the University of Michigan Health System (UMHS). Collaborators at the University of Akron will help with analysis of de-identified data.

Recruitment Methods and Informed Consent Process

The clinical trial will be conducted at two sites. We will recruit perinatal women from The Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH) and from The Perinatal Psychiatry Clinic (PPC) within the University of Michigan Health System (UMHS). Participants will be 186 pregnant or postpartum women (up to 12 months after delivery), 18 to 45 years of age, who have received clinical services at WBH (i.e., initial assessment or treatment) within the last twelve months. We have included women who are up to 12 months postpartum, because there is general consensus in the literature that postpartum refers to 12 months after delivery [56]. In addition, the perinatal women will have endorsed any IPV during the past 12 months as measured by the Woman Abuse Screening Tool (WAST[57]). The WAST is an 8-item instrument that measures physical, sexual, and emotional abuse and is consistent with the definition of IPV as defined by The American College of Obstetricians and Gynecologists[1,57]. It has correctly classified 100% of nonabused women and 92% of abused women in a known-group analysis[57], has good internal reliability[58], and has adequate concurrent validity, even with ethnic minorities[58]. Consistent with similar studies, IPV status will be positive if a woman obtains a score of 4 or more on the WAST. Other inclusion criteria will be ability to understand study procedures in English, and willingness to complete follow-up session.

Participants will be recruited from The Center for Women's Behavioral Health (WBH) at Women and Infants Hospital (WIH) who are attending either the Postpartum Day Hospital or Behavioral Health for an intake assessment or for treatment. Contact information for potential participants who have received services at WBH in the last twelve months and are pregnant or postpartum will be extracted from the Women and Infants Hospital's electronic medical system, EPIC. The research assistant will contact these pregnant and postpartum women and asked if they are interested in participating in a brief health survey. Research Assistants (RA) will also use WhatsApp to contact women, only if already have the app. Otherwise, RAs will call regularly, not through the app. Women recruited from The Perinatal Psychiatry Clinic (PPC) within the University of Michigan Health System (UMHS) will follow a similar recruitment procedure. (The PCC study site will be overseen by University of Michigan's IRB. Dr. Tzilos (Co-I) will be responsible for all regulatory documents for and communications with University of Michigan's IRB).

This information sheet will be anonymous and will not collect any identifying information. This approach is being used as the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. Those participants who qualify at screening and wish to continue with the study will give phone consent to use their information from the screener as part of the phone consent process. The information form will explain in detail the kinds of questions that will be asked, the rights of the woman to not participate or to quit at any time, and the potential risk of distress. In the current study, the anonymous survey will not include information that will identify who does and does not choose to participate.

Women who indicate orally their interest in continuing with the survey will then be introduced to the survey by the RA, which will be described as a survey to help moms have healthier pregnancies and be healthy during the postpartum period. The RA will then over the phone conduct a short (5-10 minutes) health survey including questions to determine eligibility. Research staff would document that it was an oral consent without signature, and include the date and time the oral consent was obtained. Women who refuse to complete screening, or if after completing screening refuse to participate in the study, will be asked by the research assistant about possible reasons why she refused. The screening will not include any identifying information and will include a brief series of questions about general health, exercise, diet, smoking, access to and comfort with the internet, and a question regarding when the participant learned of her pregnancy or delivered her baby.

Those meeting study criteria will be given the opportunity to provide informed consent for the study or provide phone consent to be contacted to set up a future appointment with the research staff. RAs will ask those eligible if their contact information obtained from EPIC can be used in the future, to ensure safety and privacy. This will also include permission to text, email, and which times are best for RA to call.

Research staff will carefully explain all aspects of the study to a potential recruit, including the risks and benefits and that their participation is voluntary. Recruits will be informed of the study commitment. Prior to phone consent, recruits with a past or current abuser who is making her feel unsafe, recruits living with an abuser, or recruits who have no private email will be asked if they are willing to set up a temporary email. If no or unwilling to come to the hospital to view the intervention, these participants will be excluded. Likewise those who report no privacy to view a 40-minute online intervention on domestic violence and unwilling to come to the hospital to view the intervention will be excluded (See exclusion criteria). Questions to determine if Spyware or

