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# Web-based intervention to reduce intimate partner violence during perinatal period: A modified protocol in response to the COVID-19 pandemic

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## ARTICLE INFO

### Keywords:

Postpartum  
mental health treatment  
technology-delivered intervention

## ABSTRACT

Perinatal women are at increased risk of intimate partner violence (IPV), associated with psychiatric disorders and partner revictimization. We describe changes that were made, in response to the COVID-19 pandemic, to an in-person randomized controlled study of perinatal women with IPV who had sought mental health treatment in the last year. All phases of the study's in-person delivered computerized protocol were modified for remote delivery. Special attention was given to study participants' privacy and safety, especially with regard to the use of technology. We describe study protocol and consent procedures that were made to accommodate remote delivery of the study. All phases of remote delivery of the study have been implemented successfully and safely. Compared to the first three months of in-person delivery, the first three months of remote recruitment found that more participants were screened (69% vs. 36%) and more were enrolled in the study (13% vs. 8%). To our knowledge, this is the first remote delivered study involving participants with IPV to use the 5-item Danger Assessment and a spyware and stalkerware survey as screening tools. We demonstrate that remote delivery can reduce the risk of compromising the safety and privacy of study participants with IPV.

## 1. Introduction

In early 2020, the first cases of the 2019 novel coronavirus disease (COVID-19) were reported in the United States. As a means of limiting the spread and impact of the virus, many research institutions implemented research restrictions including social distancing guidelines, mask mandates, stay-at-home orders for non-essential workers, and limited or no in-person research study visits. What was originally estimated to be a two-week pause of in-person activities extended to nearly two years in many areas of the country. As a result, about 80% of non-COVID-19 clinical trials were stopped or interrupted, halting enrollment, and presenting challenges for continuing treatments and appointments (van Dorn, 2020). Many investigative teams redesigned their protocols to include virtual platforms and other remote approaches, engendering new challenges and advantages. The removal of the barrier

of transportation, which can place the time, effort, and resource burdens on study participants and research staff, has been cited as a major advantage of remote delivery of clinical trials (McDermott and Newman, 2021). Remote approaches can, however, present challenges such as privacy and safety with certain vulnerable study populations.

Remote delivery of a clinical trial involving individuals with intimate partner violence (IPV) exposure requires special considerations and guardrails to preserve the safety and privacy of these study participants. IPV is defined as violence (physical, psychological, or sexual) enacted against a person by a current or former intimate partner (Patra et al., 2018). Considerations for remote study delivery with this group of study participants include the potential for the abuser to overhear interactions with research staff or to view study materials focused on IPV, which could result in further abuse as retaliation. Likewise, a study participant could be a victim of technology abuse in which the abusive partner

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monitors and accesses a participant's digital activities, compromising the study participants' safety and privacy during a study delivered online (Fraser et al., 2010).

A recent United Nation Women report cited a surge in IPV during COVID-19 which was referred to as the "shadow pandemic," and creating a "perfect storm" of IPV and child abuse, aggravating family violence. Data suggest, because of the pandemic, women are less likely to report IPV and use IPV-related resources. This is concerning, as IPV rates often increase during times of crisis associated with social isolation (Bright et al., 2020). For women at risk of IPV, staying at home to mitigate the spread of COVID-19 infection increases the risk of IPV (Taub et al., 2020). In a systematic review and meta-analysis of 12 US studies, IPV incidents increased by 8.1% after COVID-19 lockdown mandates were imposed. Effects of COVID-19 lockdowns such as financial insecurity and social isolation are likely factors that elevate IPV risk (Piquero et al., 2021).

