Cover Page

Study Title:
An Adaptive Intervention to Improve Health, Safety and Empowerment Outcomes Among Immigrant Women with Intimate Partner Violence Experiences

Date of the Protocol: 1/2/2025

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JHM IRB - eForm A – Protocol

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1. Abstract

Intimate partner violence disproportionately affects immigrant women. However, immigrant women remain an understudied and underserved population in need of evidence-based rigorously evaluated culturally competent interventions that address their health and safety needs. This study uses a sequential, multiple assignment, randomized trial design to rigorously evaluate an adaptive culturally informed intervention tailored to the needs of immigrant women with intimate partner violence (IPV) experiences. For the first stage randomization, the abused immigrant women are being randomized to the It's weWomen Plus online intervention or the usual care control arm and safety, mental health and empowerment outcomes are assessed at 3, 6 and 12 month follow up. In this study, women who do not report significant improvement in safety (i.e., reduction in frequency and severity of intimate partner violence) and in empowerment from baseline to 3 months (i.e., non-responders) will be re-randomized to a second stage randomization with augmented intervention components (i.e., text messages and phone calls).

In Phase 1, the formative phase, using a concurrent mixed methods design, we will conduct in-depth interviews with non-weWomen participants and current weWomen (1R01HD08117901A1) participants. The participants will be asked about the utility of the It's weWomen Plus intervention components. We will also analyze moderators of intervention response. Further, based on input from experts on IPV among immigrant women and from diverse groups of immigrant survivors of IPV, we will culturally tailor and pre-test the content of the augmented components (text messages and phone calls' protocol) (qualitative).

Also as part of Phase 1, we will conduct a pilot test of the present study's intervention components with 5 to 10 immigrant survivors of IPV to ensure that the registration process, surveys, online intervention, text message intervention, and phone intervention work as intended and to identify any technology issues in our intervention. The eligibility criteria of survivors will be the same as the Phase 1 in-depth interview participants.

In Phase 2 (Enhanced intervention evaluation) phase, by re-randomizing participants, we will assess the relative effectiveness of two strategies for augmenting the It's weWomen Plus online intervention (text messaging only or a combination of text and phone) on safety and empowerment outcomes among the non-responders of the It's weWomen Plus online intervention. In addition, the study will compare the non-responder group of women to the responder group of the It's weWomen Plus online intervention to determine if the strategies of augmentation brought the non-responders to the level of responders on safety and empowerment. Furthermore, a subsample of 55 women with abuser's access/ownership of guns will be receive a gun safety intervention and their outcomes will be compared with 55 women with abuser's access/ownership of guns in the control arm who did not receive the gun safety intervention.

In Phase 3 (Dissemination and Implementation) phase, the study will identify facilitators and barriers to the adoption, implementation and maintenance of use of the original and augmented intervention by programs serving immigrant women and design strategies to decrease barriers and build on strengths. For this, the study will collect data from providers serving immigrants and organizational leaders as well as immigrant survivors of intimate partner violence (those who received the It's weWomen Plus online intervention only as well as those who received the augmented intervention components). The intervention will result in an evidence-based culturally informed intervention for immigrant survivors of IPV for use by practitioners serving immigrant women.

2. Objectives

Our objective for this study is to develop and assess the effectiveness of additional culturally tailored, technology-based support for reducing the likelihood of future IPV and improving mental health and empowerment of women who do respond to the It's weWomen Plus online intervention after in-depth investigation of the barriers to their response. Our specific aims are:

Phase 1 AIM 1 (Formative)

a) To identify and understand factors related to response or non-response to the It's weWomen Plus intervention
b) To culturally tailor and pre-test the content of the new enhanced support components (text messaging and phone) for It's weWomen Plus intervention with a diverse group of immigrant women.

Phase 2 AIM 2 (Enhanced Intervention Evaluation)

a) To assess the relative effectiveness of two strategies for augmenting the It's weWomen Plus intervention (text messaging only or a combination of text and phone) on safety, mental health and empowerment outcomes among the non-responders.
b) To compare the non-responder group of women to the responder group to determine if the strategies of augmentation brought the non-responders to the level of the responders on safety, mental health and empowerment
c) To pilot test a gun safety intervention with a sub-sample of 55women who reported partner's ownership or access to a gun and compare their outcomes to 55 women who reported partner's ownership or access to a gun who did not receive the gun safety intervention

Phase 3 AIM 3 (Dissemination and Implementation)

To identify facilitators and barriers to the adoption, implementation and maintenance of use of the original and augmented intervention by programs serving immigrant women and to design strategies to decrease barriers and build on strengths

3. Background

Foreign-born immigrant women are at high risk of IPV and intimate partner homicide (IPH). Prevalence rates of IPV in community-based studies of immigrant women range from 24% to 60%. However, there are no rigorously evaluated interventions for abused immigrant women, who most likely remain at high risk of revictimization and negative effects of IPV and are underserved. The It's weWomen Plus online intervention (i.e., myPlan intervention culturally adapted for immigrant women via input from immigrant survivors of IPV and from practitioners serving immigrant women) uses the web-based platform to assess women's level of danger for severe IPV/IPH in abusive relationships using the Danger Assessment (DA). The DA assesses level of danger in relationships using 20 yes/no questions about risk factors (e.g., increase in frequency and severity of violence). A weighted scoring system identifies women at the following levels of danger: variable