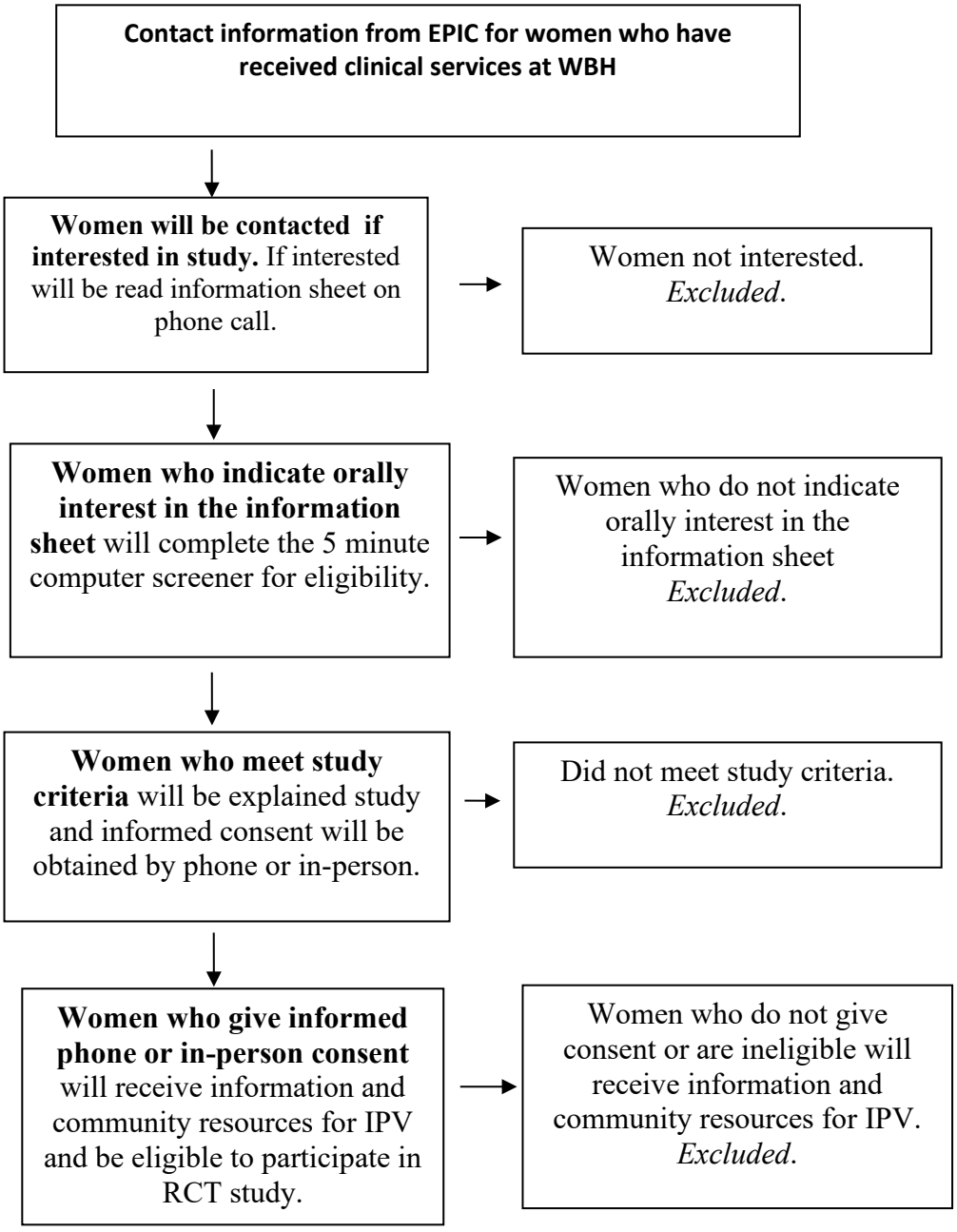
Stalkerware is operating on the recruit's devices will be asked. To establish safety, women living with a current abusive partner will be asked about their risk for severe injury or homicide as determined by the 5-item Danger Assessment. If women meet criteria for severe injury or homicide risk or risk of spyware or Stalkerware, they will be given the option to come into the hospital to be consented and view the intervention,

As part of the phone or in-person consent those who qualify will be asked to share the information gained from the screener survey as part of the study data. Participants will be reminded that they are not required to participate in the study and that they will receive the standard care provided by WBH and Women and Infants Hospital regardless of whether or not they choose to participate.
For those recruits who need to set up a temporary and secure email for safety reasons to view the online intervention, the research assistant (RA) will guide the recruit on how to set up a temporary and secure email that once deleted cannot be accessed/retrieved. The RA will send the study consent in the body of the email (to prevent a download) to the temporary and secure email address or to a woman's private email. The research assistant will orally describe the material written in the informed consent document and answer any questions the participant may have. Participants will be asked to complete a brief (five-question) true/false quiz after reviewing the consent form to ensure subject comprehension. If not in-person, women will not be asked to sign the consent for the online intervention. Return of the consent would involve downloading the document, printing it, scanning or mailing it back; activities that could pose safety issues. Research staff will therefore obtain phone consent. Research staff will document that it was an oral consent without signature and include the date and time the oral consent was obtained in password-protected document on a secure server.
For in-person , they All women who meet study criteria whether they choose to participate in the study or not will be provided information (online resources and relevant phone numbers) and community resources (online resources and relevant phone numbers) for IPV, if interested. These resources can be provided on the phone or emailed, if safe to do so. If the participant decides to view the intervention in-person, research staff will provide handouts on resources. Women who agree to participate in the study remotely will be asked what device they will use to view the intervention and if they say they will use their iPhone or iPad, the RA will proceed to provide the participant instructions on how to download the CIAS app.