To date, there are only four published randomized controlled trials examining the use of online interventions for women with IPV. While some of these studies found a reduction in IPV for both the intervention and control condition, none of these studies reported that the online IPV intervention was associated with a reduction in IPV relative to the control in their target sample of women with IPV. One double-blinded, randomized control trial with women who reported recent IPV assigned women to either a tailored, interactive intervention (*iCAN Plan 4 Safety*) or a static, non-tailored version of this tool. Overall, women in both groups improved over time in depressive and posttraumatic stress disorder (PTSD) symptoms at 12 months post intervention. Effects on reductions in IPV, however, were not assessed and therefore unknown (Ford-Gilboe et al., 2020). Likewise, another RCT of women who screened positive for IPV or have feared their partner in the last 6 months were assigned to view an intervention website with modules on abuse and safety, and a tailored action plan, or to a control website with static IPV information. This study did not report on differences between the two groups in IPV at 12 months and there were no differences in primary outcomes of self-efficacy and depression at 12 months. However, while there were no differences between the control and intervention groups, both groups reported improvements in fear of partner, self-efficacy, and depression at 12 months (Hegarty et al., 2019). A study of women with recent IPV compared an internet-based tailored safety decision aid to a control website that offered typical domestic violence safety information available online. At 12 months, both the intervention and control group reported a decrease in IPV instances, depression symptoms, and PTSD symptoms, but there were no significant differences between the two groups in these outcomes (Glass et al., 2017). The only other RCT study with an online intervention reported no reductions in IPV for the active intervention group but found an effect in reductions of IPV in a subgroup of indigenous Māori women (Koziol-McLain et al., 2018).

Each study had safeguards for safety and privacy in varying degrees. Three studies reported that the use of safe email addresses was one of their study's inclusionary criteria (Ford-Gilboe et al., 2020; Glass et al., 2017; Koziol-McLain et al., 2018), and Glass et al. (2017) specified in an earlier article that participants could create a safe email if they did not already have one (Eden et al., 2015). Two studies implemented a safe button for participants to use while accessing the intervention or aid remotely on their device, which diverts the participant to a neutral web page to hide her study activity (Ford-Gilboe et al., 2020; Glass et al., 2017). All four studies required a username and password to be created to access study information (Ford-Gilboe et al., 2020; Glass et al., 2017; Hegarty et al., 2019; Koziol-McLain et al., 2018). Additionally, two studies gave participants information on internet and computer safety, such as how to access the site in private mode in order to prevent internet history from being retroactively retrieved (Ford-Gilboe et al., 2020; Glass et al., 2017). Finally, Ford-Gilboe et al. (2020) specified in their protocol that participants were offered training on internet safety (e.g., how to delete browser history and enter private/incognito mode)

as needed (Ford-Gilboe et al., 2017).

Prior research with online IPV interventions provide a valuable foundation of safety measures to include in our research with perinatal women. However, extant research has not focused on perinatal women with IPV—a vulnerable group of women who are often isolated and are at high risk for morbidity and mortality (Pastor-Moreno et al., 2020). For instance, a recent study based on an analysis of birth and death records from 2016 to 2017 found that homicide is a leading cause of death among pregnant and postpartum women in Louisiana (Wallace, 2020). Although the victim-perpetrator relationship was not reported in this study, recent review studies have found that IPV is a significant risk factor for attempted and completed homicide with pregnancy-associated homicide rates highest in the US (Samandari et al., 2010). Studies on IPV during the COVID-19 pandemic among perinatal women have been scarce. A cross-sectional survey of 216 perinatal women at the start of the pandemic found that one in four women reported IPV, a rate that is higher than previous studies of perinatal women (Muldoon et al., 2021).

During this pandemic and beyond, perinatal women with IPV may be unable to attend medical appointments without their abuser present. For these women, routine doctor's visits are typically a potential source of IPV identification and referral to IPV services. However, during the pandemic, this opportunity decreased as many clinics conducted most routine prenatal and postpartum visits via telehealth video or e-visits. (Evans et al., 2020). The use of telehealth for perinatal visits may continue well beyond the pandemic. In 2020, The American College of Obstetricians and Gynecologists (ACOG) pushed to maintain expanded telehealth policies and improve perinatal women's access to remote services (ACOG, 2020). Thus, online IPV interventions are essential for perinatal women where remote practices are preferred, and sometimes the only way of reaching this population.