(<8), increased (8-13), severe (14-17) and extreme (≥18) danger. Women receive immediate graphic feedback on the DA score with level of danger and evidence-based messages to inform interpretation of the danger level and taken through a priority-setting activity where they can consider values (e.g. privacy, feelings for partner, having resources, safety and well-being of children) with regard to relationships. Information provided by the users, (such as relationship status) and the DA score are combined with the safety priorities of the users to develop a tailored safety action plan with links to resources and services. However, due to the varying needs of immigrant women, all immigrant women may not experience improvement in outcomes via intervention at the same intensity level. Immigrant women unable to implement a safety plan on their own using an online app may benefit from additional support via phone and/or text focusing on other strategies to increase support from other immigrant women and specific strategies aimed at their abusive partners building further on the knowledge gained in the formative phase of It's weWomen Plus.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures

The study will use a mixed methods design and will be conducted in three phases: Formative (phase 1), Enhanced Intervention Evaluation (phase 2) and Dissemination and Implementation (phase 3).

a) For formative phase (Phase 1), the study will use a concurrent triangulation mixed methods design that includes:

(i) 45-50 in-depth, semi-structured interviews that explore the perceptions of newly recruited immigrant women as well as current weWomen participants. The newly recruited participants and any participants from the weWomen study with whom we conduct in-depth interviews will be asked about the utility of online intervention components and also provide feedback on phone and text intervention components. We have added the newly recruited women to the in-depth interview portion of Phase 1 since we have very few participants from the weWomen study who completed 12 months of follow up. Additionally, not all women from the weWomen study agreed to be contacted for future studies. The inclusion criteria for newly recruited non-weWomen participants will be the same as weWomen participants. The non-weWomen participants who participate in the in-depth interviews will be compensated the same amount as the participants in the in-depth interviews who completed weWomen. To achieve maximum variation in country of origin/ethnicity, participants from various regions (e.g., Latin America, Asia, and Africa) will be purposefully recruited for the in-depth, semi-structured interviews. The follow-up interviews for current participants in the ongoing weWomen study will take place only for those women who complete 12 months assessments and agreed to be contacted for follow up interviews. Trained research assistants will conduct these interviews by phone or in person (depending on the participant's location and preference).

(ii) In addition input will be obtained from 15-30 experts on IPV in immigrant women from multiple disciplines and from diverse groups of 30 immigrant survivors of IPV not part of the weWomen RCT via 5 focus groups (4-8 immigrant women/group) to further develop and culturally tailor the added text messaging and phone components to the It's weWomen Plus intervention. The input from cultural experts will be obtained over the phone, in-person or via email depending on their preference. The

focus groups will be conducted in-person and in exceptional circumstances via zoom if the participants are unable to attend the in-person group session. The interviews and focus groups will last for approximately one hour to two hours, depending on the information shared by participants.

(iii) Also as part of Phase 1, we will conduct a pilot test of the weWomen intervention components with 5 to 10 immigrant survivors of IPV (eligibility criteria will be the same as survivors for Phase 1) to ensure that the registration process, surveys, online intervention, text message intervention, and phone intervention work as intended. Participants selected will not have been exposed to the It's weWomen Plus online intervention.

(iv) Analyze moderators of intervention response (e.g., change in frequency and severity of IPV) in the current WeWomen RCT at 3 or 12 months (quantitative, *n*=375). If the sample size is lower than 375, we will do a descriptive moderator analysis. The secondary analysis of quantitative data from the current WeWomen RCT will identify predictors of intervention response to safety, mental health and empowerment and malleable factors specific to the sub-set of immigrant women whose safety does not improve to target with the added intervention components. Selection of moderators will be informed by the qualitative findings from step (i), and will include demographic (e.g. age, socio-economic status, time in country, country of origin, language), family and relationship (e.g. marital status) and psychosocial and health related factors (e.g. social support, depression).

b) For enhanced intervention evaluation (Phase 2), the study will use a sequential, multiple assignment, randomized trial design. For the 1st stage of the intervention, immigrant women will be randomized to the It's weWomen Plus technology-based online (computer/smartphone) intervention arm, the usual care control arm. Only women who indicate that their abuser owns a firearm or has access to a firearm will be randomized to one of the three conditions: the It's weWomen Plus technology-based online (computer/smartphone) intervention arm, the usual care control arm, or a gun safety intervention plus usual care arm.. Eligibility screening and consent are both administered through self-guided processes via the study online portal. Once enrolled, women are randomized 1:1 to the It's weWomen Plus online intervention or usual care. Women who have an abuser who owns or has access to a gun will also be randomized equally to the three different possible treatment arms. Further, we will introduce a 2nd stage RCT with augmented technology-based intervention components (i.e., text and phone using evidence-based techniques) based on individualized needs of the immigrant women and their responses in the first stage intervention**.** Responders will be those immigrant women who report significant reduction in severity and frequency of IPV and improvement in empowerment from baseline to 3 months in the weWomen Plus first stage randomization. The non-responders will be those who show no significant reduction from baseline to 3 months in IPV and/or no improvement in empowerment. In this study, data will be collected from *1266 women for Phase 2 as well as 55 additional women who received the gun safety intervention.*

(i) Also as part of Phase 2 we will do a brief once per month check-in phone call for retention purposes. If there is no response, we will send a text message. This plan for once-a-month check-in for retention was based on input by our partner advocates as well as participants in our focus groups. These communications will take place once per month depending upon participants convenience and preference. The retention phone

check ins will only occur in months where participants have no contact with the team for text and/or phone intervention sessions. These include months 1, 2, 5, 7, 8, 9, 10, and 11 of the weWomen Plus study. We are engaging in retention messaging in an effort to promote participant engagement since we experienced poor retention in the prior WeWomen study.

ii) We will conduct 20-30 semi-structured post-12 month follow up interviews with women who received the gun safety intervention and agreed to be contacted for the interview. The interview guide will be developed to obtain feedback on their experience and how to further refine the intervention for future large scale trial. We will pay each woman $35 for participating in the interview.