After consent has been obtained, the RA will complete a locator form for the participant (if over the phone) or the participant will complete the form in the office. The baseline assessment will then be conducted on the phone or in-person. After the participant completes the screener assessment, is eligible for the RCT, has consented for the RCT, and has completed the baseline assessment, research staff will send a link to the intervention or will set up the intervention on the tablet at the hospital. The computer program will randomize participants into control vs. ROSE conditions. For participants coming to the hospital, optimal procedures to minimize risk of COVID-19 exposure will be used. At the time of screening, 3-month, 6-month, and 12-month assessments, we will as participants when their last appointment at WBH was.

Participants will be able to change their contact preferences at any point. Participants will be told they are able to drop out of the study at any point and that dropping out will not have any impact on the care that they receive at Women and Infants Hospital.

Recruitment procedure graphic



Data Collection Procedures

Participants meeting inclusion criteria for the RCT will complete an approximately 15-20 minute assessment session or a computer assessment on the Tablet PC if at research site. All of the self-report measures included in this study have good psychometric properties (see Table 1, below)

All follow—up assessments will involve the research assistant administering follow up assessments via a phone session or at the hospital.

The booster session will be audio recorded so that adherence and competence ratings of the booster sessions can be conducted. These digital recordings which will be labeled with the study identification number and the booster session date and will be transferred to Women and Infants Hospital secure computer server via a secure server access. Access to the audio recordings will be limited to research staff. Participants can still participate if they do not want to be audio recorded. The informed consent form asks the participant to select if they do or do not want to be audio recorded.

In cases when research staff are working remotely from home or other locations, they will have remote and secure access to study documentation and will be able to conduct booster sessions, assessments, referral follow-ups, as well as set up and confirm appointment times using study phones. If working remotely, research staff will conduct these calls in a private and confidential setting and will not carry or have in their possession any hard copy PHI (e.g., participant telephone numbers) at home or any other location outside of the hospital setting.

The follow-up sessions will consist of administering the various scales, as seen below.

Sources of Materials

The following assessment measures will be administered at the baseline assessment:

1. Demographic information, including age, race, ethnicity, marital/partner status, parity, employment, socioeconomic status.
2. Relationship information, such as current relationship to abuser/s, length of relationship/s, etc.

Primary Outcome Measure:
At baseline *frequency of IPV* for the past 12 months will be measured using the Composite Abuse Scale (CAS[60]). The CAS assesses the frequency of psychological, physical, sexual, and combined severe violence for each intimate relationship over a specified period of time. The CAS has demonstrated face, content, criterion, and construct validity[61]. The scale as a whole and its 4 subscales have all demonstrated good internal consistency and reliability[61]. The instrument will be administered at baseline and at each follow-up interval.

Secondary Outcome Measures:
1. *Positive affect and well-being* (i.e., aspects of a person's life that relate to a sense of well-being, life satisfaction or an overall sense of purpose and meaning) will be measured by using the NIH Neuro-QoL scale for positive affect and well-being, a computerized adaptive test 9-item scale[62]. This self-report measure for adults is intended for use in clinical trials and allows for cross-disease comparisons, which is well suited to our target population who present with an array of mental health difficulties. The measure has demonstrated sufficient reliability, internal consistency, and concurrent validity[63,64].
2. *Perceived emotional support* will be measured using a 4-item scale developed by the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS is a National Institutes of Health (NIH) Roadmap initiative that provides precise, reliable, valid, and standardized questionnaires measuring patient–reported outcomes across the domains of physical, mental, and social health[65]. The PROMIS emotional support item bank specifically aims to assess perceived feelings of being cared for and valued as a person[66,67].
3. COVID-19-related stress since the outbreak will be measured using a 7-item scale assessing different types of stressors.

Costs:
A secondary aim of this study will be to measure the total costs of ROSE vs. usual care for those at risk of IPV at participating study sites. Adhering to Second Panel on Cost-Effectiveness in Health and Medicine Guidelines[68], we will perform a cost-effectiveness analysis (CEA) to estimate the cost per IPV incident prevented by ROSE. Cost will be measured relative to usual care, with IPV reduction proxied by comparison to the research assistant blindable control condition that should be equivalent to usual care. We will collect data on three types of costs: 1) Implementation costs of establishing the ROSE program in a mental health clinic, including staff training time and resources, costs of hardware, software licensing, and adaptation of the program content to be relevant to the location; 2) Operational costs, including the human labor involved in identifying eligible patients, conducting screening, introducing patients to the program and demonstrating how to use it, obtaining follow-up information, and conducting the booster call, and 3) Participant costs in terms of time spent at the intervention and booster session, plus any travel costs related to intervention attendance, beyond the session where the person was screened. To record the first two sets of costs and distinguish them from research activities, the research assistants and the interventionist will track and log times for all study activities. The third set of costs will be captured by including questions about travel/waiting time, occupation, wage rate, and out-of-pocket expense in the survey at each added visit.