In the current paper, we describe study challenges and adaptations as a result of COVID-19 research restrictions. The study was initially conducted in-person at two sites (one site in Rhode Island, and one site in Michigan) and modified to be delivered remotely in a sample of perinatal women who endorse IPV in the last year and had sought mental health treatment. The primary aim of the clinical trial is to examine the efficacy of an IPV-focused intervention in reducing IPV in this high-risk group of women.

## 2. Methods

### 2.1. Design/approach

#### 2.1.1. Clinical trial aims

The design of the clinical trial is a two-group, randomized controlled design with a baseline session, a booster session 4 weeks later, and follow-up assessments at 6-weeks, 3-month, 6-months, and 12-months from the baseline. The aims of the overall trial are to examine whether the intervention compared to an attention- time and information matched control condition will be associated with a lower frequency of IPV (primary aim) as well as greater positive affect and well-being and greater perceived emotional support (secondary aims) among perinatal women seeking mental health treatment at follow-up time points. Cost effectiveness of the intervention will also be estimated compared with treatment as usual by estimating the resources needed and costs of intervention delivery (for more study design details, see Johnson et al. 2020). The original protocol included in-person study recruitment and computerized components: screener, IPV-focused intervention, control condition, and assessments delivered in-person at each of the research sites. The original protocol at both sites was approved by the site's respective Institutional Review Board and the study's Data Safety Monitoring Board and is registered on ClinicalTrials.gov (NCT04218864).

Due to the COVID-19 research restrictions placed on in-person research at both study sites, our team adapted the research procedures to accommodate for full remote administration of all study-related

activities, including altered recruitment methods, screening tools, delivery of intervention and control condition, and study communication methods. As of March 2020, in-person recruitment and enrollment in the study was halted at both study sites as per IRB guidelines until the end of June 2020. At the recruitment site in Rhode Island, all mental health appointments were conducted via telehealth until October 2020 and at this time research staff returned to the research site. The site in Michigan continues to encourage research staff to work remotely. IRB approval was obtained in June 2020 to change the in-person study protocol to a remote study protocol at the site where research staff continue to work remotely. At the other site IRB approval was obtained in October 2020 to change the in-person study protocol to mostly remote study delivery (see details below). The study's Data Safety Monitoring Board approved the study changes in April 2020.

### 2.1.2. Current study aims

The aim of the current study is to describe changes that were made, in response to the COVID-19 pandemic, to an in-person randomized controlled study of perinatal women with IPV who had sought mental health treatment in the last year. We describe study protocol and consent procedures that were made to accommodate remote delivery of the study.

## 2.2. Recruitment

Originally, in-person recruitment involved research staff who approached women waiting for their appointments at clinics specifically for mental health services for perinatal women. If women expressed interest in participating in a health survey, women would be consented for the survey in a private setting and administered on a tablet a 5–10-min survey which was described as a survey on health behaviors and relationship conflict. Eligible recruits include women ages 18–45 who screen positive for IPV on Women's Abuse Screening Tool (WAST), are pregnant or up to 12 months postpartum, and are receiving some form of mental health care at one of the study sites.

As a result of the pandemic, changes were made to accommodate for remote recruitment of the study at both sites. For the most part, sites followed a similar recruitment protocol. The Rhode Island site, however, offered an in-person option under certain circumstances, which are described below.

For remote recruitment, at both sites, research staff identify a pool of potential recruits (that is based on perinatal status, age, and attendance at the mental health clinic) using an electronic medical system (EPIC). Research assistants (RAs) attempt to contact potential recruits via phone call, text message, WhatsApp message, and/or email. Once contact is made, women are asked if they are interested in taking a brief women's health survey over the phone, and IPV is not mentioned at this stage. The name of the hospital or health care system (i.e., the participating research site) is mentioned in the texts, emails, and calls. If interested, women are verbally consented over the phone by RA; the time and date of consent are documented, and women are then verbally administered the screener over the phone. Women are asked to take this phone call in an area that is safe and private.