c) For dissemination and implementation (Phase 3), the study will use a qualitative design. This phase involves purposefully sampling providers from a range of different types of organizations that serve immigrant women, including those that have an explicit violence response mission and those which do not. It will also seek maximum variation in organizational size, geographic location, and population of immigrant women served. The plan is to interview 25-30 providers from immigrant focused organizations (in each case, to be comprised of 12-15 providers from IPV focused organizations and 12-15 from non-IPV focused organizations). In addition to the 25-30 providers, 25-30 organizational leaders from both types of organizations will be interviewed. To be eligible for participation, the providers or organizational leaders must have extensive experience (two or more years) providing services to immigrant survivors of IPV. Further 25-30 immigrant survivors of IPV from Phase 1 and/or Phase 2 will be interviewed to follow up on emergent themes related to implementation developed during Phase 1 and Phase 2 analyses. This will include those who received the augmented components (*n*=22-25) as well as those who just received the It's weWomen Plus online intervention alone (*n*=12-15). These interviews will be done after completing Phases 1 and 2 and in the final years of the study. The interviews will last for approximately one hour to two hours, depending on the information shared by participants.

b. Study duration and number of study visits required of research participants.

For qualitative phases, we will collect data at only one time point. For quantitative phase 2, we will collect data from women at four time points: Baseline, 3 months, 6 months, and 12 months. There will only be 4 time points for the SMART trial analysis, baseline, 3 months, 6 months and 12 months. The overall goal will be to ensure that women are safe and empowered to live abuse free lives. For 15-20 women with abuser's access and/or ownership of guns and those who agree for and participate in a follow-up interview post-12 months survey, there will be an additional time point for a one-time follow up interview.

At follow up contacts, women will be asked to complete a follow-up on-line survey. These are extended sessions that should last 45 minutes – 1 hour. Safety will be the priority of researchers whenever contacting participants using safety precautions first developed for the Canadian IPV survey and since used by this research team in 4 federally funded studies. Nothing is required of participants in the interim between data collection windows; however, via their unique weblink that is provided in the welcome email, participants can access their safety plan and resources at any time during their study participation.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
Quantitative data collection will involve an RCT, where in the first stage, participants will be randomly assigned to either the internet/and or smartphone app accessible It's weWomen Plus

intervention website or the control website. The intervention group will receive the It's weWomen Plus online intervention. The control group will receive non-DA informed usual safety planning resources modeled on national and state DV online resources. In the second stage re-randomization, non-responder participants will be re-randomized to additional text-only or text messaging and phone intervention. Participants will not be informed about their assignments to the intervention content or the control content. It is anticipated by this process, any differences in safety, mental health and empowerment outcomes can then be linked to the internet/and or accessible intervention and not to the participants' knowledge of the new intervention or expectations that the safety planning informed by the DA is better than the usual non-DA informed safety planning.

d. Justification of why participants will not receive routine care or will have current therapy stopped.
Not applicable (N/A)

e. Justification for inclusion of a placebo or non-treatment group.
N/A

f. Definition of treatment failure or participant removal criteria.

The Principal Investigator may take a participant out of the study if they experience significant psychological distress that prevents them from continuing discussion during the face-to-face interviews, focus groups, or other in-person activities as well as during phone intervention. The decision to remove a participant from the study may be made either to protect the participant's health and safety or because the Principal Investigator believes the participant is not appropriate for the study.

During phase II, in order for participants to enroll in the study, participants will enter their information over a secure registration site at https://itswewomenplus.org/. The It's weWomen Plus study system has protocols in place to ensure that only valid registrants are enrolled in the study. A registrant will be found ineligible if any of the following is detected/true:

- Phone number used to register is a Voice of Internet Protocol (VoIP) number
- Phone number was used in a previous registration
- Email used in a previous registration
- Does not meet screening criteria
- (May also exclude if same IP address as a separate registration, but not at the start of the study since the study be recruiting from organizations using a shared computer)

When a registrant begins the registration process, they will receive the following email:

Hello [Participant Name],

Thank you for registering with weWomen Plus.

If for some reason you leave the registration, you can get back to it by clicking on your registration link below. You can only register once.

[LINK TO REGISTRATION PAGE]

As part of the validation process, a Research Assistant (RA) will call the registrant once the registrant has filled in the registration information to verify that the registrant is a real person and meets the eligibility criteria. Once the RA verifies that validity of the participant over the phone, then the RA will validate the participant's registration via the It's weWomen Plus study system. If the RA finds that the registrant is not valid, because they do not meet one or more of the research criteria, then the RA will not validate the registrant, and the individual will not be enrolled in the study.

Once the registrant is validated as a participant, the participant will be sent a number code via text message and receive the following email:

Hello,

Below is the link to put in the code you received by text message.

[LINK TO INPUT CODE]

The participant will input the code that the participant received via text message in the secure portal to which the above referenced link leads. The participant will then receive the following email giving them access to the baseline survey:

Hello [Participant Name],

Welcome to weWomen Plus. Thank you for agreeing to participate.

The link to complete your first survey is at the end of this message. Once you complete the survey and the online safety plan, we will send you {$incentive}. You will need about 1 - 1.5 hours to do everything, so please plan your time as you need in order to complete it.

We will ask you to complete 3 more surveys over the next year. After each survey you complete, we will compensate you for your time.

OPPORTUNITY: You can help other women learn about It's weWomen Plus! All you need to do is share this coupon code {$token} and our website {$link} with friends, family members, neighbors, or co-workers. Tell them to enter the code if registering for the study. You can share the coupon with as many women as you want. If at least 2 women you give the coupon to join the study, we will send you $20.