Exploratory Potential Mediators:
We hypothesize that self-efficacy and empowerment will mediate the relationship between the effects of ROSE and the presence of IPV (see Figure 2).
1. *Empowerment* will be measured using the Personal Progress Scale-Revised (PPS-R[69]) for accessing skills, social supports, and resources to cope more effectively with relationship stress and trauma. PPS-R is often used to evaluate empowerment-based interventions. The measure has shown good reliability and validity[69].
2. *Self-efficacy* will be assessed with the General Self-Efficacy Scale, a 10-item self-report measure[70]. It measures personal competence to deal effectively with a variety of stressful situations. The scale has been found to be reliable, homogeneous, and unidimensional across 25 nations[71].

Perinatal Depression:
At all follow-up assessments, participants will be screened for perinatal depression because the majority of women seen at both sites report perinatal depression and perinatal depression is strongly associated with IPV [72,73]. Any participant who screens positive for postpartum depression (The Pregnancy Risk Assessment Monitoring System 6 (PRAMS-6) score of 17 or more) will be referred for appropriate local clinical care [74].

Danger Assessment (DA)-5. The DA-5 was developed for use in healthcare settings, including emergency and urgent care settings to evaluate the risk of an intimate partner violence victim being killed, nearly killed or severely injured by an intimate partner [59]. The DA-5 was found to have adequate validity and is recommended for a quick assessment of homicide or near homicide risk among IPV survivors [59]

(See Protection of Human Subjects).

Data Collection at the University of Michigan Site
The University of Michigan site is the other site in this study. This site will be conducting the same data collection procedures. This site will send de-identified data to the Women and Infants site to be analyzed. The Women and Infants site will not send any data to the University of Michigan site.
Table 1: Study Measures

	Intake	6-weeks	3-months	6 months and 12 months
Self-report Measure				
Demographics and IPV information	X	X	X	X
Composite Abuse Scale	X	X	X	X
Positive Affect and Well-being	X	X	X	X
Perceived Emotional Support	X	X	X	X
Personal Progress Scale-Revised	X	X	X	X
General Self-efficacy Scale	X	X	X	X
Edinburgh Postnatal Depression Scale		X	X	X
COVID-19 Family Stress Screener	X	X	X	X
Economic Measure				
Cost Analysis	X	X	X	X

3. RISKS AND BENEFITS

Potential risks

There are five potential low- to moderate-risks to subjects associated with this research project:

Breach of confidentiality: Assessment procedures could reveal sensitive information about participants' medical history and history of IPV. Risk of breach of confidentiality is possible, though highly unlikely. Specifically, if a participant tells research staff that she is planning to harm herself or her children, the research staff will report this information to the appropriate agency, as required by law. Other than the need to report those incidents that are regulated by mandatory reporting laws, we feel that there is minimal risk to participants with regard to other breaches in their confidentiality.

Coercion: Coercion occurs when potential participants feel compelled to participate in research for reasons such as perceived demand or the availability of large sums of reimbursement. This can be particularly true when there is little benefit to the individual for their participant (not an issue in this study). In the present study, the inclusion of a protected population and protection from coercion is of the utmost importance.

Discomfort: Participation in the study may lead to psychological distress due to the sensitive nature of questions regarding disclosure of IPV during the perinatal period and the related negative social and psychological consequences.

Study-related partner violence: Participants who return to or continue to have contact with their abuser may be at increased risk for abuse if he or she were to find out about the woman's participant in the research project.

Social or legal consequences: Possible social or legal consequences due to revelations of IPV during the perinatal period.

Adequacy of protection against risks

At each point of contact in the studies, participants will be reminded of the alternative of not participating in the study (or once enrolled, to discontinue participation), and will be informed that their care at The Center for Women's Behavioral Health at Women and Infants Hospital and in any other follow-up medical care will in no way be affected by their decision to participate or not to participate in the study. Moreover, we will provide referral information to all participants at each point of contact. We will also remind participants that they should only keep handouts related to the study if they feel it is safe to do so. If they feel that it may be unsafe to keep any handouts, participants will be advised to discard these prior to leaving the assessment/intervention session. Further procedures to minimize each of these risks are described below.

Protection against risk
We will take the following steps to protect against risks associated with this research project:

We will minimize the risk of breach of confidentiality.
Risk of social or legal consequences as a result of disclosure of IPV within the past year will be dealt with in several ways. We will minimize the potential risks due to loss of confidentiality by strictly adhering to the guidelines for research outlined by Women and Infants Hospital IRB, Rhode Island state law and the DHHS Federal Policy for the Protection of Human Subjects (45 CFR Part 46 Subpart D). As described in the previous section, there will be full informed phone or in-person consent prior to participation in the study (a two-part consent process). Participant data will be encrypted in transit between user and server. No identifying information will be entered into the ACASI. The use of a linking table will provide the participant with confidentiality as the link between the participant code number and name will be kept in a password protected file on password protected computer. Lastly, potential participants will be informed of the situations in which they may not be protected under the Certificate of Confidentiality. No information about participants will be released without their permission or where required by law.