If a woman is eligible, then she is informed verbally on the phone about the nature of the study. If interested, she is asked if the remainder of the phone conversation can take place in a safe and private area or to schedule a time when this would be possible. If not interested, research staff offer relevant IPV community resources and mental health referrals.

At this stage, prior to the consenting process, research staff first establish whether participants are comfortable using the internet. If not, the woman is excluded from the study, unless she is willing to participate in-person for the consenting process and viewing the intervention at one study site, since these components requires remote internet access. Next, the potential recruit is asked series of questions via phone to reduce the risk of a participant remotely viewing an online IPV focused

intervention. As part of this series of questions, women who live with their abuser complete the 5-item Danger Assessment (DA-5; Campbell, 2015), which assesses if women are at risk for severe injury and/or homicide. If a woman screens positive on the DA-5, she is excluded from participating in the study remotely. Research staff offer to review a safety plan with her and provide the woman with relevant IPV community resources and mental health referrals over the phone or sent via email, if it is a safe and private account. At the site where in-person visits are allowed, research staff offer women the option to proceed with the study on site and in-person.

For women not at risk for severe injury or homicide, research staff ask several questions to assess the risk of the recruits having Spyware or Stalkerware software installed on their device. The questions used in this study were developed with the aid of a phalanx of researchers studying technology safety and security for victims of IPV. The Clinic to End Tech Abuse (CETA) is a group that provides technology consultations to IPV survivors to determine if they are also a victim of technology abuse. They developed the Technology Assessment Questionnaire (TAQ) to assess the risk of spyware and stalkerware on their devices (Havron et al., 2019). Risks include an ex-partner or partner knowing where you are or what you're doing when they shouldn't, suspicious apps or potentially compromised accounts. These factors are associated with the risk and suspicion that the recruit has about spyware, stalkerware, and/or loss of technological privacy. Examples of the screener items from the TAQ include, "Does (or do you suspect) your partner somehow know(s) things they shouldn't or where you are?" and "If you look at the settings app on your smartphone and view applications, are there any applications that you don't recognize?" If a woman endorses an item on the TAQ, the study considers this woman at risk of spyware or stalkerware on their device, and she is excluded from participating in the study remotely. At the site allowing in-person research, women are given the option of participating in-person at the research site. If eligible to participate remotely, women are offered a pair of headphones to use and view the intervention more privately, and research staff send participants headphones in the mail. For all recruits who screen positive for IPV on the WAST but are ineligible for any reason listed above, they are given IPV-related community resources by research staff, including numbers for domestic violence shelters in her area and a list of mental health referrals over the phone or email, if safe and private.

At the Rhode Island study site, which allowed in-person participation, amendments were not approved by the IRB until December 2020 to allow women living with their abusers to participate remotely. During recruitment at this site from October to December 2020, eligible recruits living with their abuser were only given the option to come to the research site for study participation. After IRB approval in December, women living with their abuser could participate remotely, provided they do not meet criteria on the DA or endorse any spyware or stalkware questions, in addition to being willing to create a temporary email to access study materials. All women who are eligible for the study are provided with IPV related resources over the phone or via a safe and private email.

### 2.3. Consenting procedure

For the consenting process, research staff call the participant and review the consent form with her, which is emailed within the body of the message rather than as an attachment that may be downloaded onto her device. Verbal consent is given by the participant, documented by research staff in a password-protected document. Both IRBs at each study site have approved a waiver of obtaining a signed consent form. After consenting and completing the telephone portion of the first study, the research staff will then email the participant an individual URL link to complete the intervention from the privacy of her home. If a participant is unable to complete the intervention within the work hours of the research team, they are instructed to delete the email from both her inbox and trash folder and are sent a new email at an agreed upon date

and time so that research staff can be available if the participant needs assistance.