If you do not know how to talk about the study with other women, you could try this:

I know about an opportunity to participate in a study on health and safety of women in the community and thought you might be interested. If you would like to see if you are eligible, you can go to this website {$link} and complete the screening. You will need to enter this coupon code {$token} on the website. {$msgCredentials}

Also, for your safety, please be sure to follow guidelines for staying safe while on the internet. Here"s a resource from the American Bar Association for you: http://www.abanet.org/domviol/internet.html
Again, thank you for participating! What you have to tell us is extremely important, and we are really thankful for your time. Have a great day, and please let us know if you have any questions at {$staffEmail} or {$staffPhone}.

Thank you,
{$msgSignature}

Once a participant finishes the survey referenced in the above email, the participant will receive the following email that will give them access to the online resource (referred to as "Part 2" in the email):

Hello [PARTICIPANT NAME],

Thank you for completing the survey! We know it was long, and we really appreciate you taking the time to fill everything out. When you're ready to start Part 2, click on the link below. We'll send you your incentive once you've gone through Part 2.

[LINK TO ONLINE RESOURCE]

We wanted to remind you about the opportunity to earn extra money through our study. You can help other women learn about It's weWomen Plus! All you need to do is share this coupon code, [XXXXXXXX] and our website https://itswewomenplus.org with friends, family members, neighbors, or co-workers. Tell them to enter the code during screening at our website. You can share the coupon with as many women as you want. If at least 2 women you give the coupon to join the study, we will send you $20.

If you do not know how to talk about the study with other women, you could try this:

I know about an opportunity to participate in a study on health and safety of women in the community and thought you might be interested. If you would like to see if you are eligible, you can go to this website https://itswewomenplus.org and complete the screening. You will need to enter this coupon code [XXXXXXX] on the website.

If you have any questions about anything, please contact us at info@itswewomenplus.org or [STUDY PHONE NUMBER].

Again, thank you for your time, and have a great week!

weWomen Plus
info@itswewomenplus.org

Upon completion of the online resource, the participant will receive an email with their compensation per the template below:

Hello [Participant Name,

Below is your $40 Amazon Gift Code link:

[LINK TO COMPENSATION]

To redeem, just follow these steps

Go to www.amazon.com
Log into your Amazon account
Click View Amazon Pay Balance.
In the field under Add Gift Card / Voucher Code to Account, enter your claim code and click Add to Your Account.

weWomen Plus
info@itswewomenplus.org

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

If a participant must drop out at the request of the Principal Investigator (rather than because they have decided on their own to drop out), the participant will still be paid for the portions of the study they complete. If the participant decides to withdraw from the study, they will not be paid for any portion of the study that they did not complete.

5. Inclusion/Exclusion Criteria

For Phase 1 (Formative Research):

a) *to identify and understand factors related to response/non-response to the It's weWomen Plus intervention*,

The following inclusion criteria will be used to select women for in-depth interviews:

- Over 18 years of age
- Foreign born immigrant background
- Have experienced IPV within the past year

b) to culturally-tailor and pre-test the content of the new enhanced support components (text messaging and phone calls) for the It's weWomen Plus intervention with a diverse group of immigrant women,

The inclusion criteria for experts will be:

- Two or more years of experience serving immigrant survivors of IPV, and
- Psychology, social work, public health or nursing background.
  OR
- Expertise in any discipline, and
- Served survivors of IPV for 10 years or more

The inclusion criteria for women will be

- Not a current participant in the WeWomen RCT;
- over 18 years of age,
- Foreign-born immigrant woman from Africa, Asia or Latin America, and
- have experienced IPV within the past year.

For Phase 2 (Enhanced Intervention Evaluation):

The following inclusion criteria will be used to select women for quantitative data collection:

- 18 to 64 years of age
- Identify as a woman (assigned female as at birth or have a gender identity as a woman)
- Experience of IPV in the past 12 months
- Have been in an intimate relationship in the past 12 months
- Foreign-born immigrant from any race and background
- Access to a safe computer/smartphone and are comfortable using it to access the study internet site.

- Willing or able to be contacted via phone or text for second-stage randomization and enhanced intervention evaluation

For Phase 3 (Dissemination and Implementation)

The eligibility criteria for providers and organizational leaders will be:

- Two or more years of experience providing services to immigrant survivors of IPV.

The eligibility criteria for women will be:

- Participated in Phase 1 and/or Phase 2 interviews and/or focus groups;
- over 18 years of age,
- Foreign-born immigrant woman from Africa, Asia or Latin America, and
- Survivor of IPV.

6. Drugs/ Substances/ Devices

N/A

7. Study Statistics

a. Primary outcome variable:

- Safety: Change in severity and frequency of physical violence from baseline to follow-up)

b. Secondary outcome variables:

- Mental Health: Change in PTSD and/or depression symptoms from baseline to follow-up

- Empowerment (Overall empowerment and empowerment related to safety): Change in empowerment scores from baseline to follow-up

c. Statistical plan including sample size justification and interim data analysis.