Possible distress due to sensitive items will be noted clearly in the informed consent information sheet (for screening) and in the written informed consent form (for participants). All participants will be told that they can skip any question or quit at any time if they become uncomfortable. To further address possible distress due to sensitive items, participants will be periodically asked by the research assistant (RA) if anything the RA has asked or done is making them feel upset right now. For both the online intervention and in-person computer-delivered intervention, the research assistant will contact the participant after 40 minutes, the time it takes to watch the intervention and inquire if anything in the intervention distressed her. . At a minimum, all participants indicating some distress will be given a list of referral options. If in treatment women will be encouraged to contact their mental health provider.

We will minimize the risk of study-related partner violence.
Participants who return to or continue to have contact with their abuser may be at increased risk for abuse if he or she were to find out about the woman's participation in the research project. The measures suggested by Sullivan and Cain (2004) will be taken to maximize participant safety throughout the research[75]. The office research line is a number that is blocked and the line will be answered, "Women and Infants Program," and partner violence will never mentioned. Likewise, staff work cell will be answered with Women and Infants Program. When potential participants are contacted through text or email using contact information obtained from EPIC, RAs will let potential participants know that they are from Women and Infants Hospital and that they will be calling them and provide their study cell number. If reference to the screener is made in text or email, it will be referred to as a brief women's health survey. Details of the research are not provided to anyone other than the actual participant. During each contact, participants will first be asked if it is a safe time to speak. Safe contact for follow-up assessments will be negotiated at each stage of the research. Both written and verbal contacts will be vague and never mention that the research involves partner violence. Safety plans will be negotiated up front (e.g., code words, cover story for reason for interview) if ever the abuser were to interrupt a phone call or assessment or –if during a call to the participant there is noise and concern for the safety of the participant, research staff will ask the participant if she is safe and ask if the police needs to be contacted. If participant says yes to police being contacted, the research staff will call the police. Any handouts with important information (e.g., hotline numbers) will be available in wallet size copies without any reference to the study or name of organization. Participants' safety contact information, including the Locator Form, will be updated and confirmed at each assessment to determine if the

contact information they previously provided is still accurate and safe. Initial contact information collected prior to screening in the contact form will be placed in a secure, password protected excel sheet the same day. Contact forms will then be shredded by the RA. After one month the contact information will be deleted from the protected excel sheet. Participants will be given contact information for the research team and asked to let us know if the contact information they provided is no longer safe. All research personnel (i.e., PI, research assistant, interventionists) will be able to call the PI for advice on cases where there is a concern for the safety of the respondent and the PI will be available at all times by pager. Research staff will contact PI, if there are any safety concerns.

The online intervention will be sent to a secure email as a link (i.e., URL) to the intervention. The link will not contain any wording that could reveal the nature of the intervention/study. The link will become inactive once the intervention is completed. Women can hit the stop button at any time during the intervention and it will stop immediately. Women can also click an escape button during the intervention that will redirect her to the Google search page. The link (URL) can then be sent again and the participant can continue with the intervention from the place where she stopped. If the woman chooses to view the online intervention remotely through their iPhone or iPad, they will have to download the CIAS app from the app store to open the link for the intervention. The app itself has as its only description as "Medical" and "Wayne State University". The image of the app has a yellow heart with a stethoscope. When the participant uses the emailed link to view the intervention, the CIAS app will automatically open. This is the only time the CIAS app will show information about the study. If another person were to open the app at another time, they would be unable to see the completed intervention. Although the proposed intervention seeks to help a woman to develop strategies for keeping herself safe, it is possible that a woman who participates in the study might be at increased risk of partner violence because of increased assertiveness. At each follow-up assessment, our assessment of community resource use will ask about participants' visits to emergency rooms, health professionals, etc. The Composite Abuse Scale (CAS) will be administered to monitor abusive experiences in the context of a woman's relationship since the last assessment. Women will be asked at follow up sessions about any instances of hospitalizations, emergency room visits, life threatening threats of IPV, rape, or sexual assault to better gather information regarding any potential adverse events to report to the Data Safety Monitoring Board (DSMB) (see section D5 below for more details), which will monitor these events.

For the duration of the study, if a woman discloses that she is in an abusive relationship, she will be provided with the battered women's crisis line for emergencies, referrals to battered women's shelters, and told how to obtain a restraining order. If the partner of the participant is also abusing her child[ren], the research staff person involved will let the woman know that she has a choice to make, either she herself will call child welfare or the research staff will report the concern. She will be reminded that she as the mother is responsible for protecting her child[ren] and if her partner hurts them and she fails to call child welfare or the police, she could be charged with neglect and her children could be taken away. However, the woman must determine if calling child welfare herself will place her at further risk from the abuser. The research personnel involved will also remind the woman that if she calls herself, child welfare is more likely to view the woman favorably under these circumstances. The research personnel involved will provide the woman with the relevant phone number/s. The research personnel involved will let the woman know that let she will be calling child welfare herself because it is the law. This same procedure will be followed for any other case of suspected child abuse.