#### 2.4. Remote participation

It is essential that a woman participating remotely uses a private email address to reduce the likelihood that others may have access to her email and therefore the link to the intervention. If a woman is unsure of whether her current email address is private, or if she is currently living with an abuser, a member of the study team will assist her in creating a private email address and instruct her on using an “incognito window,” which is an internet browser window that does not record internet history, in addition to deleting her computer history. When finished with the intervention, she will then delete her email with research staff’s instructions.

While viewing the intervention, participants always have the option to click on the program’s “stop” button which will redirect them to the Google homepage. This is meant to serve as an “escape” button in case a participant needs to quickly exit the material she is viewing. After viewing the intervention, a study team member calls the participant to ensure that she was not upset by any of the intervention materials. Mental health and IPV-related community resources are provided if necessary, and are offered at the end of each visit, along with legal advocacy information and local shelter information. These resources include phone numbers and hotlines. Research staff provides these resources by email, if the participant has safe and private access, or over the phone.

### 3. Results

Since the in-person delivery of the study was halted after three months from study onset due to COVID-19 restrictions, we have compared this phase of the study to the first three months of remote recruitment at both sites (that is, one site from June 2020 to August 2020, the other site from October 2020 to December 2020). In the three months of in-person recruitment, 363 women at both sites were approached to take the survey. Of these, 130 women (36%) took the survey, 26 (20%) of those who took the survey were eligible, and 8 women were enrolled in the study. In contrast, in the first three months of remote recruitment at both sites, research staff attempted to contact 502 women, 265 (53%) women answered, and 184 (69%) of those women took the survey. Overall, 27 women were eligible and 14 were enrolled. In the first three months of remote study delivery, none of the women were excluded because they met criteria on the DA or spyware or stalkerware questions. At one study site, 4 women were excluded because they lived with their abuser and were unwilling to participate in-person, prior to IRB approval for them to participate remotely. To date, no breach of confidentiality at either site has occurred and no study-related SAEs have been reported.

### 4. Discussion

The current study demonstrated that changes from an in-person clinical trial protocol to a mostly remotely delivered clinical trial with a vulnerable study population during a global pandemic reduced study disruption and reduced the risk of study exposure to COVID-19. More specifically, the study to date has shown that remote recruitment, enrollment, intervention participation, and follow-up appointments were implemented successfully and safely with perinatal study participants with IPV exposure and were comparable to the in-person delivered phase of the study. Our findings show that remote study delivery had a greater outreach than in-person study delivery in terms of recruitment and completion of the screening phase of the study. Given the risks of technology abuse and loss of privacy that women with IPV exposure can face, our study team revised protocols and recruitment with these issues in mind. Further, as result of the study’s transition from in-person to

remote delivery, our study design and protocol notably differ from those of the previous online IPV interventions that were described above.

Other studies evaluating online interventions for women with IPV exposure have included safety measures such as password protection (Ford-Gilboe et al., 2020; Glass et al., 2017; Hegarty et al., 2019; Koziol-McLain et al., 2018), a “safe button” (Ford-Gilboe et al., 2020; Glass et al., 2017), providing study participants with information on how to delete history and browse the internet privately (Ford-Gilboe et al., 2020; Glass et al., 2017), and training participants on how to delete browser history and enter private mode as needed (Ford-Gilboe et al., 2017). Some of these studies also required participants to have a safe email address as an additional safety measure (Ford-Gilboe et al., 2020; Glass et al., 2017; Koziol-McLain et al., 2018).

The present study, like some of these previous studies, also uses a safe button, provides information on taking steps toward internet safety (e.g., directing participants to resources on internet safety), and guides participants through internet safety directions as needed (e.g., helps participants delete browser history and study emails from both their inbox and trash folders). The current study’s research staff via phone also guide study participants who do not have a safe email through the steps of creating one and subsequently deleting it after its intended use. While providing information and written directions on internet safety and safe email creation can be helpful, guiding participants through these steps may be optimal as not everyone has the focus, skills, or knowledge needed to do this on their own (Moyer et al., 2022). For this reason, it was decided that research staff would offer their assistance. To our knowledge, we are the first online IPV study to use an assessment of spyware or stalkerware, which if implemented, can reduce the risk of losing privacy while browsing the internet (Havron et al., 2019). Unlike other studies, an additional strength of our study is the use of the DA-5 to screen out high-risk potential study recruits from remote study participation.