Based on results from our prior Risk Assessment Validation Study, we expect 30% of women to be non-responders (e.g., increase in severity and frequency of IPV) in the It's weWomen Plus intervention arm. Assuming an 80% retention rate at 12 months, we determined the sample per group needed to detect an effect is of .25 or greater. The addition of the phone component will focus on multiple issues using evidence-based approaches to interaction whereas the text messaging is tailored to the safety plan only. The phone-based intervention will allow more rapport building and personalized care via interaction with a trained interventionist using strengths-based approaches, so we expect an effect size in the small to moderate range (Cohen's d' of .2-.4). Interventions drawing from SMART design/SMART interventions may be powered similar to a standard RCT, if stage-specific questions (e.g., a comparison of first-stage interventions averaging over response and second stage interventions) are of primary interest and embedded dynamic treatment regimen development is of secondary interest. With power = 0.80, alpha = 0.05, and N=253 per group, we will be able to detect significant differences in the change over time between the two groups when the effect size is 0.25 or greater. This will require a total sample size of N=1,266 with 633 randomized to the It's weWomen Plus

intervention and 633 to usual care. With a 30% nonresponse rate, 190 women will be eligible to be randomized to It's weWomen Plus online intervention+text messaging or the It's weWomen Plus online intervention+ text messaging + phone contact with 95 per group. We expect a higher rate of non-responders in the control arm, with 50% of women (N=316) eligible for randomization into groups (the It's weWomen Plus online intervention +Text Messages or the It's weWomen Plus online intervention + Text Messages +Phone Calls) with N=158 per group. Using the eligibility criteria of women aged 18 or older, foreign-born Latina, Asian or African, have experienced IPV in the past year, and have access to a safe computer/smartphone and are comfortable using it to access the study, we will recruit 1,266 women for the proposed study. In addition, we will recruit 55 women with abuser's access/ownership of firearm for pilot test of the gun safety booster intervention and compare it with 55 women with abuser's access/ownership of firearm in the main trial usual care control arm.

To identify and understand factors related to response/non-response to the It's weWomen Plus intervention will be tested among those randomly assigned to the It's weWomen Plus intervention group. Logistic regression will be used to identify baseline variables related to response/non-response. We will examine 2 indicators of response (safety and empowerment). For safety, non-response will be defined as no change or an increase in severity and frequency of IPV at follow-up; for empowerment non-response will be defined as no improvement in empowerment scores (at least a 0.25 standard deviation increase in scores) from baseline to follow up. Predictors of response will include demographic factors of age, race, marital status, and time in the US; risk factors (i.e., attitudes towards violence against women, discrimination, previous experience of IPV), and social support. Results from these analyses will be triangulated with results for the qualitative analyses to identify key factors for tailoring in future implementation of the intervention. To assess the relative effectiveness of two strategies for augmenting the It's weWomen Plus online intervention on safety, mental health and empowerment outcomes among the non-responders, Generalized Estimating Equations (GEE) with robust variance estimation will be used. Variables in the model include time (baseline and 12 months) and group which will have two levels: It's weWomen Plus online intervention and the addition of text messaging and It's weWomen Plus online intervention and text messaging and phone contact. Baseline variables on which the groups are not balanced by randomization will be included as covariates. The parameter of interest is the group by time interaction which will determine if the change over time in the outcome variables differs between the two groups. We will conduct sensitivity analyses including baseline variables found to predict intervention response and dose of the initial intervention. Dose will be captured by the number and duration of prescribed sessions/timepoints of intervention completed, number of and duration of unprescribed sessions (i.e., woman visiting intervention website outside the prescribed time points) and receipt of usual care services. These variables will be added to the GEE models described above to determine if significant differences in change over time remain controlling for predictors of non-response and dose of the initial intervention. Similarly, to determine if the strategies of augmentation brought the non-responders to the level of the responders on outcomes, GEE also will be used controlling for baseline variables on which the groups are not balanced by randomization. In this analysis there will be four groups: responders to usual care control arm and responders to the It's weWomen Plus online intervention, the It's weWomen Plus online intervention and the addition of text messaging and the It's weWomen Plus online intervention and text messaging and phone contact. Responders will be coded as the reference group in order to compare responders to the two groups of non-responders that received augmentation. Once again, the group by time interaction will be the parameter of interest to determine if the change over time in the outcomes differs between the responders and those receiving either adaptive intervention. We will use the 'weighted and replicated' estimation

method that effects for the adaptive interventions can be simultaneously estimated in the same model. Inverse probability weighting for probability of receiving an adaptive intervention will be relative to the number of times an individual is randomized (e.g. responders have a weight of ½ and non-responders have a weight of ¼). As observations need to be used in more than one comparison, data will be replicated. Sensitivity analyses will include dose of initial intervention (as described above) and baseline variables found to predict intervention response in Phase 1 as covariates in the models.

Potential Confounding Variables. T-test and chi-square tests will be used to examine if each randomization succeeded in creating balance on key demographic and baseline outcome variables. We will control for any variables that are found to be significantly different in the corresponding main analyses.

d. Early stopping rules.

Participants completing the questions on intervention and control websites may stop at any time. The web-based informed consent will provide details about study procedures and risks and benefits of participation. It will include statement that participant can stop at any time. All participants will be provided with a resource list. In qualitative interviews, if the participant becomes too distressed to continue with the interview may stop and withdraw from the study or stop temporarily and resume if she wishes to do so.

8. Risks

a. **Medical risks, listing all procedures, their major and minor risks and expected frequency**.

It might be stressful for women to think about negative events in their lives. Other potential risks to the abused women include loss of confidentiality, time involvement, fatigue, and embarrassment because of the nature of some of the questions, and potential retaliation from the intimate partner. All women will be informed about the potential risks in participating and measures to take to protect one's self. Women will be notified that they can withdraw from the study at any time without penalty. While no woman's safety can ever be completely guaranteed, we feel that with our safety procedures there is minimal safety risk to women. Although the circumstances of abuse may be distressing for women to discuss during qualitative interviews, traumatized persons generally find expression of feelings useful. The research plan was developed with deliberate attention toward minimizing the risk of harm to abused women. If during the course of participating in the research study, the participant reveals current abuse/neglect or planned danger to self or others, the Research Assistant will report this to Dr. Sabri and other team members who will make the appropriate referral as required by law.

b. Steps taken to minimize the risks.