Potential benefits of the proposed research to the subjects and others

The potential benefits to women participating in this study include participants' increased awareness of resources for IPV. Half of the participants in this study will not receive any form of intervention, and thus are unlikely to receive any direct health benefit; however, women in both conditions will receive a list of referrals and community resources for IPV. Furthermore, the treating mental health providers of women who screen positive for IPV will (with the women's consent) be provided a print-out of women's survey responses. Half of the participants will receive a brief intervention designed to increase the likelihood of self-change and/or obtaining resources for IPV.

We believe that the risks to participants in this study are very low, particularly given the lack of connection between identifying information and data. We believe that the risks that are present are justified given the tremendous potential of this research to produce a replicable and low-cost motivational intervention that is appropriate for this group. Such an intervention, then, could potentially be presented to unprecedented numbers of persons in a way that is financially and logistically feasible, potentially leading to beneficial effects for large numbers of women as well as their infants.

4. DATA MANAGEMENT

Adequacy of Sample Size
The primary purpose of pilot studies is to develop interventions and test feasibility/acceptability of interventions and research procedures and sample size guidelines for treatment development from Rounsaville and colleagues[76] recommend 15 to 30 participants per cell. A trial of such size is not adequately powered to detect between group differences. Although it can be used to suggest the potential promise of the intervention and associated effect sizes, we are well aware that these effect size estimates have large standard errors, and we primarily aim to find a pattern of results that is supportive of the experimental treatment. With baseline data from 50 participants in intent to treat analyses (about 25 per condition), we would only have statistical power adequate (.80) to detect large effects (d = .81) with alpha of .05. Therefore, our primary emphasis will be on examining the direction of effects and the range of effect sizes for differences between conditions. All estimates of effect size resulting from this study will include 95% confidence intervals.

Data Analysis: Descriptive statistics will be calculated to summarize baseline characteristics for the full cohort and by intervention arm. Quality inspection will be carried out periodically to screen for missing-ness and data anomalies, and entry error. T-tests and chi-square-tests will be used to compare study arms with respect to demographic characteristics, IPV relationship variables, and baseline measures of frequency of IPV. Any identified confounders with $p \leq 0.05$ will be included in major subsequent analyses.

Site Differences: In the preliminary analyses, participants from the two sites will be compared on all demographic and background information. We will also check for site effects with each specific hypothesis by including site as a fixed effect factor in the analysis. Site main effects and, as appropriate, interactions of site with relevant factors will be included. If site differences (and the interactions) are non-significant, this factor will be removed. Including site as a fixed effect and assuming an equal distribution of participants between sites and by treatment within each site will not change the overall sample size needed. However, the study may lack power to detect a site-by-treatment interaction unless the difference is large. Powering the study to detect the expected treatment effect separately by site is not feasible and would elevate the site-effect to a higher aim as opposed to being a check on the analysis[77].

Aim 1: For hypothesis 1 (primary outcome), the outcome (frequency of IPV) will be analyzed under a clustered count regression framework (Poisson or Negative Binomial) with frequency as outcome, and time (6-weeks, 3-, 6- and 12 months,), group (ROSE, control) and time-by-group interaction, with the

baseline (BL) IPV frequency as the primary covariate. A generalized linear mixed models (GLIMMIX) approach will be adopted by means of a random subject intercept to account for the clustering within each participant. Changes over time within each group will be estimated post-hoc by sliced effects derived from the regression model with adjustment for multiple comparisons. In additional analysis, reduction in proportion of participants experiencing a binary outcome of IPV ≥ 1 days within the 90-day period will be analyzed using a clustered logistic regression with a dichotomous outcome, again with BL IPV frequency as a covariate.

Aim 2: Similar analyses will be conducted for the secondary outcomes of positive affect and well-being and for perceived emotional support (Aim 2a and 2b). For cost estimation (Aim 2c) see below.

Aim 3: The mediation tests will examine the ability of the proposed mediators, empowerment and self-efficacy, to account for all or part of the possible main effect of treatment on outcome. The mediators will be assessed at the end of treatment, and outcome will be taken from subsequent time points. We will use the product of coefficients test[78] to determine the magnitude and significance of mediated effects. This method multiplies the parameter estimate for the intervention predicting the mediator with the parameter estimate for the mediator predicting the outcome (αβ). We will estimate the standard error and 95% confidence interval of αβ by bootstrapping, a re-sampling method that performs well when the assumption of normality may not hold.

Missing Data: Missing data will be handled by a weighted complete data analysis, using only complete cases after weighting the cases with the inverse probability of being missing. The probability is calculated as a function of the variables that are simultaneously associated with the outcome of interest and the event of being missing itself.