While the authors note the valuable contribution of the existing research (e.g., procedures such use of safe emails and a safety button), given our target population, we included some additional and unique strategies to maximize participant safety. Some of the safeguards mentioned in other RCTs, such as requiring a username and password to access study materials, may increase the risk of losing privacy. A participant may write their username and/or password down or store this information on a device. While intended to conceal the study website and participant information, documentation of the username and/or password could be found by an abuser, placing the participant at risk of retaliation. This can also occur if a study uses a secure web application for participants to complete online study surveys such as REDCap and Qualtrics. It is not uncommon to recommend that women with IPV exposure change their passwords to their accounts frequently (Sabri, 2019). However, an abuser with access to an account or device’s data may become suspicious by this activity. The study’s use of a temporary and secure email provides increase protection from spyware or stalkerware.

Currently there exists no standardized or validated measure to assess for spyware and stalkerware on a study participant’s device. Although our study has taken steps to reduce the risks of an abuser accessing a study participant’s interactions with research staff and online activities on a device, it is unknown if these measures provide sufficient safety and privacy protection. Another limitation of the current study is that remote recruitment and enrollment in the first three months at each site took place at different times in the year due to separate IRB approval of protocol modifications. One site received approval in June 2020, while the other did not receive approval until December 2020. In-person recruitment took place in the beginning of 2020. Conducting recruitment at different times of the year may affect women’s availability and interest in study participation. The study uses active recruitment methods (e.g., texts, calls, and emails) and passive recruitment methods (e.g., flyers). While these strategies have various strengths and limitations, both methods can result in a selected sample. Additionally, while

in-person participation is an option at the Rhode Island site, it is still not an option (as of the summer of 2022) at the Michigan site. As a result, Michigan participants who screen positive on the DA-5 cannot participate. This means that the study at this site is unable to reach all high-risk participants, which reduces the generalizability of our findings. Finally, COVID-19 related events and challenges might also pose barriers to study participation. Future studies should compare an in-person delivered study to a remotely delivered study for a longer period than three months to assess more accurately differences in recruitment, retention, and safety violations rates. Finally, it is unclear if the safety guardrails introduced in this study would be as effective for other populations with IPV exposure.

Strategies to increase safety and privacy in remote delivered studies beyond the COVID-19 pandemic remain important, especially for vulnerable populations who are home bound, have limited access to transport, and/or have far to travel for study participation (e.g., rural individuals), and perinatal women with childcare issues. Many of the safety strategies that the current study has employed have relevance for providers who are delivering virtual treatment to women with IPV exposure and for domestic violence agencies working with women remotely or assisting women with technology safety. The rapid developments in the field of technology pose challenges for researchers who need to ensure that study strategies implemented remain current and relevant to their target study population.

#### CRedit authorship contribution statement

**Elizabeth Johnson:** Investigation, Writing – review & editing. **Sofia Janssen:** Investigation, Writing – original draft, Writing – review & editing. **Golfo Tzilios Wernette:** Project administration, Conceptualization, Methodology, Writing – review & editing. **Tasneem Tweel:** Investigation, Project administration, Writing – review & editing. **Dawn Johnson:** Conceptualization, Methodology, Writing – review & editing. **Caron Zlotnick:** Conceptualization, Methodology, Supervision, Project administration, Funding acquisition, Writing – review & editing.

#### Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

#### Acknowledgments

This work was funded by the Eunice Kennedy Shriver National Institute of Child Health & Human Development [R01 HD094801]. The authors would like to thank Catherine Cerulli, the chair of the DSMB, for her contributions to the study's remote delivery protocol.

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