The study investigators, who have extensive experience in the field of IPV, qualitative, quantitative and internet-based research will train all research staff. All research team members will be required to complete a mandatory training on protections against risk offered by Johns Hopkins University Institutional Review Board. Research training will include sensitization to the experience of abused women and safety issues, as well as issues related to informed consent. The informed consent procedure will be implemented according to institutional review board guidelines. All participants will be provided information essential for informed consent prior to participation in the study. Steps to be taken to protect the safety and confidentiality of all participants include the use of study code

numbers for identification, reporting of aggregate data, omitting identifiers in the data collected and maintaining contact information separately from data, and destroying all contact information within 3 years after completion of the study. Should a research team member discover child abuse, suicide or homicide intent, a report to the appropriate agency will be made, and this will be included in study consent forms. The suicide protocol will include an algorithm for assessment, maintaining contact with participant, accessing study investigators and consultants for support and follow-up, accessing community suicide hotlines and connecting the participants to the trained counselors. All research team members will be trained using the approved protocol. The research team member and women will further discuss need for access to a safe computer to access the study website. If the potential participant does not have a computer in her home or does not feel safe using her home computer, the research team member can brainstorm with the participant a safe location to use a computer (e.g. family, friend, public library, community based agency, domestic violence program). We will also provide training to all participants about how to use the Internet safely, based on the work of the American Bar Association, www.abanet.org/domviol/internet.html. These steps will include using computers at a friend's home, her workplace or public locations, e.g., a library or shelter. The women will also be advised on how to password-protect their email accounts and how to clear the history (or cache file) in their browser settings.

Women's confidentiality is considered primary to this study protocol. Implementing important safety procedures for the internet and handling study data will serve to protect women from harm. During the study, women may stop at any time. The website accessed by participants will include information on safety resources in the area of the study participant (i.e., information on multiple community and domestic violence resources). No information will be given out to anyone outside the research team about whether a particular woman participates in the study. The study will generally be referred to as dealing with "women's safety and health." Trained research staff will conduct all aspects of the study.

Safety Procedures for Internet Use by Participants To women affected by IPV, the Internet may seem to be an abundant source of information that is not only easily accessible but offers some level of anonymity. However, the web browsing software that most of us use on a daily basis does not support anonymous browsing. Web browsers store a history of the URL's that are visited, which can be left on a computer indefinitely. This history is easily accessible from within the browser, yet many Internet users may be unaware that their own computer is monitoring their activity. In addition to the Internet history log, browsers also store certain web site elements on the hard drive once a site is visited. This is called file caching and it is done to improve the performance of the web site and reduce redundant downloading of static content such as images or text files. Browsers today can maintain a large folder of content downloaded from each site that a user visits. All of this browser behavior creates an unsafe browsing environment for women privately seeking information to help with an abusive relationship. It can compromise the woman's security if her partner were able to discover her Internet browsing habits. Fortunately, there is a way to minimize or reduce the risk that an abusive partner could uncover the trail of sites visited by woman seeking help. The steps involve deleting the browsers' history file and clearing the cache folder. Unfortunately, though, it is not a complete solution and should only be used if the woman does not have access to another computer such as those offered at a public library, Internet cafe, or domestic violence shelter. Using the same computer as the abusive partner to search for supportive information could put the woman at risk. It is our intention to provide this information on clearing the browser trail to women using the online tool at both the beginning and at the end of using the tool to help them protect their internet viewing habits. In addition to supplying this information, there are a few computer-coding habits that we can employ to eliminate or reduce the caching of our tool by the browser.

Safety Procedures for Telephone Contact:

Research staff will be trained to assess for immediate danger including the following items and follow the procedures below detailing safety mechanisms during telephone contact:

- Is the woman in immediate danger?
- Where is the batterer now?
- Does that batterer have access to a weapon?
- Where will the batterer be when the woman is finished with participating in the study?

All follow-up calls will be made from a private phone with Caller ID Block to avoid the chance of callback. When telephone contact is made, the interviewer will follow a prepared script identifying herself as an employee of the participating university/organization calling to follow-up on health care services and ask to speak with the woman. When the woman answers, she will always be asked if it is safe time to talk ("Is this a quiet, safe and private time to talk?") before proceeding with the interview. The woman will also be given a 1-800 number and instructed that she can hang up at any time during the interview without explanation and can call back when it is safe to resume the interview. She will also be given the code phrase, "I'm sorry I have to go now" that she can use to terminate the interview if she wants. If that code is used or if the interviewer is concerned about safety (due to suspicious sounds or other cues), the interviewer is trained to assess for immediate safety as follows:

- Are you in danger right now?
- Is someone making you feel unsafe now?
- Is that person in the room?
- Does the person have a weapon?
- Do you want me to call the police to come to your house now?"

If she says yes, the interviewer will say "I will now call the police on another line and instruct them to go to your house. Once I have spoken with them I will get right back on the line with you and stay on the line with you until the police arrive." If a woman says no (she does not want the police called), the interviewer will say, "Do you want me to stay on the line?" If the woman says yes, the interviewer will say, "You can hang up at any time. If you do, do you want me to call you back in 30 minutes to check to see if everything is ok?" If the woman says yes, the interviewer will do so in 30 minutes after the woman hangs up. When the interviewer calls back she will check-in to see if it will be a safe time to call, and will ask again about calling the police if the woman says no. If the woman will want the interviewer to stay on the line, the interviewer will then read from a prepared "script" about satisfaction with health care (in case an abusive partner is on the other line or within distance of hearing the conversation) until the woman either indicates she wishes to continue or hangs up and then the interviewer will wait until the woman re-establishes contact. The investigators may be called at any time if a research staff person is ever worried about how to proceed in an individual case (for example, if woman reports abuser has gun, or if she is worried about suicide). Dr. Campbell has extensive experience providing care and consulting on abuse cases that are at a crisis point. Dr. Sabri has worked as a crisis intervention and suicide hotline counselor for five years and has significant experience with the physical and mental health consequences of IPV. If a woman is afraid for her safety or to return home, she will be assisted in contacting domestic violence resources *or the police* in her area, The PI, co-investigators and site coordinators may serve as liaisons between women and battered women's shelters or other community health and social services if a woman so desires.