Power: We calculated the sample size using mean, standard deviation, and within-subject correlation estimates for IPV frequency from our R21 study. IPV frequency was measured by the CAS Total score. In our pilot data, we observed participants in ROSE demonstrated a significantly larger change in frequency of IPV than the control condition. The observed between-group effect size for change in IPV frequency at follow up was moderate to large: Cohen's *d* of 0.59 and 0.68 with and without adjustment for baseline score. Therefore, a more conservative effect size of $d = 0.4$ was selected for sample size estimation. With four follow up IPV assessments, a within-subject correlation of 0.62, and a standard deviation of 20, 74 participants per group are needed to detect an effect size of $d = 0.4$ for the overall intervention vs. control group difference with 80% power at the 5% significance level. A minimum effect size of $d = 0.4$ will be detectable for the secondary outcomes of positive affect and well-being and perceived emotional support. The secondary outcome measures are reported as T-scores based on a normative mean of 50 and standard deviation of 10. With 74 patients per group and assuming an observed SD of 10, a 4-point difference in positive affect and well-being or perceived emotional support will be detectable. Moderate effect sizes (Cohen's *f* for multiple regression = 0.39) for mediated effects of the intervention (α and β) will be detectable with 80% power and 74 patients per group[79]. For all the outcomes, our proposed sample of 186 should be adequate for detecting small to moderate effect sizes. Even assuming the worst-case scenario of up to 20% drop-out in both the ROSE and control groups, we plan to recruit 93 participants per arm.

Costs: RAs, interventionist, training, and supervisory time will be priced based on actual salaries, plus fringe benefits and overhead (drawn from institutional records), with sensitivity analysis on salaries at average wage rates for job titles nationally based on Bureau of Labor Statistics (BLS) annual Occupation and Employment Survey (OES) data. Participant time will be priced at the participant's hourly wage, with the state minimum wage used to price time of those who are not presently employed. This pricing approach is widely accepted[80]. Because treatment as usual has no cost and the incremental costs of treatment are directly measurable, power to detect a difference is not a consideration; the standard error of the added costs can be calculated directly and cannot overlap with $0. Data from different years will be adjusted to same-year dollars using the appropriate Employment Cost Index from BLS for wages and the Consumer Price Index for other costs. The cost-effectiveness ratio will be computed as number

of IPV incidents prevented divided by total cost. To judge the CEA estimate, we will compare it to the average cost of an IPV incident. Bid economist Ted Miller is about to submit a manuscript updating IPV costs based on recent data and an amalgam of his prior estimates and estimates for the Centers for Disease Control[81,82]. Our cost of an IPV includes the quality-adjusted life years lost to the incident, so it can be used to estimate a second cost-effectiveness ratio, namely the cost per quality-adjusted life year saved. The numerator in that calculation is intervention costs minus the medical and other direct (criminal justice) costs of the incident. The IPV costs include lifetime costs related to medical care and criminal justice, converted to present value using the 3% discount rate recommended by the PCEHM[68]. We will use the Crystal Ball® add-in to Excel to bootstrap standard errors for the cost-effectiveness ratios. We also will conduct one-way sensitivity analyses on non-probabilistic parameters, notably the discount rate and the wage rates of the clinical staff. NB: a much larger sample would be needed to directly track the cost of the IPV incidents.

Data checking
Data will be collected using computer-based self-interview (ACASI) technology, and will only be identified with the study's ID of the participant. The PI will keep the link between the participant code number and name under lock-and-key. The accuracy with which data input matches data output using the software will be checked prior to beginning the trial and every five participants thereafter. Although no problems are expected given past experiences with this technology, any evidence of errors in data recording by the ACASI will result in dropping all participants since the last quality check. Data will be checked once per month for out of range values and other quality issues. Dr. Raker will analyze the data using SPSS software.

Primary outcomes of the Reach Out for a Safe Environment (ROSE) will be measures of the intervention's efficacy compared to a time, attention, and information matched control condition in reducing frequency of intimate partner victimization (IPV) at 6-weeks, 3-, 6- and 12-months after baseline assessment. Secondary outcomes will be measures of the ROSE efficacy compared to control in increasing positive affect and well-being and emotional support as well as collecting and measuring the cost effectiveness of ROSE to determine if sufficiently favorable. Tertiary aim will be to explore the role of theorized mediators of empowerment and self-efficacy on the effect of ROSE. Effect sizes with 95% confidence intervals will be calculated, and outcome data will be analyzed with alpha set at 0.05.

Data acquisition and transmission:
Data will be collected using computer-based self-interview technology (ACASI), and will only be identified with the study's ID of the participant. The use of computer technology for gathering self-report data further enhances overall protection. This software (ACASI) utilizes SSL technology for encrypting of communications between remote computers and the server itself, is HIPAA-compliant, and is currently used in a number of major NIH-funded research studies, including those of the PI.

At the Women and Infants Hospital research site, the link between the participant code number and name will be kept in a password protected file on password protected computer. The accuracy with which data input matches data output using the software will be checked prior to beginning the trial and every five participants thereafter. Data will be checked once per month for out of range values and other quality issues. ACIAS data is password protected and only research personnel will be able to access. Results and the response to whether or not she agrees to participate in the study will be transferred by secure, encrypted electronic file and downloaded to a secure Women and Infants Hospital server. Importantly, no identifying information will be entered into the ACASI. Dr. Christina Raker will analyze the data using SPSS software. Booster session data will be recorded using a credit-card size digital audio recorder with data encryption capabilities, which can hold hundreds of hours of

voice recordings so that adherence and competence ratings of the booster sessions can be conducted. These digital recordings which will be labeled with the study identification number and the booster session date and will be transferred to Women and Infants Hospital secure computer server via a secure server access. Access to the audio recordings will be limited to research staff.

Data will be destroyed two years after the completion of the study. We expect the study to be completed by 2024, so we expect the data to be destroyed in 2026.

5. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS

Frequency of Data Safety Monitoring:
In this study, we will use the FDA definition of serious adverse events (SAEs). The RAs will report SAEs to Dr. Zlotnick immediately. Data and safety of patients will be monitored by the PI. At a weekly meeting at Women and Infants Hospital, the PI will review participants' safety and will present participants' clinical status and adverse experiences. Entrance criteria of all participants will be reviewed at these meetings. The PI will ensure that information on participants' adverse effects are systematically collected and evaluated.

Dr. Zlotnick will immediately report any adverse events that are observed to the Women and Infants Hospital Internal Review Boards (IRB), DSMB (see below) and NIH. The initial SAE report will be followed by submission of a completed SAE report to both institutions and the DSMB (see below). Outcomes of SAEs will be periodically reported to NIH. A summary of the SAEs that occurred during the previous year will be included in the annual progress report.

An external Data and Safety Monitoring Board (DSMB) will be assembled to evaluate the data and safety to women enrolled in the study. The DSMB will consist of 4 senior doctoral-level/MD board members who have experience in clinical trials and/or IPV intervention research and/or research with perinatal women as the ethical issues involved with a randomized controlled study, as indicated by peer-reviewed journal articles in these areas. We do not anticipate any difficulty in recruiting these qualified, independent, board members as there is a pool of such researchers at several universities in Rhode Island, Michigan, and Massachusetts who have the relevant experience.

The DSMB will convene twice in year 1, once during year 2 to 5 for a meeting. Initially, the Board will convene with the PI to review the study protocol and review the guidelines for data and safety monitoring. This will include establishing standard procedures for daily (whenever there has been contact with a participant) and weekly monitoring by the local internal reviewers (PI and study personnel). At each subsequent meeting, the DSMB will evaluate recruitment, the progress of the trial, subject retention, data quality and confidentiality. In addition, they will review participants' clinical status, rates of adverse events and whether or not there have been any changes in risk to participating subjects. This review will ensure that subject risk does not outweigh study benefits. In the DSMB's review of adverse events, if non-serious adverse events are occurring at a significantly higher rate in one condition than the other, then the DSMB will make appropriate recommendations for changes in the protocol, if needed. If Serious Adverse Events (SAEs) occur at a significantly higher rate in one condition than the other, then the DSMB might consider terminating the trial, if changes to the protocol are unlikely to address the high occurrence of the SAEs. We do not anticipate that this will occur, because we have taken several steps to avoid or protect against the occurrence of SAEs as outlined in the Section on Protection against Risk. A report generated from each of these meetings will be retained at each study site and will be forwarded to the each study site's IRBs and to NICHD in the annual progress report.

The DSMB will be available to convene outside of the appointed meeting schedule, if necessary, due to concerns regarding a particular subject, or due to any troublesome developments in subjects'

experiences during the study. The DSMB will make appropriate recommendations for changes in the study protocol, if needed. The safety of participants will be monitored during each contact with study participants. Both anticipated and unanticipated adverse events and problems will be formally monitored and recorded. Unanticipated serious adverse events or problems will be reported to Women and Infants Hospital and University of Michigan IRBs and to NICHD within 24 hours.

6. WITHDRAWAL OF SUBJECTS

Study staff will be trained on understanding the various potential risks of participation in this study, as explained above, in the section "Risks and Benefits." As explained in this section, various procedures will be put into place to mitigate these potential risks. However, if when discussing the safety of a subject's participation in the study, study staff decides that stopping a subject's participation is necessary for safety reasons, then study staff will withdraw the subject from the study. As explained in the "Risks and Benefits" section, we anticipate that potential circumstances in which this might need to occur include breaching of confidentiality, coercion of participants, participant discomfort, the occurrence of study-related partner violence, and/or social or legal consequences related to study participation.

If participants voluntarily withdraw from the research, study staff will keep the data that has already been collected, and will use this data in the study analysis procedures. If a participant is physically present when she decides to withdraw from the study, she will be checked in with by research staff, be given any relevant informational handouts if it is safe for her to receive and take with her, and be given any relevant referrals.

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