Safety Procedures to Ensure Data Privacy In the ongoing WeWomen trial, to complete online measures, participants are given a username and password to access a secure online survey application that allow them to self-report and store their de-identified data. This system uses usernames that do not identify the participant, but simply allow them to have a unique identifier to access the system. When the member of the research team is contacted by an interested participant,

the team member logs into the tracking system and creates a new screening record for the interested participant after collecting identifying information. The system creates a unique subject ID for the participant along with a password, which is sent to the participant via email. The actual identifying information of the participant is recorded by the research team member in a different system to be used just for tracking the study participants. This Johns Hopkins University hosted system is also username and password protected with SSL encryption enabled to ensure all transactions over HTTP are not decipherable. The system logs all access attempts and sessions for any authorized user and is designed to collect study participant identifying information as well as their schedule and progress with the study. On enrolling a study participant, the system generates a unique, non-identifying study ID and password which is used by the participant to access the self-reporting system. At the termination of the study and after analysis has been completed, a copy of the de-identified data set will persist as a file only. The transactional databases used to store personal information and study information will both be deleted. There will be no key to link any of the de-identified records to any identifiable individual. All persons with access to data (i.e., research team members) will rigorously follow procedures to ensure confidentiality of data. All data, including hard copies and backup storage devices will be kept in locked file cabinets. Only a single encrypted computer file at the study site will contain information linking subject identifying information (names) with study ID code. All other study materials and files will only include the study ID code (that is, all original forms, instruments, and computer data files). The Computer Services department at the schools is responsible for overall management and security of the system. The computer system and security measures are audited approximately every two years. The computer system meets or exceeds the level and scope of security advised by the Office of Management and Budget. No data will be released that would allow the identification of any respondent, unless written informed permission for this is obtained from a participant.

c. Plan for reporting unanticipated problems or study deviations.

Several procedures will be used to monitor participant safety and to detect adverse events: A three-member Safety Monitoring Board (SMB) will be established to ensure the safety of participants with expert knowledge of culturally competent care to survivors of IPV and expert knowledge in human subject safety issues. . The DSMB will have the responsibility of assuring that participants are not being exposed to unnecessary or unreasonable risks as a result of the pursuit of the study's scientific objectives. The members will be selected based on their clinical expertise in providing culturally competent care to survivors of IPV and expert knowledge in human subject safety issues. One of the selected members will be appointed as Chair of the DSMB by the PI. The DSMB will be responsible for ensuring that all study and intervention protocols to ensure safety are adhered to consistently. The DSMB will receive periodic monitoring reports from the PI about the progress of the study and the implementation of study protocols. The reports will contain information on any deviations from study protocols with rationale and outcomes and the DSMB will communicate or meet with the research team within 2 weeks of receiving the monthly reports. The DSMB will be responsible for clarifying concerns with any deviations in study protocols and providing recommendations to ensure the research team continues to adhere and implement the study protocols safely and consistently. Statements of confidentiality will be signed by all DSMB members. The DSMB shall cooperate with the timely preparation of summaries of all DSMB activities and of all recommendations made to investigative team and shall be responsible for ensuring that the summaries accurately represent the decisions of the DSMB. The DSMB will be required to exclude from these summaries any information that would compromise the privacy or confidentiality afforded research project participants and exclude any information that could compromise the scientific integrity of the trial.

There will be minimum risk to study participants. The study team in collaboration with community partners will develop a critical incident report for documenting adverse events, action taken and follow-up procedures for the action. If any adverse event is identified by the study staff, it will be reported directly to the PI and the Research Program Coordinator and by e-mail to the Data Safety Monitoring Board (DSMB). All adverse events will be tracked and incorporated in the evaluation of safety. The only major adverse event anticipated is further violence victimization. Every attempt will be made to protect participants from further victimization. All members of the research team will be trained to strictly follow the safety protocols. Abused women will be asked to determine a safe and convenient time for participation.

Adverse events will be reported to the Johns Hopkins University (JHU) IRB according to the policy of the JHU IRB using the standard Protocol Event Report form in the electronic IRB system. The event will be reported to the IRB as soon as possible after the PI learns of the event, but in all cases within 10 working days with the exception of death of a participant. If the person dies within 30 days of participating, whether expected or unexpected, the event will be reported promptly to the IRB when the PI learns of the death using a Further Study Action for Protocol Event Report in the eIRB system. For adverse events that are not serious, the PI will report to the NIH not more than 14 days after the PI first learns of the event. For events that are serious (e.g., fatal, life-threatening), the PI will report to the NIH as soon as possible but not more than 7 days after the PI first learns of the event. The NIH Problem Report form will be used to report adverse events

d. Legal risks such as the risks that would be associated with breach of confidentiality.

Steps to be taken to protect the safety and confidentiality of all participants include the use of study code numbers for identification, reporting of aggregate data, omitting identifiers in the data collected and maintaining contact information separately from data, and destroying all contact information within 3 years after completion of the study. The research team will be trained to promote standardized and objective collection and recording of participants' information. Efforts will be made to consistently monitor intervention and assessment implementation and maintain high quality data and data management. All persons with access to data (i.e., research team members) will rigorously follow procedures to ensure confidentiality of data. All data, including hard copies and backup storage devices will be kept in locked file cabinets. Only a single encrypted computer file at the study site will contain information linking subject-identifying information (names) with study ID code. All other study materials and files will only include the study ID code (that is, all original forms, instruments, and computer data files). The Computer Services department at the School is responsible for overall management and security of the system. The computer system and security measures are audited approximately every two years. The computer system meets or exceeds the level and scope of security advised by the Office of Management and Budget. No data will be released that would allow the identification of any respondent, unless written informed permission for this is obtained from a participant. During the study, we will randomly check for completeness and quality of data and generate progress reports by examining frequencies, ranges, outliers, and missing data. Only authorized study staff will be able to log on or access the master study database. Moreover, the data on the mobile devices (i.e., laptop computers for computerized surveys) will also be encrypted and the decryption of the mobile data will only take place on the Server. This will ensure that even if a client device is compromised (e.g. stolen or lost), the access to data will not be possible. All the mobile devices will also be enabled with remote data wipe feature to account for lost or stolen devices.

Participants self-register into the study using a web-based registration system hosted on a secure server at Johns Hopkins Mt. Washington Data Center and maintained by the School of Nursing IT. Each participant that registers into the study is given a random 8-digit identifier as their registration record is automatically created in the relational database. As participants progress through the study, they receive notifications containing links that are specific to the user and can only access their survey from the assigned links. Once the survey is completed, the link is still active, but no data is made available to the participant.

Research assistants are assigned usernames and passwords, along with access rights, to access the trial management system for participant management and retention. Access to the system is logged with each use and accessing the system also requires a PIN code to be entered. All data entered by research assistants through the trial management system and by participants via their survey links, is stored in a password protected relational database on the JHU server. Direct access to the server is only permitted by critical JHU SON IT personnel and the study database administrator. In turn, the server can only be accessed from within the JHU firewall. PHI is stored separately from any study related data in the relational database and the system does not permit the exporting of PHI, only de-identified study data. All data transmission between the server and a client is encrypted and the server itself undergoes regular security scans using the Johns Hopkins Data Security Center Tenable scanning tools to ensure no vulnerabilities exist.

On enrolling a study participant, the system generates a unique, non-identifying study ID and password which is used by the participant to access the self-reporting system. At the termination of the study and after analysis has been completed, a copy of the de-identified data set will persist as a file only. The transactional databases used to store personal information and study information will both be deleted. There will be no key to link any of the de-identified records to any identifiable individual.

No data will be released that would allow the identification of any respondent, unless written informed permission for this is obtained from a participant. Should the research team discover child abuse, suicide or homicide intent during the study (e.g., during the in-depth interviews and focus group sessions), a report to the appropriate agency will be made. Participants will be informed of this protocol in study consent forms. To protect participants' confidentiality, only the research team will have access to information about the participants. In qualitative interviews and focus groups, no names will be used in recordings and the transcripts. The interview audio files will be deleted after transcription and any identifying information will be removed from the transcripts.

e. Financial risks to the participants.

There are no financial risks to the participants. Participants needing referrals for financial assistance will be connected to these resources.

9. Benefits

With the growing number of immigrant populations in the US (accounting for 13.3% of the US population in 2014, approximately half being women), and the risk of IPV/IPH among abused immigrant women, practitioners in various arenas are becoming more likely to encounter situations that require culturally competent and tailored interventions. Current interventions for IPV survivors do not take into account culture or immigration status. This study will be the first research specifically intended to address this need by developing an augmented technology-based intervention for immigrant women. The technology-based intervention can be used in a variety of settings such as healthcare settings, social service organizations and domestic violence agencies serving immigrant women. The intervention can also be useful for women who are not seeking

services and can help practitioners to provide more culturally informed services. For primary care clinics or other organizations that are not focused on IPV, this will be a useful tool for them to address needs of immigrant IPV survivors. Using rigorous methods, this study will address unmet needs of immigrant women by providing additional intervention support for those who do not show positive outcomes via the current It's weWomen Plus online intervention only. Further, the study will provide empirical evidence for the culturally tailored augmented technology-based intervention components (text messaging and phone support) added to the existing It's weWomen Plus online intervention. The resulting empirically supported culturally tailored intervention for immigrant women will be available for women to access from any location. Such empirically supported technology-based intervention is especially needed for immigrant survivors who are socially isolated and face numerous barriers in accessing in-person services

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

For Phase 1, each participant in the in-depth interviews will be paid $35. Participants in the focus groups and experts reviewing content will be paid $40. The compensation will be given via visa gift cards. For the pilot test, participants will be compensated $35 after each interview.

For Phase 2, each participant will receive gift cards worth: $40 at each survey time point, including baseline, 3 months follow-up, at 6 months follow up, and at 12 months. Additionally, participants will have the opportunity to earn $20 each time a participant recruits a minimum of 2 women for the study. Participants may be paid $15 for active participation and full completion of the re-randomization components of the study (i.e., text messaging or text messaging and phone intervention component). The compensation will be distributed via online amazon gift cards. For participants who are recruited on site, some may choose to receive physical gift cards. For these participants we will provide them gift cards on site.

Participants who will participate in semi-structured follow up interviews to provide feedback on the gun safety intervention will receive additional $35.

For Phase 3, each participant will be paid $35 via visa gift cards

All safety procedures used in our prior studies for compensating participants will be followed in this study.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.
N/A